



The NIH Almanac

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Begun as a one-room Laboratory of Hygiene in 1887, the National Institutes of Health (NIH) today is one of the world's foremost medical research centers. An agency of the Department of Health and Human Services, the NIH is the Federal focal point for health research.

NIH is the steward of medical and behavioral research for the Nation. Its mission is science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend healthy life and reduce the burdens of illness and disability. The goals of the agency are as follows: 1) foster fundamental creative discoveries, innovative research strategies, and their applications as a basis to advance significantly the Nation's capacity to protect and improve health; 2) develop, maintain, and renew scientific human and physical resources that will assure the Nation's capability to prevent disease; 3) expand the knowledge base in medical and associated sciences in order to enhance the Nation's economic well-being and ensure a continued high return on the public investment in research; and 4) exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science.

In realizing these goals, the NIH provides leadership and direction to programs designed to improve the health of the Nation by conducting and supporting research: in the causes, diagnosis, prevention, and cure of human diseases; in the processes of human growth and development; in the biological effects of environmental contaminants; in the understanding of mental, addictive and physical disorders; in directing programs for the collection, dissemination, and exchange of information in medicine and health, including the development and support of medical libraries and the training of medical librarians and other health information specialists.

NOTE: The 2003 Almanac is now available on CDROM. E-mail the [Online Information Branch](#) at to request a copy.

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About the NIH Almanac

Published annually, the NIH Almanac contains pertinent facts about the National Institutes of Health – the Federal government's principal medical research agency. As of December 1, 2001, NIH was composed of [27 Institutes and Centers](#). Of these, 24 receive direct appropriations from the U.S. Congress to award research grants and support scientific programs. The remaining three include the Warren Grant Magnuson Clinical Center (clinicalcenter.nih.gov/) – a combined research hospital and laboratory complex on the NIH campus – the Center for Scientific Review (www.csr.nih.gov), which supports the scientific review of grant applications, and the Center for Information Technology (www.cit.nih.gov), which provides, coordinates, and manages information technology for the NIH.

Prepared by [Office of Communications and Public Liaison, Online Information Branch](#).

This page was last reviewed on March 14, 2005 .

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President Franklin D. Roosevelt dedicated the new NIH campus in Bethesda on October 31, 1940. This event was held to celebrate NIH's historic move from one building in Washington, D.C. to its new campus setting in Maryland on 45 acres of land donated by Luke and Helen Wilson.



[lo-res](#) | [hi-res](#)

On June 22, 1951, President Harry S. Truman applied the first trowel of mortar to the NIH Clinical Center cornerstone. To symbolize advances in clinical medicine at the time, the cornerstone included samples of therapeutic aids, drugs, and techniques and devices to represent diagnosis, treatment and prevention of disease.



[lo-res](#) | [hi-res](#)

President Lyndon B. Johnson stepping off helicopter onto the lawn of the NIH Clinical Center, August 9, 1965. He is being greeted by PHS Surgeon General William H. Stewart, NIH Director Dr. James Shannon, and Dr. Jack Masur, Clinical Center Director.



[lo-res](#) | [hi-res](#)

President Johnson with PHS Surgeon General William H. Stewart and NIH Director Dr. James Shannon arrived at the NIH on August 9, 1965, to sign into law an extension of the Research Facilities Construction Program. In his remarks, President Johnson noted that "Here on this quiet battleground our Nation today leads a worldwide war on disease."



[lo-res](#) | [hi-res](#)

Dr. Theodore Cooper, President Gerald Ford, and Dr. Donald S. Fredrickson listening to HEW Secretary Casper Weinberger speak at the July 1, 1975, swearing in ceremonies of Dr. Cooper as the HEW Assistant Secretary for Health, and Dr. Fredrickson as Director of the NIH.



[lo-res](#) | [hi-res](#)

President Gerald Ford speaking at the July 1, 1975, ceremony swearing in Dr. Donald S. Fredrickson as NIH Director. In his speech, President Ford says of the NIH "Through your accomplishments, NIH has become a symbol of hope, not just for the patients who are here in this or the other buildings, but all people, everywhere."



[lo-res](#) | [hi-res](#)

President Gerald Ford observes Dr. Donald S. Fredrickson taking his oath of office as Director of the National Institutes of Health on July 1, 1975. HEW Secretary Casper Weinberger administers the oath as Mrs. Fredrickson holds the family Bible.



[lo-res](#) | [hi-res](#)

President Gerald Ford shakes hands with NIH staff, patients, and guests at the Clinical Center. He was on hand to observe the swearing in of Dr. Donald S. Fredrickson as the Director of the NIH, July 1, 1975.



[lo-res](#) | [hi-res](#)

First Lady Rosalyn Carter, and Mrs. James Callaghan, wife of the British Prime Minister, are shown speaking with a patient in the Clinical Center's Laminar Flow Room facilities. Mrs. Carter and Mrs. Callaghan visited the Clinical Center on March 11, 1977.



[lo-res](#) | [hi-res](#)

On March 11, 1977, First Lady Rosalyn Carter, and Mrs. James Callaghan, wife of the British Prime Minister, visited the NIH campus and met with NIH Director Dr. Donald S. Fredrickson for a tour of the Clinical Center.



[lo-res](#) | [hi-res](#)

On July 23, 1987 President Ronald Reagan visited the NIH Clinical Center to announce his 13-member Commission on the Human Immunodeficiency Virus Epidemic. HHS Secretary Otis R. Bowen and President Ronald Reagan listen as NIH Director James B. Wyngaarden briefed the president on the NIH's efforts in fighting AIDS.



[lo-res](#) | [hi-res](#)

HHS Secretary Otis R. Bowen and NIH Director James B. Wyngaarden greet President Ronald Reagan during his July 23, 1987 visit to the NIH Clinical Center. President Reagan visited the NIH to announce his 13-member Commission on the Human Immunodeficiency Virus Epidemic.



[lo-res](#) | [hi-res](#)

President Ronald Reagan, HHS Secretary Otis R. Bowen, Dr. James B. Wyngaarden and members of the Commission on the Human Immunodeficiency Virus Epidemic. In his remarks, the president said, "I hope the commission will help us all put aside our suspicions and work together with common sense against this threat."



[lo-res](#) | [hi-res](#)

President Bill Clinton speaking with HHS Secretary Donna Shalala and NIH Director Dr. Harold Varmus after the cornerstone dedication ceremony for the Dale and Betty Bumpers Vaccine Research Center on June 9, 1999.



[lo-res](#) | [hi-res](#)

Mrs. Betty Bumpers, President Bill Clinton, and Sen. Dale Bumpers during the cornerstone dedication ceremony for the Dale and Betty Bumpers Vaccine Research Center on June 9, 1999. In his speech, President Clinton praised the Bumpers by saying "It is entirely fitting that today we dedicate this state-of-the-art facility to them. They are two great Americans."



[lo-res](#) | [hi-res](#)

On June 9, 1999, HHS Secretary Donna Shalala, President Bill Clinton, Arkansas Sen. Dale Bumpers, and Mrs. Betty Bumpers unveil the cornerstone to the Dale and Betty Bumpers Vaccine Research Center. President Clinton called the NIH "one of America's great citadels of hope, not only for our people, but also for the world."



[lo-res](#)

President George W. Bush tours the Vaccine Research Center accompanied by (from left) NIAID Director Anthony Fauci, NIH Director Elias A. Zerhouni, HHS Secretary Tommy Thompson, and Secretary of the Department of Homeland Security, Tom Ridge.



[lo-res](#)

President George W. Bush delivers an address on Project BioShield to a full audience at Natcher Auditorium during his visit to NIH on February 3, 2003.



[lo-res](#)

President George W. Bush visits NIH on January 26, 2005 to hold a 40-minute town hall meeting in Masur auditorium called strengthening health care. Greeting him in the lobby of the Clinical Research Center is: NIH director Dr. Elias Zerhouni joined by NCI director Dr. Andrew von Eschenbach (I) and Maryland Gov. Robert L. Ehrlich, Jr.

Campus Photos



[lo-res](#) | [hi-res](#)

Building 1, the "Shannon Building," serves as NIH headquarters in the heart of the campus in Bethesda, Maryland.



[lo-res](#) | [hi-res](#)

Building 10, the "Warren Grant Magnuson Clinical Center," has served as the nation's clinical research hospital since 1953.



[lo-res](#)

The Mark O. Hatfield Clinical Research Center was dedicated on September 22, 2004. The facility is home to new inpatient units, day hospitals and research labs and connects to the existing Warren Grant Magnuson Clinical Center, which opened its doors to patients in 1953.



[lo-res](#) | [hi-res](#)

The Children's Inn at NIH provides pediatric patients and their families a place to stay during treatment at the Clinical Center.



[lo-res](#) | [hi-res](#)

Building 16, the "Lawton Chiles International House," is a locus for international activities supported by NIH and the Department of Health and Human Services (HHS).



[lo-res](#) | [hi-res](#)

Building 38 houses the National Library of Medicine, the world's largest collection of medical literature, and the Lister Hill National Center for Biomedical Communications, the research component of the NLM.



[lo-res](#) | [hi-res](#)

Building 40, the "Dale and Betty Bumpers Vaccine Research Center," was established to facilitate research in vaccine development.



[lo-res](#) | [hi-res](#)

Building 45, the "William H. Natcher Building," is the gateway to the NIH campus. It houses a 1,000-seat auditorium, nine conference rooms, a spacious cafeteria, and underground parking for visitors.



[lo-res](#) | [hi-res](#)

Building 50, "The Louis Stokes Laboratories," provides 250,000 GSF of state-of-the-art laboratory, office and conference facilities for scientists from nine NIH Institutes.



[lo-res](#) | [hi-res](#)

This view of the NIH campus looks north past the Natcher Building (right) to the Stokes Labs (center) and beyond to the Clinical Center (upper left). Building 31, the "Claude D. Pepper Building," (upper right) provides office space for most Institute directors and their immediate staff.



This view of the NIH campus looks south beyond the Stokes Labs and Natcher Building (center) to the reflective façade of the National Library of Medicine (upper right).

[lo-res](#) | [hi-res](#)

Historical Photos of Scientists



The NIH began in 1887 as a one-room Hygienic Laboratory in this Marine Hospital on Staten Island, New York. The Hygienic Laboratory was located here until 1891, when it was moved to Washington, D.C.

[lo-res](#)



This is a photograph of a PHS research laboratory, circa 1899. The staff is shown at workstations with microscopes and laboratory glassware.

[lo-res](#)



In 1910, U.S. Public Health Service workers prepared poisons to be used for the extermination of plague-carrying rats.

[lo-res](#)



In 1910, researchers worked at a U.S. Public Health Service laboratory equipped with a bunsen burner, microscope, and petri dishes.

[lo-res](#)



In 1916, Dr. Ida A. Bengston became the first woman on the professional staff at the U.S. Public Health Service Hygienic Laboratory. Dr. Bengston worked on ways of developing vaccines for spotted fever.

[lo-res](#)



In 1929, field laboratory technicians for the Rocky Mountain Laboratory collected research specimens from the north side of Blodgett canyon, Montana.

[lo-res](#)



[lo-res](#)

A 1937 NIH laboratory technician surrounded by tools of the trade; a rack of cotton-stoppered test tubes, a microscope and various glass jars.



[lo-res](#)

In 1939, laboratory technicians performed tick research at a field laboratory in Boulder, Colorado. The laboratory was equipped with a refrigerator, an autoclave, and a wood-burning stove.



[lo-res](#)

In 1946, researchers work at a field laboratory set up in the basement of the Kew Gardens apartments in New York City.



[lo-res](#)

In 1953, NIH scientists were seeking the cause of the hypersensitivity that develops during a 10-21 day lapse after infection before the onset of rheumatic fever or nephritis.



[lo-res](#)

In 1954, NIH researchers were studying weight and blood changes in rats with folic acid deficiency.



[lo-res](#)

In 1975, NIH's central computer facility housed computers to aid in the collection, analysis and display of data from laboratory instruments, such as this mass spectrometer.

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Chronology of Events

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1700

1798 The Marine Hospital Service was established with the July 16 signing by President John Adams of an act for the relief of sick and disabled seamen.

1799 An amending act of March 2 extended benefits of the Marine Hospital Service to officers and men of the U.S. Navy.

1800

1802 The admission of foreign seamen to Marine hospitals on a reimbursable basis was authorized on May 3.

1803 The first permanent Marine hospital was authorized on May 3 to be built in Boston, Mass.

1807 Dr. Benjamin Waterhouse was appointed physician in charge of the Boston Marine Hospital on November 27. He was the first to introduce interns and residents into hospitals in the United States.

1836 The Library of the Office of the Surgeon General of the Army was established (the present National Library of Medicine).

1865 John Shaw Billings, M.D., was assigned to supervise the Surgeon General's Library, which he built into a national resource of biomedical literature.

1870 A bill dated June 29 provided for administration of Marine hospitals within a Bureau of the Treasury Department with a medical officer in charge.

1871 Dr. John Maynard Woodworth was appointed supervising surgeon of the Marine Hospital Service in April, marking the beginning of central control of Marine hospitals.

1873 Regulations were approved on December 1 for appointment and promotion of physicians in the Marine Hospital Service, establishing the first career service for civilian employees in the Federal Government.

- 1875** A bill passed on March 3 authorized admission of Navy seamen and seamen of other government services to Marine hospitals on a reimbursable basis.
- In recognition of Dr. Woodworth's progress in reorganizing the Marine Hospital Service, his title was changed by law to supervising Surgeon General on March 3.
- 1878** The first Federal Quarantine Act was passed April 29.
- On December 21, Congress appropriated funds "for investigating the origin and causes of epidemic diseases, especially yellow fever and cholera."
- 1879** The National Board of Health was created by law on March 3. It represented the first organized, comprehensive, national medical research effort of the Federal Government.
- Dr. John B. Hamilton was appointed Surgeon General of the Marine Hospital Service, April 3.
- 1884** The seamen's hospital tax was abolished on July 1. The cost of maintaining Marine hospitals was paid out of a tonnage tax, which continued until 1906.
- 1887** A bacteriological laboratory, known as the Laboratory of Hygiene, was established under Dr. Joseph J. Kinyoun at the Marine Hospital, Staten Island, N.Y., in August, for research on cholera and other infectious diseases (renamed Hygienic Laboratory in 1891.)
- 1889** The commissioned corps was authorized on January 4 establishing by law the policy of a mobile corps subject to duty anywhere upon assignment.
- 1890** Congress gave the Marine Hospital Service interstate quarantine authority on March 27.
- 1891** The Hygienic Laboratory moved from Staten Island, N.Y., to the Butler Building, Service Headquarters, Washington, D.C., in June.
- Dr. Walter Wyman was appointed Surgeon General of the Marine Hospital Service on June 1.
- 1893** A new Quarantine Act, passed February 15, strengthened the Quarantine Act of 1878 and repealed the act establishing the National Board of Health.
- 1899** The Marine Hospital Service was directed by Congress on March 2 to investigate leprosy in the United States.
- Dr. Milton J. Rosenau succeeded Dr. Kinyoun as director of the Hygienic Laboratory on May 1.

1900

1902 The earliest studies of Rocky Mountain spotted fever took place in Montana.

A bill approved July 1 changed the name of the Marine Hospital Service to the Public Health and Marine Hospital Service and established an advisory board for the Hygienic Laboratory. It later became the National Advisory Health Council.

The 57th Congress enacted Public Law 244 to regulate the shipment of biologics. The technical responsibilities of the program were assigned to the Hygienic Laboratory.

The Advisory Board for the Biologics Control Division was established July 1.

The Pan American Sanitary Bureau was established December 2. The Public Health and Marine Hospital Service began international health cooperation.

1904 The Hygienic Laboratory moved to a new building on a 5-acre tract at 25th and E Streets NW, Washington, D.C., on March 16.

1906 Medical care for merchant seamen and other beneficiaries of the Public Health and Marine Hospital Service began to be supported by direct congressional appropriations, with the repeal of the tonnage tax on June 30.

1909 Dr. John F. Anderson was appointed Hygienic Laboratory director on October 1.

1910

1912 Dr. Rupert Blue was appointed Surgeon General of the Public Health and Marine Hospital Service on January 13.

The name Public Health and Marine Hospital Service was changed to Public Health Service (PHS) on August 14, and the research program was expanded to include other-than-communicable diseases field investigations, navigable stream pollution, and information dissemination.

1914 Dr. Joseph Goldberger announced his views of pellagra as a dietary deficiency, emphasizing the importance of dietary deficiency diseases.

1915 Dr. George W. McCoy was appointed Hygienic Laboratory director on November 20.

1918 The Chamberlain-Kahn Act, passed July 9, provided for the study of venereal diseases. The PHS made grants to 25 institutions, establishing a precedent for the Federal Government to seek assistance of scientists through grants.

The PHS reserve corps was established by law on October 27, during the influenza pandemic, as a means of coping with the emergencies.

1920

1920 Dr. Hugh Smith Cumming was appointed PHS Surgeon General on March 3.

1921 The Rocky Mountain Spotted Fever Laboratory was established in a former school building in Hamilton, Mont., on September 20 as a recognized PHS field station.

1922 The Library of the Office of the Surgeon General (Army) was renamed the Army Medical Library in January.

A Special Cancer Investigations Laboratory was established by PHS investigators at Harvard Medical School on August 1.

1929 On January 19, the Narcotics Control Act was passed, authorizing construction of two hospitals for drug addicts, and creation of a PHS Narcotics Division.

1930

1930 On April 9, the Advisory Board for the Hygienic Laboratory became the National Advisory Health Council.

On May 26 the Ransdell Act redesignated the Hygienic Laboratory as the National Institute of Health, authorizing \$750,000 for construction of two buildings for NIH, and creating a system of fellowships.

On June 14, Public Law 357 authorized creation of a separate Bureau of Narcotics in the Treasury Department and changed the PHS Narcotics Division to the Division of Mental Hygiene. The law gave the Surgeon General authority to investigate the causes, treatment, and prevention of mental and nervous diseases.

1935 A narcotic "farm" at Lexington, Ky., was completed and opened on May 29.

On August 10, Mr. and Mrs. Luke I. Wilson made a gift of 45 acres of their estate "Tree Tops" for use of the National Institute of Health in Bethesda, MD.

Title VI of the Social Security Act was passed August 14 authorizing the expenditure of up to \$2 million on health grants to the states for "investigation of disease and problems of sanitation."

1936 Dr. Thomas Parran was appointed PHS Surgeon General on April 6.

1937 The Rocky Mountain Laboratory became part of the National Institute of Health in February, and was administratively made part of the Division of Infectious Diseases.

Dr. Lewis R. Thompson was appointed director of the National Institute of Health on February 1.

With the reorganization of the National Institute of Health into eight divisions, the biologics control program, previously the responsibility of the Division of Pathology and Bacteriology, NIH, was assigned to a newly established Division of Biologics Control (redesignated Biologics Control Laboratory, 1944).

The National Cancer Institute Act was signed on July 23.

1938 The National Advisory Cancer Council recommended approval of the first awards for fellowships in cancer research on January 3.

Mrs. Luke I. Wilson made a second gift of 10.7 acres, to NIH on May 28.

The cornerstone for Building 1 was laid June 30.

Congress approved construction of new, larger laboratory facilities, and NIH moved to Bethesda, MD., in July.

Mrs. Luke I. Wilson made a third gift, 14.4 acres of land, to NIH on September 30.

The narcotics hospital at Fort Worth, Tex., was dedicated on October 28.

1939 Under a Reorganization Act dated April 3, the PHS was transferred from the Treasury Department to the Federal Security Agency.

1940

1940 Mrs. Luke I. Wilson made a fourth gift, 11.6 acres of land, to NIH on September 27.

President Franklin D. Roosevelt dedicated the buildings and the grounds of the National Institute of Health on October 31.

1942 Dr. Rolla Eugene Dyer was appointed director of the National Institute of Health on February 1.

A final gift of land was made by Mrs. Luke I. Wilson on March 17 bringing the total to 92 acres. This was the nucleus of the present 306.4-acre reservation. Additional land was acquired through a series of purchases.

1943 NIH was given bureau status in the PHS on November 11.

1944 The PHS act was approved on July 1, consolidating and revising existing public health legislation, and giving NIH the legislative basis for its postwar program, with general authority to conduct research. Under this act NCI became a division of NIH.

1946 The Research Grants Office was created at NIH in January to administer the Office of Scientific Research and Development projects transferred to the PHS at the end of World War II and to operate a program of extramural research grants and fellowship awards.

The National Mental Health Act was passed July 3.

On August 12, the Research Grants Office became the Research Grants Division (later renamed Division of Research Grants). The division was instructed by the National Advisory Health Council to establish study sections for scientific and technical review of research grant applications, and to explore neglected areas of research in the health sciences.

The Hospital Survey and Construction Act, introduced by Senators Lister Hill and Harold H. Burton, was passed on August 13, authorizing the Hill- Burton program.

1948 Dr. Leonard A. Scheele was appointed PHS Surgeon General on April 6.

On June 16 the National Heart Act was signed. It authorized the National Heart Institute and changed the name of the National Institute of Health to National Institutes of Health.

The National Dental Research Act, passed June 24, authorized the National Institute of Dental Research.

The National Heart Institute was established August 1.

The National Institute of Dental Research was established September 16.

Construction of the Clinical Center was started in November.

The National Microbiological Institute and the Experimental Biology and Medicine Institute were established on November 1.

The Rocky Mountain Laboratory and Biologics Control Laboratory became two of the four components of the National Microbiological Institute on November 1.

1949 The purchase of 115.8 acres from the Town & Country Golf Club, Inc., for \$600,000 was concluded February 11.

The purchase of 47.9 acres of land from Mr. and Mrs. G. Freeland Peter for \$505,000 was concluded on February 14.

The National Institute of Mental Health was established on April 15, with the abolishment of the Division of Mental Hygiene.

The first issue of *The NIH Record* was published May 20.

The purchase of 50.2 acres of land from the Sisters of the Visitation for \$173,058 was concluded on June 28.

Dr. Frank B. Rogers became director of the Army Medical Library in October.

1950

1950 The Omnibus Medical Research Act, signed August 15, authorized the National Institute of Neurological Diseases and Blindness and the National Institute of Arthritis and Metabolic Diseases, the latter absorbing the Experimental Biology and Medicine Institute. The act also gave the Surgeon General authority to establish new institutes.

Dr. William H. Sebrell, Jr. was appointed NIH director on October 1.

The National Institute of Neurological Diseases and Blindness and the National Institute of Arthritis and Metabolic Diseases were established November 22.

1951 The first R. E. Dyer Lecture was given by Dr. George W. Beadle, California Institute of Technology, June 21.

President Harry S. Truman laid the Clinical Center cornerstone on June 22.

1952 The Army Medical Library was renamed Armed Forces Medical Library in April.

1953 The first NIH Lecture was given on January 21 by Dr. Severo Ochoa of New York University College of Medicine.

PHS became part of the newly created Department of Health, Education, and Welfare on April 11.

The Clinical Center was dedicated on July 2, extending the clinical dimension of PHS research programs.

The first patient was admitted to the Clinical Center on July 6.

1954 A central data processing facility was established in the Office of the Director, NIH.

The NIH Graduate School Program began on September 27.

1955 The biologics control function was placed in the newly formed Division of Biologics Standards in June. The Division of Research Services and Division of Business Operations were also formed.

The Cancer Chemotherapy National Service Center was established April 1 to coordinate the first national cancer chemotherapy program.

The Mental Health Study Act was passed July 28.

Dr. James A. Shannon was appointed NIH director on August 1.

The National Microbiological Institute became the National Institute of Allergy and Infectious Diseases (NIAID) by order of the Surgeon General on December 29. The Biologics Control Laboratory was detached from the institute and expanded to division status within NIH.

1956 In January the biometric facility became the Biometrics Branch in the new Division of Research Services.

Dr. Leroy E. Burney was appointed PHS Surgeon General August 8.

The Armed Forces Medical Library was designated the National Library of Medicine (NLM) and placed under PHS October 1.

1957 The Center for Aging Research was established November 27 as the focal center for NIH extramural activities in gerontology.

1958 On July 16 the Division of General Medical Sciences was established by order of the Surgeon General, extending research into noncategorical areas covered until that time by the Division of Research Grants.

The Center for Aging Research was transferred from the National Heart Institute to the Division of General Medical Sciences on November 4.

1959 The Office of Administrative Management was formed July 15, consolidating the Division of Business Operations and other managerial responsibilities.

Congress appropriated \$2 million for the establishment of one or two private research centers on August 19.

1960

1960 On March 8 the Surgeon General approved establishment of a Computation and Data Processing Branch in the Division of Research Services.

NIH acquired 513 acres of farmland near Poolesville, MD., on May 6. This land became the site of the NIH Animal Center.

The International Health Research Act was passed July 12, extending NIH international programs.

1961 The Surgeon General established the Center for Research in Child Health in the Division of General Medical Sciences on February 17.

Dr. Luther L. Terry was appointed PHS Surgeon General March 24.

On May 26, DHEW Secretary Abraham A. Ribicoff dedicated the new NIDR building.

The first Jules Freund Lecture was given by Dr. Merrill W. Chase of the Rockefeller Institute on November 15.

The NIH European Office was established in Paris, France, on December 18.

1962 The NIH Latin American Office was established in Rio de Janeiro, Brazil, July 1.

The Division of Research Facilities and Resources was established July 15.

Public Law 87-838, passed October 17, authorized the National Institute of Child Health and Human Development and the National Institute of General Medical Sciences.

Five acres of land for a Gerontology Research Center were donated by the City of Baltimore in December.

1963 The NIH Pacific Office was established in Tokyo, Japan, on January 1.

The National Institute of Child Health and Human Development and the National Institute of General Medical Sciences were established on January 30.

The Center for Research in Child Health and the Center for Research in Aging (established in 1956) were transferred from NIGMS to NICHD.

The surgical wing for the Clinical Center was dedicated September 5.

The first NIH International Lecture was given October 31 by Dr. Walsh McDermott of Cornell University Medical College.

1964 The Medical Literature Analysis and Retrieval System (MEDLARS) became operational at the NLM in January.

The Division of Computer Research and Technology was established on April 16.

On September 19 Congress authorized planning funds for a central environmental health research facility.

A special virus-leukemia program was initiated under a special appropriation, included in the FY 1965 appropriation signed into law on September 19.

1965 On January 7, the Surgeon General announced that the National Environmental Health Sciences Center would be located in Research Triangle Park, N.C.

The NIH Animal Center, Poolesville, MD., officially opened May 27 with 2 days of orientation for NIH employees, area residents and the press after completion of the first of three phases of an \$18 million construction program.

NIH received a \$20,250,000 supplemental appropriation on August 31 to intensify and expand support of research in heart disease, cancer, stroke and related diseases.

Dr. William H. Stewart, appointed PHS Surgeon General September 24, took office on October 2.

A reorganization of the DHEW provided for an expansion of the secretary's office with the creation of three new assistant secretaries, including an assistant secretary for health and

scientific affairs.

Dr. Philip R. Lee was appointed to the new position of assistant secretary for health and scientific affairs on November 2.

1966 The Division of Regional Medical Programs was created on February 1 to administer grants under the Heart Disease, Cancer and Stroke Amendments of 1965. Dr. Robert Q. Marston was appointed NIH associate director for regional medical programs and chief of the division.

At a White House meeting June 27, the NIH director and institute directors discussed with the President how the benefits of research findings in health could be brought more rapidly to all the people. Later in the year, a report to the President described current NIH research efforts on the major U.S. disease problems and set forth the status of those problems, the nature of present and planned investigative efforts and the problems of and opportunities for further research.

A Division of Environmental Health Sciences was established in NIH November 1 to conduct, foster and coordinate research on the biological, chemical, and physical effects of environmental agents. Dr. Paul Kotin, scientific director for etiology, NCI, was named director of the new division.

An advisory committee to the NIH director was appointed on November 9 to provide advice on the further development of NIH research and related programs.

1967 The National Institute of Mental Health was separated from NIH and raised to bureau status in PHS by a reorganization that became effective January 1. NIMH's Division of Clinical, Behavioral and Biological Research, within the mental health Intramural Research Program, comprising activities conducted in the Clinical Center and other NIH facilities, continued here under an agreement for joint administration between the two companion bureaus. The Toxicology Information Program was established at NLM, January 1, in response to recommendations of the President's Science Advisory Committee. The program includes the entire range of chemical effects on living organisms.

The PHS Audiovisual Facility, renamed the National Medical Audiovisual Center, became an NLM component July 1.

On September 26, the deed for 509.25 acres of Research Triangle Park, N.C., to serve as a permanent site for the Division of Environmental Health Sciences, was presented to the Surgeon General.

1968 Establishment of the John E. Fogarty International Center for Advanced Study in the Health Sciences (FIC) was given departmental approval February 26. The center became operational on July 1, at which time the NIH Office of International Research was abolished and certain of its functions were transferred to FIC and NIAID.

Under a reorganization of health activities announced on April 1, NIH assumed status as a new operating agency within the department, with the NIH director reporting directly to the assistant secretary for health and scientific Affairs. Under the reorganization, the Bureau of Health Manpower and the National Library of Medicine became components of NIH.

On June 15 the four-story \$7.5 million Gerontology Research Center building, located at and operated in cooperation with Baltimore City Hospitals, was officially opened.

A proposed facility to house the biomedical communications network was designated the Lister Hill National Center for Biomedical Communications by passage of P.L. 90-456 on August 3.

Established by the DHEW secretary on August 9, the Center for Population Research conducts a contract and grant program in population and reproduction research. The center was designated by the President as the primary Federal agency responsible for population research and training.

On August 16 the National Eye Institute was created to build an enlarged program based on blindness research formerly conducted in the National Institute of Neurological Diseases and Blindness. The legislation also changed the NINDB name to the National Institute of Neurological Diseases.

Dr. Robert Q. Marston was sworn in as NIH director on August 29.

A Nobel Prize in Physiology or Medicine was awarded on October 16 to Dr. Marshall W. Nirenberg, chief of NIH's Laboratory of Biochemical Genetics, for discovering the key to deciphering the genetic code. He was the first NIH Nobel laureate, and the first Federal employee to receive a Nobel Prize.

On October 24 the President signed into law (P.L. 90-639) legislation changing the name of the NIND to the National Institute of Neurological Diseases and Stroke.

The National Eye Institute was established on December 26.

1969 A further reorganization of the NIH internal structure announced January 4 renamed the Bureau of Health Manpower as the Bureau of Health Professions Education and Manpower Training and expanded it to include seven divisions, one of which was the Division of Research Resources (DRR).

The Division of Environmental Health Sciences was elevated to institute status on January 12, thus becoming the 10th NIH institute.

Dr. Roger O. Egeberg was named DHEW assistant secretary for health and scientific affairs on July 14, succeeding Dr. Lee.

On November 10, the DHEW secretary redesignated the National Heart Institute as the National Heart and Lung Institute (NHLI).

1970

1970 A reorganization of the Bureau of Health Professions Education and Manpower Training renamed it the Bureau of Health Manpower Education on September 18. DRR was separated from the bureau and became a division within NIH.

1971 Dr. Merlin K. DuVal was appointed DHEW assistant secretary for health and scientific affairs on July 1, succeeding Dr. Egeberg.

The White House Conference on Aging recommended creating a separate National Institute on Aging on December 2.

On December 23 the President signed the National Cancer Act of 1971 initiating a National Cancer Program, establishing the President's Cancer Panel, a National Cancer Advisory Board and 15 new research, training and demonstration cancer centers.

1972 The National Institute of Arthritis and Metabolic Diseases was renamed the National Institute of Arthritis, Metabolism, and Digestive Diseases on May 19. On July 1, DBS transferred from NIH and officially became a sixth bureau, the Bureau of Biologics in the Food and Drug Administration. The bureau continues to use NIH facilities and buildings.

The DHEW secretary approved a reorganization of NHLI on July 14, elevating the institute to bureau status within NIH. A bureau-level organization was established for the National Cancer Institute on July 27.

On October 25 Public Law 92-564 established a temporary National Commission on Multiple Sclerosis (supported by NINDS).

Dr. Christian B. Anfinsen, NIAMDD, won the Nobel Prize in Chemistry for his work on ribonuclease.

1973 Dr. Charles C. Edwards was appointed DHEW assistant secretary for health on April 18, succeeding Dr. DuVal.

Dr. Robert S. Stone was sworn in as the 10th NIH director on May 29.

The Bureau of Health Manpower Education was transferred from NIH to the new Health Resources Administration on July 1 and renamed the Bureau of Health Resources Development.

The National Institute of Mental Health rejoined the National Institutes of Health on July 1. On September 25, NIMH became part of the new Alcoholism, Drug Abuse and Mental Health Administration.

1974 The Research on Aging Act of 1974, creating the National Institute on Aging, was signed into law on May 31.

On July 23, the National Cancer Act Amendments of 1974 were signed by the President to improve the National Cancer Program. It also established a President's Biomedical Research Panel.

The National Institute on Aging was established on October 7.

The Interagency Primate Steering Committee was established by the DHEW assistant secretary for health with NIH as the lead agency.

Institutional Relations Branch was transferred on October 27 from DRG to the immediate Office of the Director, NIH, and renamed the Office for Protection From Research Risks.

1975 On March 13 the National Institute of Neurological Diseases and Stroke was renamed the National Institute of Neurological and Communicative Disorders and Stroke.

Dr. Theodore Cooper was appointed DHEW assistant secretary for health on July 1, succeeding Dr. Edwards.

Dr. Donald S. Fredrickson was sworn in as the 11th NIH director on July 1.

The Adult Development and Aging Branch and the Gerontology Research Center were separated from NICHD to become the core of the National Institute on Aging, also on July 1.

1976 On June 25, the National Heart and Lung Institute was renamed the National Heart, Lung, and Blood Institute.

Dr. D. Carleton Gajdusek, NINCDS, shared the Nobel Prize in Physiology or Medicine with Dr. Baruch Blumberg, Institute for Cancer Research. Dr. Gajdusek was honored for his research on kuru and Dr. Blumberg for his work on the Australia antigen at the National Institute of Arthritis and Metabolic Diseases (1957-1964).

1977 Construction of the Ambulatory Care Research Facility was started in April.

On July 13, Dr. Julius B. Richmond took the oath of office as DHEW assistant secretary for health and Surgeon General, becoming the first person to hold both offices simultaneously.

1978 On November 15 the DHEW secretary announced the establishment of the National Toxicology Program under the direction of NIEHS.

1979 Dr. Hans J. Muller Eberhard, Scripps Clinic and Research Foundation, delivered the first Kinyoun Lecture on April 24.

A protocol of cooperation in the exchange of information on medicine and public health between the United States and China was signed on June 22 in Beijing's historic Great Hall. The DHEW secretary signed on behalf of the United States.

On July 18 NCI and the National Naval Medical Center, Bethesda, MD., agreed to cooperate in a cancer treatment research program.

1980

1980 DHEW became the Department of Health and Human Services (DHHS) on May 14.

A separate Department of Education was established.

On May 22, the Lister Hill Center for Biomedical Communications was dedicated as part of NLM.

1981 On May 14 Dr. Edward N. Brandt, Jr., was sworn in as assistant secretary for health.

The National Institute of Arthritis, Metabolic, and Digestive Diseases was renamed the National Institute of Arthritis, Diabetes, and Digestive and Kidney diseases on June 23.

On June 30 Dr. Fredrickson stepped down as NIH director. Dr. Thomas E. Malone was appointed acting director.

The Ambulatory Care Research Facility was officially dedicated on October 22. The research hospital was renamed the Warren Grant Magnuson Clinical Center in honor of the former chairman of the Senate Committee on Appropriations. Sen. Magnuson was involved in support of biomedical research at NIH since 1937.

Dr. C. Everett Koop became PHS Surgeon General on November 16.

1982 On April 22 NIADDK was converted to bureau status, joining NCI, NHLBI, and NLM. Dr. James B. Wyngaarden, chairman of the Duke University department of medicine, was appointed NIH director on April 29.

The National Institute of Child Health and Human Development marked its 20th anniversary on September 20.

NIGMS celebrated its 20th anniversary by establishing the DeWitt Stetten, Jr., Lectureship. Dr. David S. Hogness, Stanford University, gave the first lecture, October 13.

The National Institute on Aging opened its first on-campus research unit in the NIH Clinical Center.

The NIEHS facility in Research Triangle Park, N.C., was dedicated on November 15.

Lasker Foundation Awards were presented on November 17 to three NIH scientists: Dr. Elizabeth Neufeld, NIADDK; Dr. Roscoe O. Brady, NINDS; and Dr. Robert C. Gallo, NCI.

1983 On January 18, Building 1 was officially named the James A. Shannon Building in honor of the former NIH director (1955-1968).

The first multidisciplinary pain clinic in the United States devoted exclusively to research was opened in the Clinical Center March 21 by NIDR.

NCI dedicated its R.A. Bloch International Cancer Information Center on October 2. The building houses the institute's information programs that serve health professionals and scientists.

In December, the Clinical Center celebrated its 30th anniversary of operation.

1984 NIH purchased the Convent of the Sisters of the Visitation of Washington along with about 11 acres of land for \$4.5 million.

In May NCI scientists headed by Dr. Robert C. Gallo, Jr., uncovered strong evidence that variants of a human cancer virus called HTLV-III are the primary cause of acquired immunodeficiency syndrome (AIDS).

DCRT celebrated its 20th anniversary in May.

NIH and Howard Hughes Medical Institute launched a multimillion dollar cooperative program in August to help increase the vigor of American biomedical research and continue the flow of new doctors into research areas.

The former Convent was dedicated September 19 as the Mary Woodard Lasker Center for Health Research and Education.

1985 NIH and the Howard Hughes Medical Institute chose the first 25 HHMI-NIH research scholars in June.

In July the NIA celebrated its 10th anniversary.

1986 In May the National Institute of Arthritis and Musculoskeletal and Skin Diseases became a separate institute separated from its parent NIADDK - now called the National Institute of Diabetes and Digestive and Kidney Diseases. Also created was the National Center for Nursing Research.

NIH held the First Intramural Research Day on September 25 featuring symposia and poster sessions.

In June NIAID funded 14 centers to evaluate experimental drugs in the treatment of AIDS.

NIH opened its year-long centennial celebration - A Century of Science for Health - on October 16.

1987 NIH scheduled monthly events, hosted by individual components throughout the year, to commemorate its 100th anniversary.

NIAID awarded contracts to five medical centers to establish AIDS treatment evaluation units.

NIEHS celebrated its 20th anniversary, while NIGMS and DRR marked their 25th.

Fifty-six promising science students - one from each state and U.S. possession - were honored by NIH as centennial scholars.

On July 23 President Reagan named a 13-member Commission on the Human Immunodeficiency Virus Epidemic, which held its first meeting following the announcement.

NIH became a smoke-free agency on September 1, banning smoking in all buildings.

Hundreds of NIH alumni from the United States and abroad returned to the campus on October 15-16 to help close out the year-long celebration of the NIH centennial.

1988 NIH was honored by Spain with the presentation of the Grand Cross of the Civil Order of Health.

The NICHD celebrated its 25th anniversary and NIAID and NIDR marked their 40th.

The Children's Inn at NIH, a temporary home away from home for NIH pediatric patients, was dedicated. A gift of \$2.5 million from Merck and Co., Inc. was donated toward the construction of the building.

"Sky Horizon," a sculpture created by Louise Nevelson, was given to NIH by Edwin C. Whitehead, founder of the Whitehead Institute of Biomedical Research.

Officials from NICHD, NINDS, and NIMH broke ground for a facility they will share - Building 49, the Child Health and Neurosciences Building.

November marked the establishment of the National Institute on Deafness and Other Communication Disorders. The parent institute was renamed the National Institute of Neurological Disorders and Stroke.

1989 On May 10, Building 31 was named the Claude Denson Pepper Bldg. to honor NIH's "legislative father."

The NIH Record marked its 40th year of publication in May.

On May 22, NIH conducted its first gene transfer in humans. A cancer patient was infused with tumor-infiltrating lymphocytes (TIL) that had been altered by insertion of a gene. This allowed scientists to track the special cancer-fighting cells in the body to increase the understanding of TIL therapy.

1990

1990 The National Center for Human Genome Research was established in January.

DRR and DRS merged in March and named the National Center for Research Resources.

On June 21 the Children's Inn at NIH opened its doors to pediatric patients and their families. The President and Mrs. Bush attended the ceremonies.

The Recombinant DNA Advisory Committee approved the first experiments involving transfer of human genes for therapeutic purposes on July 31. The treatment was initiated on September 14 in a 4-year-old girl with adenosine deaminase deficiency.

The National Institute of Neurological Disorders and Stroke and the National Institute of Diabetes and Digestive and Kidney Diseases marked their 40th anniversaries.

It was announced in September that the gene that caused osteoarthritis was isolated by scientists supported by the National Institute of Arthritis and Musculoskeletal Diseases.

The Office of Research on Women's Health was established to strengthen NIH's efforts to improve the prevention, diagnosis and treatment of illness in women and to enhance research related to diseases and conditions that affect women.

1991 On January 29, NIH scientists treated the first cancer patients with human gene therapy. Two patients received transfusions of special cancer-killing cells removed from their own tumors and armed in the laboratory with a gene capable of producing a potent antitumor toxin, tumor necrosis factor.

Dr. Bernadine Healy was confirmed as NIH's 13th director on March 21. She was the first woman appointed to this post.

In August the National Center for Human Genome Research announced the start of a new, unified effort to develop a "framework" map of the human genome - expected to take 2 to 3 years to complete.

1992 The National Institute on Drug Abuse, National Institute on Alcohol Abuse and Alcoholism, and National Institute of Mental Health were transferred from the Alcohol, Drug Abuse, and Mental Health Administration to become part of the NIH.

Two components - NICHD and NIGMS - celebrated their 30th anniversaries on September 21 and October 17, respectively.

1993 NIH Director Bernadine Healy stepped down to return to the Cleveland Clinic Foundation.

The Clinical Center celebrated its 40th anniversary.

Sixteen university medical programs were launch sites for the 15-year, \$625 million Women's Health Initiative. About 3,000 women will be enrolled at each center to investigate women's most common causes of death and disability.

Dr. Harold Varmus was appointed NIH's 14th Director.

FIC noted its 25th anniversary.

The National Center for Nursing Research became the 16th institute.

1994 Former director, Dr. James Shannon, died.

NHLBI scientists for the first time successfully transferred a normal cystic fibrosis gene into the cells lining a CF patient's lungs.

Researchers at NIEHS isolated the BRCA1 gene - responsible for about 5 percent of all breast cancers and 25 percent in women under age 30.

Dr. Martin Rodbell, NIEHS, shared the Nobel Prize in physiology or medicine for research on G proteins, key components of the communication system that regulates cellular activity.

1995 NLM unveiled the "Visible Man," a detailed atlas of human anatomy created from thousands of images of a human body collected by radiographic and photographic techniques.

NIAAA celebrated its 25th anniversary.

1996 The first multicenter trial of bone marrow transplantation in children with sickle cell disease demonstrated that the procedure can provide a cure for young patients that have a matched sibling, according to NHLBI-supported scientists.

DRG celebrated its 50th anniversary and NIEHS noted its 30th.

1997 Researchers with NHGRI completed a map of chromosome 7, an important milestone within the Human Genome Project.

DRG was renamed the Center for Scientific Review and DCRT became the Center for Information Technology.

Vice President Al Gore performed an "inaugural search," opening up free access on the world wide web to NLM's MEDLINE.

Results from the NIH-supported Dietary and Systolic Hypertension trial indicated that blood pressure can be swiftly and significantly lowered through a diet low in fat and high in vegetables, fruits, and low-fat dairy foods.

A team led by NHGRI scientists identified a defective gene that causes some inherited cases of Parkinson's disease.

Results from an NIH trial showed that a low-dose diuretic cuts by half the chance that an older person with high systolic blood pressure will develop heart failure. In those who had already had a heart attack, their chance of developing heart failure dropped by 80 percent.

A team led by NIH-funded scientists determined the complete genome sequence of the *E. coli* bacterium, a laboratory workhorse. This accomplishment gives researchers a powerful new tool for understanding fundamental questions of biological evolution and function.

On November 4, Vice President Al Gore and Senator Mark O. Hatfield attended the groundbreaking ceremonies for the new Clinical Center, which will be called the Mark O. Hatfield Clinical Research Center.

1998 Building 20, NIH's apartment building, was carefully demolished to make way for the new Mark O. Hatfield Clinical Research Center.

NICHHD's new zebrafish facility opened. Zebrafish have become the mainstay of developmental biologists for studying the development of the vascular system and central nervous system, as well as the functional genomics of the zebrafish.

A large prevention trial conducted by NCI showed that long-term use of a moderate-dose vitamin E supplement substantially reduced prostate cancer incidence and deaths in male smokers.

In a cooperative endeavor (NeuroLab) between NASA, NIH and others, astronauts on Space Shuttle Columbia conducted research on how the neurological system responds to the challenges of space flight.

Results from a NCI-sponsored clinical trial showed that women at high risk of developing breast cancer who took the drug tamoxifen had 49 percent fewer cases of breast cancer than those who didn't. Tamoxifen was hailed as the first drug to prevent breast cancer in women at high risk for the disease.

The new NIH Intramural Sequencing Center opened in Gaithersburg. NISC is a 14-institute consortium that is dedicated to large-scale sequencing of human and animal DNA.

NIDR celebrated its 50th anniversary, with a name change to the National Institute of Dental and Craniofacial Research.

Building 16, known as the Stone House, was renamed the "Lawton Chiles International House"; it will be the locus for international activities supported by FIC and other NIH and DHHS components.

Between 1992 and 1996, the rate of Sudden Infant Death Syndrome (SIDS) dropped by 38 percent, much of that likely being due to a 66 percent decrease during the same period in the number of U.S. infants being placed to sleep on their stomachs. A national Back to Sleep Campaign - encouraging parents to put their infants to sleep on their backs - was launched in 1994 by NICHHD, in partnership with HHS and other organizations.

The complete sequence of two bacteria that are among the major causes of sexually transmitted diseases worldwide - *Treponema pallidum*, responsible for syphilis, and *Chlamydia trachomatis*, responsible for chlamydial infections - were obtained by two

separate teams of scientists supported by NIAID and others.

NIDCD celebrated its 10th anniversary.

Senator John Glenn and six other astronauts spent nine days in space aboard NASA's Space Shuttle Discovery conducting about 83 scientific projects, the most research-intensive space journey yet. Glenn, NASA and others worked with NIA to develop the projects.

NIAID celebrated its 50th anniversary.

NHLBI's Framingham Heart Study celebrated its 50th anniversary.

An international team funded by NHGRI and others obtained the complete sequence of the 97-million-base genome of the roundworm, *Caenorhabditis elegans*. This marks the first time that scientists have spelled out the instructions for a complete animal which, like humans, has a nervous system, digests food, reproduces, and gets old, making it a very important organism in which to carry out studies that parallel human biology.

1999 The new South Entry to the Clinical Center opened, thus facilitating construction on the Mark O. Hatfield Clinical Research Center on the north face of Building 10.

A team of investigators led by an NIAID grantee discovered that a subspecies of chimpanzees native to west Africa are the origin of HIV-1, the virus responsible for the global AIDS pandemic.

Underlying vitamin D deficiency in postmenopausal women is associated with increased risk of hip fracture, according to a study supported by NIA and NCRR.

NIDA, NIMH, and NINDS moved into the new Neuroscience Center office building on Executive Boulevard, which some have dubbed "NIH North".

A meta-analysis study, led by an NICHD researcher, found that pregnant women infected with HIV could reduce the risk of transmitting the virus to their infants by about 50 percent if they deliver by cesarean section before they go into labor and before their membranes rupture.

NIH Director Dr. Harold Varmus convened the first meeting of the Director's Council of Public Representatives (COPR). The Council will provide advice and recommendations to, and consult with, the NIH Director regarding matters related to medical research, NIH's policies and programs, and public participation in NIH's activities. COPR was chartered in November 1998.

On June 9, President Bill Clinton unveiled the cornerstone for the new Dale and Betty Bumpers Vaccine Research Center, which initially will focus on accelerating the search for a vaccine against AIDS. Earlier, Dr. Varmus named Dr. Gary Nabel as the director of the new VRC, which currently exists as a "center without walls". The VRC is funded by NIAID and NCI and spear-headed by them and NIH's Office of AIDS Research.

NLM's MEDLINE added the 10 millionth journal citation to its database.

A joint Uganda-U.S. study, funded by NIAID, demonstrated a highly effective, affordable and practical strategy for preventing transmission of HIV from an infected mother to her newborn. A single-oral dose of the antiretroviral drug nevirapine given to the HIV-infected

mother while in labor and another to her baby within three days of birth reduced the transmission rate by half compared with a similar short course of AZT.

Women with preeclampsia, a potentially fatal complication of pregnancy, were found to have an imbalance of two key chemical compounds that control blood pressure, prostacyclin and thromboxane, months before their symptoms appeared, according to NICHD scientists.

NIDA celebrated its 25th anniversary.

NIH announced its plan to establish a repository called PubMed Central for free electronic distribution of primary research reports in the life sciences. The new site would be integrated with NLM's widely used bibliographic site PubMed and is intended to be one of several repositories in an international system first proposed by NIH director Dr. Harold Varmus. PubMed Central would begin receiving, storing and distributing content - including peer-reviewed articles, preprints, and other screened reports from existing journals, new journals, and reputable scientific organizations - in January 2000.

Children born to mothers with untreated hypothyroidism during pregnancy were found to score lower on IQ tests than children of healthy mothers suggesting that early detection and treatment of hypothyroidism in pregnant women may be a critical part of prenatal care, according to a study funded by NICHD and others.

In October 1999, NIH announced a major research program involving 10 laboratories, called the Mouse Genome Sequencing Network, to map and sequence the DNA in the mouse genome.

A research effort led by NIAID scientists produced the first high-resolution genetic map of *Plasmodium falciparum*, the deadliest malaria parasite, which is responsible for the death of more than two million people annually.

Scientists supported by NHGRI along with groups in England and Japan completed the first sequence of a human chromosome, chromosome 22. Genes on chromosome 22 have been implicated in immune system function, congenital heart disease, and several cancers including leukemia.

The National Toxicology Program, headquartered at NIEHS, announced that Federal regulatory agencies - FDA, OSHA, EPA and CPSC - would accept, for the first time, an alternative way to test chemicals for allergic contact dermatitis that could reduce by thousands the number of guinea pigs needed for such tests.

After leading NIH for 6 years, Dr. Harold Varmus left to become the President and CEO of Memorial Sloan-Kettering Cancer Center in New York City.

2000

2000 On January 1, Dr. Ruth Kirschstein, deputy director of NIH, became the acting director.

Scientists funded by NIDCR and NIAMS, along with an NCI scientist discovered that leptin, the product of the obesity gene, acts as a bone inhibitor by telling the brain to slow down the rate of bone formation, showing for the first time that the brain has a central role in controlling bone formation and density.

A team including NCI scientists and grantees used microarray technology to show that the most common form of non-Hodgkin's lymphoma (NHL), diffuse large B-cell lymphoma, is actually two distinct diseases, thus explaining why 40 percent of patients with this NHL can be cured through chemotherapy while others succumb to the disease. This is the first demonstration of a technology that promises to revolutionize cancer diagnosis as well as many other areas of research.

The NIEHS headquarters and laboratory Building 101 in Research Triangle Park, N.C., was renamed the Rall Building in honor of former NIEHS director, Dr. David Platt Rall.

NLM received Vice President Al Gore's Hammer Award for a series of improvements in its information services, including making its popular MEDLINE database of journal article references and abstracts free and easier for the public to use.

NIH launched the first phase of a consumer-friendly database, ClinicalTrials.gov, with information on more than 4,000 Federal and private medical studies involving patients and others at more than 47,000 locations nationwide. The new database may be reached at <http://clinicaltrials.gov/>.

CC and NIAID scientists demonstrated that the widely used herbal product St. John's wort could significantly compromise the effectiveness of a protease inhibitor often used to treat those infected with HIV.

An NIAID study showed that a nasal spray flu vaccine not only protected young children against the three strains of influenza for which the vaccine was designed to provide protection but also a flu strain not covered by the vaccine. It also protected the children against flu-related middle-ear infections.

Scientists supported by NHGRI and DOE along with the private company Celera completely sequenced the genome of the fruitfly *Drosophila melanogaster*, which is used to study a host of biological questions related to aging, development, learning, memory and more.

NIH's Office of Research on Minority Health and the Office of Research on Women's Health celebrated their tenth anniversaries.

An NHLBI-supported clinical trial showed that lowering the amount of salt for those who ate a "usual" American diet as well as those following the DASH diet - rich in vegetables, fruits and low-fat dairy foods and low in saturated fat, total fat and cholesterol - lowered blood pressure correspondingly for both those with and without hypertension, including African Americans.

NIGMS and the Indian Health Service announced plans to collaborate on a new program, Native American Research Centers for Health (NARCH), designed to promote, develop and support centers that will link the Native American community with organizations that conduct health research.

The international Human Genome Project public consortium - funded by NIH, DOE, and others - assembled a working draft of the sequence of the human genome. The information

from this project has been completely, immediately, and freely released to the world with no restrictions on its use.

Researchers supported by NIGMS demonstrated that a simple and inexpensive change in basic surgical procedures - giving patients more oxygen during and immediately after surgery - can cut the rate of wound infections in half, thus saving millions of dollars in hospital costs by helping to prevent post-surgical wound infection, nausea and vomiting.

A team of scientists funded by NIAID determined the complete sequence of the genome of the bacterium - *Vibrio cholerae* - that causes cholera.

2001 Grantees of NIAID and NHGRI and others sequenced the entire genome of a deadly strain of *E. coli*, a bacterium that is emerging as a major public health threat through contaminated ground beef, milk, fruits and vegetables. By comparing the sequence of this strain with that of harmless strains of *E. coli*, scientists may learn why only some forms cause disease and then find ways to prevent harmful strains from causing disease.

A team of NHGRI and NCI scientists and others developed a new genetic test that can distinguish between two types of hereditary breast cancer - caused by BRCA1 and BRCA2 mutations - and sporadic breast cancer. The new approach uses microarray (gene chip) technology to analyze the activity of more than 5300 genes at once. This advance should ultimately help physicians diagnose the cause of a woman's breast cancer and guide decisions about the most effective treatments.

A team composed of scientists from NHGRI and NINDS, grantees of NHLBI and NIA, and others demonstrated that adult stem cells isolated from mouse bone marrow could become functioning heart muscle cells when injected into a damaged mouse heart. The new cells at least partially restored the heart's ability to pump blood.

NIAID grantees completed sequencing the genome of *Streptococcus pyogenes*, a bacterium that causes a wide variety of human diseases including strep throat, scarlet fever, pneumonia, toxic shock syndrome, blood "poisoning," acute rheumatic fever, rheumatic heart disease, and the flesh-eating disease known as necrotizing fasciitis. This information should aid scientists in developing new ways to prevent and treat these diseases.

Scientists from NICHD developed and, along with an NIDDK scientist and others, tested the first vaccine capable of protecting children ages 2 to 5 against typhoid fever. Seemingly the most effective typhoid vaccine ever developed, it is also virtually free of side effects. About 16 million people worldwide develop typhoid each year, and 600,000 die from it, mainly in developing countries without adequate sewage and sanitation.

Under a CRADA with the drug company Novartis, NCI scientists found that a new drug known as Gleevec was effective against chronic myelogenous leukemia (CML) in patients for whom standard treatments had failed. (CML is a disease in which too many white blood cells are made in the bone marrow, the spongy tissue inside the large bones in the body.) NCI funded the lion's share of the basic research that led to the discovery and development by Novartis of Gleevec, the first anti-cancer drug specifically developed to target the molecular problem that causes a particular type of cancer.

NHGRI scientists and others developed a method that combined microarray (gene chip) technology with a form of artificial intelligence. This enabled them to tell the difference between four childhood cancers that often look alike - neuroblastoma, Ewing's sarcoma, non-Hodgkin lymphoma (Burkitt's lymphoma) and rhabdomyosarcoma. Because the treatments for these tumors are quite different, an accurate diagnosis can be critical for a child's survival. This study should help lead to the discovery of genes that are altered in

these tumors and ultimately to the development of effective new treatments.

Grantees of NHLBI and NIA found that human heart muscle cells can regenerate after a heart attack. This finding opens up the possibility of repairing heart muscle damage after a heart attack.

Animal studies by NIDA researchers found that craving for cocaine seems to increase, rather than decrease, in the days and months after drug use has stopped. This phenomenon helps explain why addiction is a chronic, relapsing disease.

People at high risk for type 2 diabetes can sharply lower their chances of getting the disease by losing weight (5 percent to 7 percent of their body weight) and by getting 30 minutes of walking or other moderate exercise every day, according to the findings of a clinical trial sponsored by NIDDK.

On August 9, President Bush announced that Federal funds could be used to support research using existing lines of human embryonic stem cells that meet certain criteria. NIH then developed a registry of the known human embryonic stem cell lines so researchers could identify in their applications for funding which sources of stem cells they plan to use.

An NEI-sponsored clinical trial showed that people at high risk of developing advanced stages of age-related macular degeneration (AMD) significantly lowered that risk by taking a high-dose combination of zinc and the antioxidants vitamin C, vitamin E and beta-carotene. These nutrients are the first effective treatment to slow the progression of AMD, a leading cause of visual impairment and blindness in Americans 65 years of age and older.

2002 NCCR-supported scientists were part of a team that cloned the world's first "knockout" pigs – ones with a particular gene removed. The gene they removed was for a molecule on the surface of the pig cells that the human immune system recognizes and attacks, leading to the failure of transplanted tissues or organs.

A team of NICHD and other scientists developed the first vaccine against *Staphylococcus aureus*, a major cause of infection and death among hospital patients.

People with elevated levels of homocysteine in the blood had nearly double the risk of Alzheimer's disease (AD), according to a team of scientists supported by NIA and NINDS. The findings, in a group of participants in NHLBI's long-running Framingham Study, are the first to tie homocysteine levels measured several years before with a later diagnosis of AD and the other dementias, providing some of the most powerful evidence yet of an association between high plasma homocysteine and later significant memory loss.

NIAID released its Counter-Bioterrorism Research Agenda, a document describing an accelerated research plan for the most threatening agents of bioterrorism. The agenda outlines the research NIAID will undertake to help protect civilian populations from diseases such as smallpox, anthrax and plague should those who wish to do harm unleash them intentionally.

Results of an NIAID study indicate that the existing U.S. supply of smallpox vaccine – 15.4 million doses – could successfully be diluted up to five times and retain its potency, effectively expanding the number of individuals it could protect from the contagious disease. The success of this study puts us one step closer to the goal of having enough vaccine for every American if needed to respond to a potential outbreak.

Dr. Elias Zerhouni became the 15th director of the National Institutes of Health.

The international Mouse Genome Sequencing Consortium, jointly funded by NHGRI and several NIH institutes along with the Wellcome Trust in the United Kingdom, announced that it had assembled and deposited into public databases an advanced draft sequence of the mouse genome, the genetic blueprint for the most important animal model in biomedical research. The sequence is freely available on the Internet.

Dr. Roderic I. Pettigrew was named the first director of NIH's new National Institute of Biomedical Imaging and Bioengineering.

Researchers used whole-genome sequencing technology and computational methods to genetically compare two important isolates of the anthrax bacterium: the well-known Ames strain and an isolate from the 2001 Florida anthrax attacks. These techniques will enable researchers to more accurately trace the origin of individual bacterial strains, determine if those strains have been genetically modified, and assess differences in their ability to cause disease or resist antibiotics. NIAID teamed with the Office of Naval Research, the National Science Foundation, and other agencies to fund the research.

NHLBI stopped early a major clinical trial of the risks and benefits of combined estrogen and progestin in healthy menopausal women due to an increased risk of invasive breast cancer. The large trial, a component of the Women's Health Initiative (WHI), also found increases in coronary heart disease, stroke, and pulmonary embolism in study participants on estrogen plus progestin compared to women taking placebo pills. There were some benefits of estrogen plus progestin, including fewer cases of hip fractures and colon cancer, but on balance the harm was greater than the benefit.

NIH licensed a new technology that allows physicians and researchers to make detailed, three-dimensional maps of nerve pathways in the brain, heart muscle fibers, and other soft tissues. The new imaging technology, called Diffusion Tensor Magnetic Resonance Imaging (DT-MRI), was invented by researchers now at NICHD.

A new approach to cancer treatment that replaces a patient's immune system with cancer-fighting cells can lead to tumor shrinkage. NCI researchers demonstrated that immune cells, activated in the laboratory against patients' tumors and then administered to those patients, could attack cancer cells in the body. The experimental technique, known as adoptive transfer, has shown promising results in patients with metastatic melanoma who have not responded to standard treatment.

NIAID-supported researchers proved conclusively that the malaria-causing parasite *Plasmodium falciparum* became resistant to the anti-malarial drug chloroquine through mutations in a single parasite gene. This finding has potentially important implications for malaria treatment and control.

An international research consortium of NHGRI, other NIH components, and other countries launched a public-private effort to create the next generation map of the human genome. Called the International HapMap Project, this new venture is aimed at speeding the discovery of genes related to common illnesses such as asthma, cancer, diabetes and heart disease.

2003 The International Human Genome Sequencing Consortium, led in the United States by NHGRI and the Department of Energy, completed the Human Genome Project more than two years ahead of schedule and for a cost substantially less than the original estimates. The international effort to sequence the three billion DNA letters is considered by many to be one of the most ambitious scientific undertakings of all time. The first draft of the human sequence was completed in June 2000. Researchers have now produced a "finished" sequence, which covers about 99 percent of the human genome's gene-containing regions, and has been sequenced to an accuracy of 99.99 percent. All of the sequence data have been deposited into public databases and made freely available to scientists around the world, with no restrictions on their use or redistribution.

The complete genetic blueprint of *Bacillus anthracis* — the microbe that gained notoriety during the 2001 anthrax mail attacks — has been completed by NIAID-funded researchers. This bacterium, which can cause potentially fatal inhalational anthrax, differs very little from a common soil bacterium related to it. Scientists hope that the genetic differences between these two may reveal valuable clues to its vulnerabilities.

NHLBI published new clinical practice guidelines for the prevention, detection, and treatment of high blood pressure — a major risk factor for heart disease and the chief risk factor for stroke and heart failure. The guidelines define a new blood pressure category called "prehypertension" that includes about 22 percent of American adults, or about 45 million people. Americans' lifetime risk of developing hypertension is greater than previously thought, according to the new guidelines. Medications and lifestyle changes are both crucial parts of treatment.

Researchers supported by NIMH found a gene called 5-HTT that influences whether people become depressed when faced with major life stresses such as relationship problems, financial difficulties and illness. The gene by itself does not cause depression, but it does affect how likely people are to get depressed when faced with major life stresses. Another study led by NIAAA researchers found that this same gene affects drinking habits in college students. These studies are major contributions toward understanding how a person's response to their environment is influenced by their genetic makeup.

A team led by NIDCR and NICHD researchers discovered that "baby" teeth, the temporary teeth that children begin losing around their sixth birthday, contain a rich supply of stem cells in their dental pulp. The cells, named SHED, remain alive inside the tooth for a short time after it falls out of a child's mouth. This easily accessible source of stem cells could be readily harvested for research. Scientists hope they can learn to manipulate them to repair damaged teeth, induce the regeneration of bone, and treat neural injury or disease.

Researchers supported by NICHD, NIGMS, NHLBI and NIDCR discovered how an embryo attaches to the wall of the uterus in what may be one of the earliest steps needed to establish a successful pregnancy. After an egg is fertilized, a specialized protein called L-selectin on the embryo surface binds to carbohydrates on the uterine wall. Scientists think that this interaction slows the embryo down to a complete stop so it can then attach to the wall of the uterus. The finding may lead to insights into infertility and early pregnancy loss.

An international research team funded by NINR found that filters made from old cotton saris cut the number of cholera cases in rural Bangladesh villages almost in half. Other inexpensive cloth should work just as well in other parts of the world where cholera is endemic. Cholera is a waterborne disease that causes severe diarrhea and vomiting, killing thousands of people around the world every year. This simple preventive measure has the potential to make a significant impact on a global health problem.

NIH director Dr. Elias Zerhouni names five new institute directors: Dr. Ting-Kai Li at the National Institute on Alcohol Abuse and Alcoholism; Dr. Thomas Insel at the National Institute of Mental Health; Dr. Nora Volkow at the National Institute on Drug Abuse, Dr.

Jeremy Berg at the National Institute of General Medical Sciences; Dr. Story Landis at the National Institute of Neurological Disorders and Stroke.

President George W. Bush visits NIH on Feb. 3 to unveil Project BioShield, a \$6 billion, 10-year effort to protect the public from various weapons of bioterrorism.

The FY 2003 appropriation for NIH completes a 5-year doubling of the NIH budget that began in 1998.

Construction begins on a new Perimeter Security System including a fence around the Bethesda campus.

Construction begins on the Bldg. 33 Complex, to include a parking garage and 150,000 gross square foot laboratory for work on infectious agents that might be used in bioterrorism.

Dr. Zerhouni announces the NIH Roadmap for Medical Research, a comprehensive plan whose purpose is to identify the major scientific opportunities and gaps in medical research that no single institute or center at NIH could tackle alone.

2004 NIH opens the Mark O. Hatfield Clinical Research Center, a 240-bed successor to the NIH Clinical Center, which opened in 1953. It is the world's largest facility dedicated to clinical research. The 870,000-square-foot addition welcomed occupants of its research wings in fall 2004, and was to admit its first patients in early January 2005.

The NIH Roadmap for Medical Research, a coordinated effort to speed the results of bench research to the patient bedside, marks its first anniversary, which includes the award of 9 grants to the inaugural class of winners of the NIH Director's Pioneer Awards.

NIH director Dr. Elias Zerhouni announces an NIH proposal to enhance public access to taxpayer-supported research by creating an online, searchable archive of all NIH-funded publications within 6 months of their appearance in journals.

NIH proposes enhancements to its rules governing potential conflicts of interest on the part of employees, thereby resolving public and congressional concerns about the outside activities of NIH staff.

NIH launches the Neuroscience Blueprint, a framework to enhance cooperative activities among 14 NIH Institutes and Centers that support research on the nervous system. The ultimate goal of the Blueprint is to accelerate neuroscience research to reduce the burden of nervous system disorders and maintain a healthy nervous system throughout life.

The Council of Public Representatives to the NIH director (COPR) holds a Public Trust Workshop aimed at increasing public participation in clinical research. COPR advocates building trust through community partnerships, building relationships with patients, building partnerships with community providers and building trust in both scientists and NIH scientific research.

An international clinical trial concluded that women should consider taking letrozole after 5 years of tamoxifen treatment to continue to reduce the risk of recurrence of breast cancer. This advance in breast cancer treatment will improve the outlook for many thousands of women. NCI supported the U.S. portion of the study, which offered one more example of the ability to interrupt the progression of a cancer using a drug that blocks a crucial metabolic pathway in the tumor cell.

As of July 2003, about 10 million American women were taking some form of hormone

therapy, including approximately 6.7 million taking estrogen alone and 3.3 million taking estrogen plus progestin. A large, multi-center prevention study of estrogen-alone hormone therapy in healthy, postmenopausal women without a uterus, was stopped in February 2004 after researchers found that estrogen-alone had no effect on coronary heart disease risk, but increased the risk of stroke. The study, part of the NHLBI-sponsored Women's Health Initiative (WHI), also found that estrogen-alone therapy significantly increased the risk of deep vein thrombosis, had no significant effect on the risk of breast or colorectal cancer, and reduced the risk of hip and other fractures. In addition, among older women in the study, estrogen-alone therapy did not prevent cognitive decline.

The International Human Genome Sequencing Consortium, led in the United States by the National Human Genome Research Institute and the Department of Energy, published its scientific description of the finished human genome sequence, reducing the estimated number of human protein-coding genes from 35,000 to only 20,000-25,000, a surprisingly low number for our species.

Adding to a developing body of research examining a possible link between diabetes and cognitive decline, a long-term study supported by NIA found that diabetes mellitus was linked to a 65 percent increased risk of developing Alzheimer's disease (AD). These results are among the first to examine how certain cognitive systems, including memory for words and events, the speed of processing information, and the ability to recognize spatial patterns, decline in people with diabetes, while others do not. Further research, some currently under way, will tell researchers whether therapies for diabetes may in fact play a role in lowering risk of AD or cognitive decline.

From language to literature, from music to mathematics, a single protein, known as mBDNF, appears central to the formation of the long-term memories needed to learn these and all other disciplines. Most of what we accomplish as human beings depends on what we learn. This discovery, led by scientists at NICHD, brings the possibility of studying this protein system in people with learning and memory disorders and perhaps designing new medications that might help to compensate for these problems.

This page was last reviewed on August 17, 2005 .

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National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892



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The NIH Almanac – Historical Data

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This legislative chronology is limited to enactments that had a major influence upon the Marine Hospital Service as it evolved into the PHS, to legislation leading to the establishment of the National Institutes of Health, and to specific NIH legislation with the exception of appropriations bills, unless such bills provided significant new authorities for or restrictions on NIH components.

1700

July 16, 1798 – "An Act for the relief of sick and disabled Seamen" established the Marine Hospital Service for merchant seamen. The Marine Hospital Service – forerunner of the present-day PHS – became a component of the Treasury Department. A monthly hospital tax of 20 cents was deducted from the pay of merchant seamen in the first prepaid medical care plan in the United States. (1 Stat. L. 605.)

March 2, 1799 – An amending act to the legislation of 1798 extended Marine Hospital Service benefits to officers and men of the U.S. Navy. This arrangement continued until 1818 after which the Navy built its own hospitals. However, the deduction of 20 cents per month from the pay of Navy and Marine Corps personnel continued until June 15, 1943. (1 Stat. L. 729.)

1800

June 29, 1870 – A bill to reorganize the Marine Hospital Service and establish a central controlling office in Washington, D.C., was enacted. This act also increased the amount of hospital tax paid by seamen from 20 cents to 40 cents per month, a tax which continued until 1884. (16 Stat. L. 169.) (After the seamen's hospital tax was abolished July 1, 1884, the cost of maintaining Marine hospitals was paid out of a tonnage tax until 1906. Since then medical care for merchant seamen and other beneficiaries of the service has been supported by direct congressional appropriations.)

March 3, 1875 – An act was passed authorizing the admission of seamen from the Navy and other government services to Marine hospitals on a reimbursable basis.

The Surgeon General of the Marine Hospital Service was to be appointed by the President, by and with the advice and consent of the Senate. (18 Stat. L. 377.)

April 29, 1878 – The first Federal Quarantine Act "to prevent the introduction of contagious or infectious diseases into the United States" was passed. (20 Stat. L. 37.)

March 3, 1879 – The National Board of Health was created by law and given quarantine powers; first organized, comprehensive Federal medical research effort. (20 Stat. L. 484.)

January 4, 1889 – A bill to establish a commissioned officer corps in the Marine Hospital Service was passed. This law established a mobile corps subject to duty anywhere upon assignment, a policy that had been in effect since Dr. Woodworth assumed leadership of the Marine Hospital

Service in 1871. (25 Stat. L. 639.)

March 27, 1890 – Congress gave the Marine Hospital Service interstate quarantine authority. (26 Stat. L. 31.)

February 15, 1893 – A new Quarantine Act was passed following outbreaks of cholera in Europe, strengthening the inadequate Quarantine Act of 1878 by giving the Federal Government the right of quarantine inspection. The act of March 3, 1879, was repealed. (27 Stat. L. 449.)

March 2, 1899 – The Marine Hospital Service was directed by Congress to investigate leprosy in the United States. (30 Stat. L. 976.)

1900

March 3, 1901 – An appropriation of \$35,000 was made for the Hygienic Laboratory building (first legislative mention of Hygienic Laboratory). Thus "investigations of contagious and infectious diseases and matters pertaining to public health" were given definite status in law. (31 Stat. L. 1086.)

July 1, 1902 – A bill to increase the efficiency and change the name of the Marine Hospital Service to Public Health and Marine Hospital Service was enacted. The law authorized the establishment of specified administrative divisions and, for the first time, designated a bureau of the Federal Government as an agency in which public health matters could be coordinated. (32 Stat. L. 712.)

Another law, usually referred to as the Biologics Control Act, authorized the Public Health and Marine Hospital Service to regulate the transportation or sale for human use of viruses, serums, vaccines, antitoxins, and analogous products in interstate traffic or from any foreign country into the United States. (P.L. 57-244, 32 Stat. L. 728.)

1910

August 14, 1912 – Under an act, the name Public Health and Marine Hospital Service was changed to Public Health Service. The legislation broadened the PHS research program to include "diseases of man" and contributing factors such as pollution of navigable streams, and information dissemination. (37 Stat. L. 309.)

July 9, 1918 – The Chamberlain-Kahn Act provided for the study of venereal diseases by the PHS. (40 Stat. L. 886.)

October 27, 1918 – A PHS reserve corps was established. The 1918 influenza pandemic emphasized the need for a reserve corps to meet such emergency situations. (40 Stat. L. 1017.)

1920

January 19, 1929 – The Narcotics Control Act provided for construction of two hospitals for the care and treatment of drug addicts, and authorized creation of a Narcotics Division in the PHS Office of the Surgeon General. (P.L. 70-672, 45 Stat. L. 1085.)

1930

April 9, 1930 – A law changed the name of the Advisory Board for the Hygienic Laboratory to the National Advisory Health Council. (P.L. 71-106, 46 Stat. L. 152.)

May 26, 1930 – The Ransdell Act reorganized, expanded, and redesignated the Hygienic Laboratory as the National Institute of Health. The act authorized \$750,000 for the construction of two buildings

for NIH and authorized a system of fellowships. (P.L. 71-251, 46 Stat. L. 379.)

June 14, 1930 – A law authorized creation of a separate Bureau of Narcotics in the Treasury Department to control trading in narcotic drugs and their use for therapeutic purposes. Also, the legislation redesignated the PHS Narcotics Division to the Division of Mental Hygiene, giving the Surgeon General authority to investigate abuse of narcotics and the causes, treatment, and prevention of mental and nervous diseases. (P.L. 71-357, 46 Stat. L. 585.)

August 14, 1935 – The Social Security Act was an event of major importance in the progress of public health in the United States. This act authorized health grants to the states on the principle that the most effective way to prevent the interstate spread of disease is to improve state and local public health programs. With this legislation, the PHS became adviser and practical assistant to state and local health services. (P.L. 74-271, 49 Stat. L. 634.)

August 5, 1937 – A law established the National Cancer Institute to conduct and support research relating to the cause, diagnosis, and treatment of cancer. The law authorized the Surgeon General to make grants-in-aid for research in the field of cancer, provide fellowships, train personnel, and assist the states in their efforts toward cancer prevention and control. (P.L. 75-244, 50 Stat. L. 559.)

April 3, 1939 – The Reorganization Act of 1939 transferred the PHS from the Treasury Department to the Federal Security Agency. (P.L. 76-19, 53 Stat. L. 561.)

1940

July 1, 1944 – The PHS act consolidated and revised laws pertaining to the PHS and divided the service into the Office of the Surgeon General, Bureau of Medical Services, Bureau of State Services, and the National Institute of Health. The act gave the Surgeon General broad powers to conduct and support research into the diseases and disabilities of man, authorized projects and fellowships, and made the National Cancer Institute a division of NIH. The act also empowered the Surgeon General to treat at PHS medical facilities, for purposes of study, persons not otherwise eligible for such treatment. (P.L. 78-410, 58 Stat. L. 682.) Under this provision, the Clinical Center was later established. (Under this act, the Research Grants Office, January 1, 1946; the Experimental Biology and Medicine Institute and the National Microbiological Institute, November 1, 1948; and the Division of Research Services, January 1, 1956, were established.)

July 3, 1946 – The National Mental Health Act was designed to improve the mental health of U.S. citizens through research into the causes, diagnosis, and treatment of psychiatric disorders. It authorized the Surgeon General to support research, training, and assistance to state mental health programs. (P.L. 79-487, 60 Stat. L. 421.) (The National Institute of Mental Health was established under the authority of this law on April 15, 1949.)

August 13, 1946 – The Hospital Survey and Construction Act (Hill-Burton Act) authorized grants to the states for construction of hospitals and public health centers, for planning construction of additional facilities, and for surveying existing hospitals and other facilities. (P.L. 79-725, 60 Stat. L. 1040.)

July 8, 1947 – Under P.L. 80-165, research construction provisions of the Appropriations Act for FY 1948 provided funds "for the acquisition of a site, and the preparation of plans, specifications, and drawings, for additional research buildings and a 600-bed clinical research hospital and necessary accessory buildings related thereto to be used in general medical research...."

June 16, 1948 – The National Heart Act authorized the National Heart Institute to conduct, assist, and foster research; provide training; and assist the states in the prevention, diagnosis, and treatment of heart diseases. In addition, the act changed the name of National *Institute* of Health to National *Institutes* of Health. (P.L. 80-655, 62 Stat. L. 464.)

June 24, 1948 – The National Dental Research Act authorized the National Institute of Dental Research to conduct, assist, and foster dental research; provide training; and cooperate with the states in the prevention and control of dental diseases. (P.L. 80-755, 62 Stat. L. 598.)

1950

August 15, 1950 – The Omnibus Medical Research Act authorized the Surgeon General to establish the National Institute of Neurological Diseases and Blindness, as well as additional institutes, to conduct and support research and research training relating to other diseases and groups of diseases. (P.L. 81-692, 64 Stat. L. 443.) (The National Institute of Arthritis and Metabolic Diseases and the National Institute of Neurological Diseases and Blindness were established under the authority of this act on November 22, 1950. Under this same act, the National Institute of Allergy and Infectious Diseases was established on December 29, 1955, replacing the National Microbiological Institute which was originally established November 1, 1948, under authority of section 202 of the PHS act.)

April 1, 1953 – Reorganization plan #1 assigned the PHS to the new Department of Health, Education, and Welfare.

July 28, 1955 – The Mental Health Study Act authorized the Surgeon General to award grants to non-governmental organizations for partial support of a nationwide study and reevaluation of the problems of mental illness. Under this act, the Joint Committee on Mental Illness and Health was awarded grant support for 3 years. (P.L. 84-182, 69 Stat. L. 381.)

July 3, 1956 – The National Health Survey Act authorized the Surgeon General to survey sickness and disabilities in the United States on a sampling basis. (P.L. 84-652, 70 Stat. L. 489.)

July 28, 1956 – The Alaska Mental Health Enabling Act provided for territorial treatment facilities to eliminate the need to transport the mentally ill outside Alaska. It also authorized PHS grants to Alaska for its mental health program. (P.L. 84-830, 70 Stat. L. 709.)

July 30, 1956 – The Health Research Facilities Act of 1956 (Title VII of the PHS act) authorized a PHS program of Federal matching grants to public and nonprofit institutions for the construction of health research facilities. (P.L. 84-835, 70 Stat. L. 717.)

August 2, 1956 – The Health Amendments Act of 1956 authorized the Surgeon General to assist in increasing the number of adequately trained nurses and professional public health personnel. It also authorized PHS grants to support the development of improved methods of care and treatment of the mentally ill. (P.L. 84-911, 70 Stat. L. 923.)

August 3, 1956 – An amendment to Title III of the PHS act, the National Library of Medicine Act, placed the Armed Forces Medical Library under the PHS, and renamed it the National Library of Medicine. (P.L. 84-941.)

June 30, 1958 – The Mutual Security Act of 1958 amended P.L. 83-480, authorizing the President to enter into agreements with friendly nations to use foreign currencies accruing under title I for collection, translation, and dissemination of scientific information and to conduct research and support scientific activities overseas. (P.L. 85-477.)

1960

July 12, 1960 – Congress passed the International Health Research Act. The law authorized the Surgeon General to establish and make grants for fellowships in the United States and participating foreign countries; make grants or loans of equipment and other materials to participating foreign countries for use by public or nonprofit institutions and agencies; participate in international health

meetings, conferences, and other activities; and facilitate the interchange of research scientists and experts between the United States and participating foreign countries. (P.L. 86-610, 74 Stat. L. 364.)

September 15, 1960 – A law amended the PHS act to authorize grants-in-aid to universities, hospitals, laboratories, and other public and nonprofit institutions to strengthen their programs of research and research training in the sciences related to health. The act also authorized the use of funds appropriated for research or research training to be set aside by the Surgeon General in a special account for general research support grants. (P.L. 86-798, 74 Stat. L. 1053.)

October 17, 1962 – An act authorized the Surgeon General to establish the National Institute of General Medical Sciences and the National Institute of Child Health and Human Development. The latter was authorized to conduct and support research and training relating to maternal health; child health; human development, in particular the special health problems of mothers and children; and the basic sciences relating to the processes of human growth and development. The former was authorized to conduct and support research in the basic medical sciences and related behavioral sciences that have significance for two or more institutes, or which are outside the general area of responsibility of any other institute. (P.L. 87-838, 76 Stat. L. 1072.) (On January 30, 1963, the NICHD and the NIGMS were established under this act.)

September 24, 1963 – A law amended the Health Research Facilities Act of 1956 (Title VII to the PHS act) to allow grants for multipurpose facilities that would provide teaching space as well as essential research space. (P.L. 88-129, 77 Stat. L. 164.)

October 24, 1963 – The Maternal and Child Health and Mental Retardation Planning Amendments of 1963 amended the Social Security Act of 1935 by authorizing a five-point grant program of \$265 million, over a 5-year period. Major provisions designed to prevent mental retardation included increased Federal grants for maternal and child health services and crippled children's service administered by the Children's Bureau; a new 5-year program of grants to the states for health care of expectant mothers who have, or are likely to have, conditions associated with childbearing which may lead to mental retardation; funds for research to improve maternal and child health and crippled children's services; and grants to the states to assist in developing plans for comprehensive state and community programs to combat mental retardation. (P.L. 88-156, 77 Stat. L. 273.)

October 31, 1963 – A companion measure to P.L. 88-156 was the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963. This act authorized a total of \$329 million over 5 years for grants to assist in the construction of mental retardation research centers and community mental health centers, and to train teachers of mentally retarded and other handicapped children. (P.L. 88-164, 77 Stat. L. 282.)

August 18, 1964 – The Hospital and Medical Facilities Amendments of 1964 extended the Hospital Survey and Construction Act of 1946 (Hill-Burton Act) for 5 years with a total authorization of \$1.4 billion. (P.L. 88-443, 78 Stat. L. 447.)

August 27, 1964 – Graduate Public Health Training Amendments of 1964 extended the authorization for public health traineeships and training grants to schools of public health, nursing, and engineering for 5 years, through June 30, 1969. (P.L. 88-497, 78 Stat. L. 613.)

September 19, 1964 – The Appropriations Act for 1965 included \$10 million for establishment of a virus-leukemia program. (P.L. 88-605.)

August 4, 1965 – The Mental Retardation Facilities and Community Mental Health Centers Construction Act Amendments of 1965 provided monies through FY 1972 to help finance initial staffing of community mental health centers which were authorized in the original act; extended and increased appropriations authority for mental retardation education research and demonstration projects; and authorized increased annual funds through FY 1969 for training teachers of the handicapped young. (P.L. 89-105.)

August 9, 1965 – The Health Research Facilities Amendments of 1965 extended the program for construction of health research facilities for 3 years with \$280 million authorized for that period in lieu of the previous \$50 million annual appropriations authorizations. (P.L. 89-115.)

August 31, 1965 – A supplemental appropriations act resulting from recommendations of the President's Commission on Heart Disease, Cancer and Stroke provided an additional \$20,250,000 (shared by NCI, NHI, NIGMS and NINDB) to intensify and expand support of research in the three major "killer" diseases. (P.L. 89-156.)

October 6, 1965 – The Heart Disease, Cancer and Stroke Amendments of 1965 provided for establishment of regional cooperative programs in research, training, continuing education and demonstration activities in patient care among medical schools, clinical research institutions and hospitals so that the latest treatment methods for the three diseases may be more widely available to patients. Under this act, the Division of Regional Medical Programs was created February 1, 1966. (P.L. 89-239.)

October 22, 1965 – The Medical Library Assistance Act was passed, authorizing NLM's extramural programs. (P.L. 89-291.)

August 3, 1968 – A law authorized the designation of a national center for biomedical communications as the Lister Hill National Center for Biomedical Communications. (P.L. 90-456.)

August 16, 1968 – An amendment to the PHS act authorized the secretary to establish a National Eye Institute and to rename NINDB the National Institute of Neurological Diseases. The new institute was formed from NINDB programs to conduct and support research for new treatment and cures, and training relating to blinding eye diseases and visual disorders. (P.L. 90-489.)

The Health Manpower Act of 1968 extended and expanded the following five health laws then in effect: Health Professions Educational Assistance Act of 1963, as amended; Nurse Training Act of 1964, as amended; Allied Health Professions Personnel Training Act of 1966; Health Research Facilities Act of 1956, as amended; and Public Health Service Act of 1944, as amended. The measure provided a 2-year extension, through FY 1971, of the above legislation except for the Allied Health Professions Act, extended only through FY 1970. (P.L. 90-490.)

October 24, 1968 – The President signed legislation further amending the name of NIND to National Institute of Neurological Diseases and Stroke. (P.L. 90-639.)

1970

March 12, 1970 – An amendment to the PHS act extended and made coterminous through June 30, 1973, the authority to make formula grants to schools of public health, project grants for graduate training in public health, and traineeships for professional public health personnel. (P.L. 91-208, 84 Stat. 52.)

March 13, 1970 – The Medical Library Assistance Extension Act of 1970 amended the PHS act to improve and extend the provisions relating to assistance to medical libraries and related instrumentalities for 3 years through June 30, 1973. (P.L. 91-212, 84 Stat. 63.)

October 30, 1970 – The PHS act was amended to provide: 1) extension of research contract authority in areas of public health through June 30, 1974; 2) authorization of mission-related clinical training (as well as research training) by the NIGMS; 3) clarification of terms in the regulation of biological products; 4) clarifying and technical directives relating to appointment, compensation and functions of advisory councils and committees, and 5) extension of statutory authority for regional medical programs, comprehensive medical planning, and health services research and development. (P.L. 91-515.)

November 2, 1970 – The Health Training Improvement Act of 1970 extended and amended allied health professions training authority (which expired June 30, 1970) and established eligibility of new health professions educational assistance schools for "start-up" grants. (P.L. 91-519.)

December 24, 1970 – The Congress enacted the Family Planning Services and Population Research Act of 1970 to expand, improve and better coordinate family planning services and population research activities of the Federal Government. (P.L. 91-572.)

May 22, 1971 – Congress passed into law the Supplemental Appropriations Bill, which included \$100 million for cancer research. This appropriation was made in response to the President's State of the Union address, in which he called for "an intensive campaign to find a cure for cancer." The appropriation includes authority under grants and contracts, as well as direct construction authority for NCI. (P.L. 92-18.)

July 9, 1971 – A law amended the Public Health Service Act to provide for extension of student loan scholarship programs for up to four fiscal years. (P.L. 92-52.)

November 18, 1971 – The President signed the Comprehensive Health Manpower Training Act of 1971 to provide increased manpower in the health professions, and the Nurse Training Act of 1971 to provide training for increased numbers of nurses. (P.L. 92-157, P.L. 92-158.)

December 23, 1971 – The National Cancer Act of 1971 enlarged the authorities of NCI and NIH in order to advance the national effort against cancer. The authority of the director, NCI, was expanded, a National Cancer Advisory Board was established, and appropriations in excess of \$400 million were authorized for 1972, with further increases in subsequent years. (P.L. 92-218.)

May 16, 1972 – The National Sickle Cell Anemia Control Act of 1972 became law and established a national program for diagnosis and treatment of, and counseling and research in, sickle cell disease. (P.L. 92-294.)

May 19, 1972 – The need for further support of research and training in the field of digestive diseases was emphasized by adding a new section 434 to the PHS act and renaming NIAMD the National Institute of Arthritis, Metabolism, and Digestive Diseases. (P.L. 92-305.)

August 29, 1972 – The National Cooley's Anemia Control Act authorized over \$9 million for 3 years for research in the diagnosis and treatment of Cooley's anemia, and for counseling and public information programs. (P.L. 92-414.)

September 19, 1972 – The National Heart, Blood Vessel, Lung, and Blood Act expanded the authorities of the National Heart and Lung Institute to augment the national effort against heart, lung, and blood diseases. Appropriations of \$375 million for 1973 were authorized with further increases in subsequent years. (P.L. 92-423.)

October 25, 1972 – The National Advisory Commission on Multiple Sclerosis Act established a commission charged to determine the most productive avenue of researching possible causes and cures of MS, and make specific recommendations for the maximum utilization of national resources directed toward MS. (P.L. 92-563.)

June 18, 1973 – The Health Programs Extension Act of 1973 extended the medical library assistance programs of NLM (with the exception of the construction program) for 1 year. Population research and family planning activities were also extended through FY 1974, along with other Federal health programs. (P.L. 93-45.)

November 16, 1973 – The Emergency Medical Services System Act of 1973 amended the PHS act to provide assistance and encouragement for the development of comprehensive area emergency

medical services systems, including grants and contracts for the support of research in emergency medical techniques, methods, devices, and delivery. (P.L. 93-154.)

April 22, 1974 – The Sudden Infant Death Syndrome Act of 1974 amended the PHS act to authorize specific and general research on the sudden infant death syndrome through the NICHD. The collection, analysis, and public dissemination of information and data and the support of counseling programs were also authorized. The act did not authorize specific funds for research, but did authorize appropriations of \$9 million over a 3-year period for the other programs. (P.L. 93-270.)

May 31, 1974 – The Research on Aging Act of 1974 established a National Institute on Aging. The act authorized the NIA to conduct and support biomedical, social, and behavioral research and training related to the aging process and the diseases and other special problems and needs of the aged. (P.L. 93-296.)

June 22, 1974 – The Energy Supply and Coordination Act directed the secretary through NIEHS to study the effects of chronic exposure to sulfur oxides, and authorized \$3.5 million for that purpose. (P.L. 93-319.)

July 12, 1974 – The National Research Act of 1974 amended the PHS act by repealing existing research training and fellowship authorities and consolidating such authorities in the national research service awards authority. The NRSAs (both individual and institutional grants) are restricted on the basis of subject area shortages and would involve service obligations and payback provisions. The act established a temporary National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research within the department to make a comprehensive investigation of the ethical principles involved in biomedical and behavioral research (including psychosurgery and living fetus research), and to develop ethical guidelines for conducting such research. Also, a permanent National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research was to be established. (P.L. 93-348.)

July 23, 1974 – The National Cancer Act Amendments of 1974 authorized \$2.565 billion over a 3-year period to extend and improve the National Cancer Program as well as \$210.5 million over 3 years for cancer control programs. The act also: 1) established the President's Biomedical Research Panel to make a comprehensive investigation of Federal biomedical and behavioral research; 2) extended indefinitely the research contract authority of section 301(h) of the PHS act; 3) provided that the director, NIH, shall be appointed by the President by and with the advice of the Senate; and 4) required peer review of NIH and ADAMHA grant applications and contract projects. (P.L. 93-352.)

The Health Services Research, Health Statistics, and Medical Libraries Act of 1974 extended and amended NLM program authorities (\$37.5 million over a 2-year period). The act also extended the FIC's authority to engage in international cooperative efforts in health. (P.L. 93-353.)

The National Diabetes Mellitus Research and Education Act provided for regional research and training centers (\$40 million authorized over a 3-year period), a long-range plan prepared by a National Commission on Diabetes, expanded research and training programs, a Diabetes Mellitus Coordinating Committee, and an associate director for diabetes in the National Institute of Arthritis, Metabolism, and Digestive Diseases. (P.L. 93-354.)

October 29, 1974 – The Federal Fire Prevention and Control Act authorized \$5 million and \$8 million for fiscal years 1975-76 for establishment of 25 research and treatment centers, 25 burn units, and 90 burn programs by NIH. (P.L. 93-498.)

January 4, 1975 – The National Arthritis Act established a National Commission on Arthritis and Related Musculoskeletal Diseases, authorized \$2 million to develop a long-range plan involving research, training, services and data systems; established an associate director for arthritis in NIAMDD; and provided 3-year authorizations for arthritis screening, detection, prevention, and referral projects and for arthritis research and demonstration centers. (P.L. 93-640.)

July 29, 1975 – A law extended and amended authorities of Title X relating to family planning and population research and made Title X sole authority for all departmental extramural, collaborative, and intramural research in "biomedical, contraceptive development, behavioral, and program implementation fields related to family planning and population;" and created two temporary national commissions for the control of epilepsy and Huntington's disease. (P.L. 94-63.)

April 22, 1976 – The Health Research and Health Services Amendments 1) extended authorization through FY 1977 and amended provisions governing the programs of the National Heart and Lung Institute, placed increased emphasis on blood-related research, and changed the institute's name to the National Heart, Lung, and Blood Institute; 2) mandated studies by the President's Biomedical Research Panel and the National Commission for the Protection of Human Subjects of the implications of public disclosure of information contained in grant applications and contract proposals; 3) authorized broad-based genetic diseases research under section 301 of the PHS act, and provided for programs of counseling, testing, and information dissemination about genetically transmitted diseases; and 4) extended authorization through FY 1977 for national research service awards for NIH and ADAMHA. The act prohibited consideration of political affiliation in making appointments to health advisory committees. (P.L. 94-278.)

October 19, 1976 – The 1976 Arthritis, Diabetes, and Digestive Diseases Amendments 1) provided for an arthritis data system; 2) emphasized public information and encouragement of proper treatment for arthritis; 3) established a National Arthritis Advisory Board; 4) provided for a National Diabetes Board; and 5) established a National Commission on Digestive Diseases to develop a long-range plan for research. (P.L. 94-562.)

October 21, 1976 – The Emergency Medical Services Amendments of 1976 extended the National Commission on Arthritis; extended the Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; and authorized research and demonstration programs on burn injuries under Title XII of the PHS act. (P.L. 94-573.)

August 1, 1977 – Health Planning and Health Services Research and Statistics Extension, Biomedical Research Extension, and Health Services Extension Acts of 1977 continued the following programs through September 30, 1978: the Medical Library Assistance Program; cancer research and control programs; heart, blood vessel, lung and blood disease research, prevention and control programs; national research service awards; population research and voluntary family planning programs; and sudden infant death syndrome information and counseling programs. It also extended various health service programs. (P.L. 95-83.)

August 7, 1977 – The Clean Air Act Amendments established a coordinating committee to review and comment on plans, execution, and results of research relating to the stratosphere. NCI and NIEHS are members. It also established a Task Force on Environmental Cancer and Heart and Lung Disease, with NCI, NHLBI, and NIEHS among the members. (P.L. 95-95.)

September 29, 1977 – The Food and Agriculture Act of 1977 designated the Department of Agriculture as the lead agency of the Federal Government for agricultural research (except with respect to the biomedical aspects of human nutrition concerned with diagnosis or treatment of disease). The act also required establishment of procedures for coordinating nutrition research in areas of mutual interest between DHEW and Department of Agriculture. (P.L. 95-113.)

November 9, 1977 – The Federal Mine Safety and Health Amendments of 1977 gave the HEW secretary authority to appoint an advisory committee on coal or other mine health research. One member of this committee is to be the director of the NIH or delegate. (P.L. 95-164.)

November 23, 1977 – The Saccharin Study and Labeling Act extended the Commission for the Protection of Human Subjects until November 1, 1978. (P.L. 95-203.)

November 9, 1978 – The Family Planning, Population Research and SIDS Amendments authorized

a 3-year extension for the aforementioned programs through FY 1981. This was the only authority for population research programs in NICHD, the Center for Population Research. (P.L. 95-613.)

Amendments to the Community Mental Health Centers Act authorized a 3-year extension for NLM programs, and NRSA's expiring September 30, 1981, and a 2-year extension for each of the following: Community Mental Health Centers, NHLBI, and NCI. This legislation also authorized the secretary, HEW, to: 1) conduct studies and tests of substances for carcinogenicity, teratogenicity, mutagenicity and other harmful biological effects; 2) establish and conduct a comprehensive research program on the biological effects of low-level radiation; 3) conduct and support research and studies on human nutrition; and 4) publish an annual report which lists all substances known to be carcinogenic and to which a significant number of Americans are exposed. (P.L. 95-622.)

Other important provisions of this act included the authority given to the director of NIH to appoint 200 experts and consultants for the use of NIH components other than NCI and NHLBI and the establishment of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.

The Health Services Research, Health Statistics, and Health Care Technology Act of 1978 (P.L. 95-623) established in the Office of the Assistant Secretary for Health, the National Center for Health Care Technology, and reauthorized for 3 years the National Center for Health Statistics and the National Center for Health Services Research.

The legislation also established the National Council on Health Care Technology on which the director, NIH, serves as an ex officio member. The director, NIH, is required annually to submit to the center a listing of all technologies under development which appear likely to be used in the practice of medicine.

NLM is required to disseminate, publish, and make available all standards, norms, and criteria developed by the council concerning the use of particular health care technologies. (P.L. 95-623.)

October 17, 1979 – The Department of Education Organization Act established a Department of Education and renamed the DHEW the Department of Health and Human Services. (P.L. 96-88.)

December 12, 1979 – The Emergency Medical Services Systems Amendments and Sudden Infant Death Syndrome Amendments of 1979 required the NICHD to assure that "adequate amounts" of its appropriated dollars are used for research into identification of infants at risk of SIDS and for prevention of SIDS. In addition, the NICHD is required to provide information on expenditure of funds for these purposes, the number of SIDS grant applications received and approved, the latest research findings on SIDS, and estimate of needs for funds in succeeding years. (P.L. 96-142.)

December 29, 1979 – P.L. 96-167 extended the tax exemption for NRSA's for 1 year.

P.L. 96-171 required that the NIH Director, in consultation with the secretary of transportation, conduct a study to determine the effect of aging on the ability of individuals to perform the duties of pilots. The report on the study was to be submitted to Congress within 1 year after enactment.

1980

September 26, 1980 – P.L. 96-359 requires the HHS secretary to conduct a study to determine the long-term effects of hypochloremic metabolic ankylosis resulting from chloride-deficient formulas. The responsibility for the study was assigned to NICHD.

December 12, 1980 – P.L. 96-517 revised the patent and trademark laws and in particular awarded title to the patent rights for inventions made with Federal assistance to nonprofit organizations and small businesses.

The Clinical Center was redesignated as the Warren Grant Magnuson Clinical Center of NIH. (P.L. 96-518.)

December 17, 1980 – P.L. 96-538 reauthorized for 2 years programs for NHLBI and NCI; changed the name of the NIAMDD to the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, extensively revised its authorities, and reauthorized its programs for 3 years; and required the NINCDS to conduct a study and submit a report on spinal cord regeneration and other neurological research.

P.L. 96-541 extended for 1 year the tax exemption on NRSAs.

August 13, 1981 – P.L. 97-35, the Omnibus Budget Reconciliation Act of 1981, reauthorized NRSAs for 2 years through FY 1983, reauthorized the Medical Libraries Assistance program for 1 year, and repealed the prohibition in Title X against using other PHS authority to fund population research, thus eliminating the need for reauthorizations for this program located in the NICHD.

July 22, 1982 – The Small Business Innovation Development Act of 1982 requires that each Federal agency with an annual research and development budget exceeding \$100 million set aside a certain portion of its extramural R&D budget for a Small Business Innovation Research (SBIR) program as follows: 0.2 percent in FY 1983; 0.6 percent in FY 1984; 1.0 percent in FY 1985; and 1.25 percent in FY 1986 and all subsequent years. (P.L. 97-219.)

September 3, 1982 – The Tax Equity and Fiscal Responsibility Act of 1982 included among its provisions an extension of the partial exclusion of NRSAs from taxable gross income. This extension will expire at the end of calendar year 1983; during this time, the Treasury Department will complete a study of the taxability of NRSA's and other government educational grants which, like NRSA's, have payback or service requirements. (P.L. 97-248.)

January 4, 1983 – The Orphan Drug Act made changes in the law to encourage development and marketing of orphan drugs (drugs for rare diseases or conditions which are not economically feasible for private industry to develop and market). The act included a requirement to prepare radioepidemiological tables relating radiation-related cancer to specific radiation doses, and a report on the risks of thyroid cancer associated with doses of I₁₃₁. These responsibilities were assigned to NIH and NCI respectively. The act further provided that NHLBI help develop and support not less than 10 comprehensive sickle cell centers. (P.L. 97-414.)

July 30, 1983 – The supplemental appropriations for FY 1983 provided funds for PHS AIDS activities, \$9.375 million of which was earmarked for NIH. This marked the first time the Congress directly appropriated money for AIDS research for NIH. The supplemental also provided \$5.9 million for NLM and development of a Biomedical Information Communication Center in Portland, Oreg. (P. L. 98-63.)

October 1 and November 17, 1983 – Continuing resolutions supported unauthorized NIH programs including NRSA and Medical Library Assistance. (P.L. 98-107 and P.L. 98-151.)

May 24, 1984 – P.L. 98-297 designated the convent and surrounding land as the Mary Woodard Lasker Center for Health Research and Education.

October 12 and November 8, 1984 – Appropriations legislation reauthorized NRSAs, provided construction funds for NIH, and medical library funding. (P.L. 98-473, P.L. 98-619.)

October 19, 1984 – The National Organ Transplant Act authorized the secretary to establish a Task Force on Organ Procurement and Transplantation to examine relevant issues and report to the Congress within 12 months. Its membership included the director, NIH, ex officio. OMAR will sponsor the required conference on bone marrow transplantation. (P.L. 98-507.)

October 24, 1984 – The Veterans' Dioxin and Radiation Exposure Compensation Standards Act required the director, NIH, to conduct a study of devices and techniques for determining previous radiation exposure and submit a report; to enter into an interagency agreement with the VA administrator to identify agencies capable of furnishing such services; and to provide an independent expert who could prepare radiation dose estimates for use by VA administrator in adjudicating claims. (P.L. 98-542.)

October 30, 1984 – The Health Promotion and Disease Prevention Amendments of 1984 amended the PHS act to extend provisions relating to health promotion and disease prevention and to establish centers for research and demonstration in those areas. It required that the director, NIH, be consulted as to procedures for peer review of applications; that NCHSR cooperate with NIH in its responsibilities pertaining to health care technologies; and that the director, NIH, serve on the newly established National Advisory Council on Health Care Technology Assessment. (P.L. 98-551.)

The Human Services Reauthorization Act, Title V, ordered the secretary, through NCI, to establish or support at least one facility for cancer screening and research in St. George, Utah, to be affiliated with a health science center and accessible to most residents of the areas that received greatest fallout from Nevada nuclear tests. (P.L. 98-558.)

August 15, 1985 – The Orphan Drug Act was amended, establishing a 20-member National Commission on Orphan Diseases, to be appointed by the secretary (including NIH representative), to assess the activities of NIH and other entities in connection with research and dissemination of knowledge related to rare diseases. NIH was required to allocate to the commission \$1 million from its FY 1986 appropriation. (P.L. 99-91.)

November 20, 1985 – The Health Research Extension Act of 1985 reauthorized NIH programs for 3 years; established the National Institute of Arthritis and Musculoskeletal and Skin Diseases, renaming the remaining component the National Institute of Diabetes and Digestive and Kidney Diseases; created a new National Center for Nursing Research; established positions of associate director for prevention in OD, NCI, NHLBI, and NICHD; and required the development of guidelines for the care and use of laboratory animals. Additional provisions included establishment of committees to develop a plan for research into methods that reduce animal use or animal pain, to study research on lupus erythematosus, to study the NRSA program, to plan and develop Federal initiatives in spinal cord injury research, to study personnel for health needs of the elderly through the year 2020, to review research activities in learning disabilities, and to review the research programs of NIDDK. The act also established NIH and all of its ICD's in law and consolidated and made uniform many authorities and responsibilities of institute directors and advisory councils. (P.L. 99-158.)

December 12, 1985 – Under the Balanced Budget and Emergency Deficit Control Act of 1985 (Gramm-Rudman-Hollings), aimed at reducing the Federal deficit to zero within 5 years, starting in FY 1986, budget authority was reduced in accordance with the deficit targets. For NIH this reduction amounted to \$236 million. The revised total NIH appropriation after "sequestration" became \$5.3 billion, 4.3 percent below the original FY 1986 appropriation. The mandated across-the-board reduction was applied again to the total amount appropriated to each NIH institute, to each research mechanism, and to each identified program, project, or activity. (P.L. 99-177.)

In the FY 1986 Labor-HHS-Education Appropriation bill, the number of new and competing renewal research project grants to be supported by NIH (6,100) was specified in law for the first time. The act, which included \$5.498 billion for NIH, provided that \$4.5 million of this amount be transferred to the departmental management account for construction of the Mary Babb Randolph Cancer Center in West Virginia and that \$70 million for AIDS research be added to the account of the Office of the Director. (P.L. 99-178.)

December 23, 1985 – The Food Security Act, title XVII, subtitle F, amended the Animal Welfare Act, requiring the secretary of agriculture to promulgate standards including exercise of dogs and

consideration of the psychological well-being of primates, minimization of pain and distress, use of anesthetics, and consideration of alternatives; formation of an institutional animal committee at each research facility; and provision of annual training for those involved in animal care and treatment. An information service was established at the National Agricultural Library, in cooperation with NLM. Title XIV, subtitle B, required an assessment of existing scientific literature relating to dietary cholesterol and calcium to be conducted by the secretaries of agriculture and HHS. (P.L. 99-198.)

December 28, 1985 – P.L. 99-231 designated 1986 as the "Sesquicentennial Year of the National Library of Medicine."

July 2, 1986 – The Urgent Supplemental Appropriations Act provided an additional \$6 million for NCI cancer research and demonstration centers and specified that funds for the Clinical Center should be available for payment of nurses at rates of pay authorized for VA nurses. (P.L. 99-349.)

October 6, 1986 – P.L. 99-443 amended the Small Business Act to extend by 5 years the Small Business Innovation Research Program.

October 16, 1986 – P.L. 99-489 designated the period from October 1, 1986, through September 30, 1987, as "National Institutes of Health Centennial Year" and requested the President to issue a proclamation calling upon the people of the United States to observe the year with appropriate ceremonies and activities.

October 18, 1986 – P.L. 99-500 and P.L. 99-591 (October 31, corrected version), making continuing appropriations for FY 1987, included \$6.18 billion for NIH, a requirement to support 6,200 research project grants, funding for 10,700 research trainees and 559 centers; and \$247.7 million in AIDS money for components.

October 20, 1986 – The Federal Technology Transfer Act amended the Stevenson-Wydler Technology Innovation Act of 1980, authorizing directors of government-operated Federal laboratories to enter into collaborative R&D agreements with other government agencies, universities, and private organizations; established a Federal Laboratory Consortium in the National Bureau of Standards; and mandated that royalties received by a Federal agency be shared with the inventor. (P.L. 99-502.)

November 14, 1986 – Title IX, the Alzheimer's Disease and Related Dementias Services Research Act, of P.L. 99-660 established an interagency council and an advisory panel on Alzheimer's disease (AD). It authorized the director, NIA, to make awards for distinguished research on AD, to plan for and conduct research, to establish an AD clearinghouse, to make a grant to or enter into a contract with a national organization representing Alzheimer's patients, to establish an information system and national toll-free telephone line, and to provide information to caregivers of Alzheimer's patients and to safety and transportation personnel. Title III – Vaccine Compensation – named the director, NIH, as an ex officio member of the newly established Advisory Commission on Childhood Vaccines.

July 11, 1987 – The FY 1987 Supplemental Appropriations bill, P.L. 100-71, allocated funds to NIA for clinical trials, to NCNR and HRSA for studies related to the nurse shortage and nurse retention, and to OD/NIH for costs associated with pay raises and the new Federal Employees Retirement System.

September 29, 1987 – The Balanced Budget and Emergency Deficit Control Reaffirmation Act of 1987 ("Gramm-Rudman-Hollings II") adjusted the original deficit target reduction in FY 1988 appropriations, including Labor-HHS-Education. (P.L. 100-119.)

October 8, 1987 – P.L. 100-126 designated October 1, 1987, as "National Medical Research Day," acknowledging 100 years of contributions by NIH and other federally supported research institutions to improving the health and well-being of Americans and all humankind.

November 29, 1987 – The Older Americans Act Amendments, Title III – Alzheimer's Disease Research, authorized the director, NIA, to provide for conduct of clinical trials on therapeutic agents for Alzheimer's disease recommended for further analysis by NIA and FDA. It also authorized the President to call a White House Conference on Aging in 1991. (P.L. 100-175.)

December 22, 1987 – P.L. 100-202, making further continuing appropriations for the fiscal year ending September 30, 1988, provided \$6.667 billion to NIH, including \$448 million to be allocated among the institutes for AIDS. It also restricted forward or multiyear funding, required expeditious testing of experimental drugs for AIDS, and included \$3.8 million for a National Center on Biotechnology Information within NLM.

September 20, 1988 – The Labor-HHS-Education Appropriations Act, 1989, provided \$7,152,207,000 for NIH (which included a 1.2 percent across-the-board reduction and a \$6.8 million reduction for procurement reform). Of the amount appropriated for NINCDS, up to \$96,100,000 was to go to the new National Institute on Deafness and Other Communication Disorders, following enactment of authorizing legislation. The pay rate for NIH nurses and allied health specialists having direct patient care responsibilities was equated to that of nurses at the Veterans Administration. Fifteen million dollars was appropriated to develop specifications and design for a consolidated office building at NIH, \$14 million for the new Building 49, and \$5 million for renovation of AIDS facilities. In addition, a biotechnology training program was established, as well as human genome and biotechnology panels.

Funds were authorized to support no less than 13,252 FTEs, including an additional 200 for AIDS and 150 for non-AIDS. Funding was also authorized for new magnetic resonance imaging equipment at the cardiac energetic laboratory and for a National Bone Marrow Registry at NHLBI; \$8.7 million was earmarked for AIDS clinical trials.

Building 31 was renamed the Claude Denson Pepper Building. (P.L. 100-436.)

September 22, 1988 – The Treasury, Postal Service and General Government Appropriations Act, 1989, provided that no Federal agency could receive funds appropriated for FY 1989 unless it had in place a written policy ensuring that its workplaces were free from illegal use, possession, or distribution of controlled substances. This restriction also applied to grant recipients, contractors, and parties to other agreements. (Subsequent legislation required implementation of this law in January 1989.) (P.L. 100-440.)

September 29, 1988 – The National Defense Authorization Act, FY 1989, provided a special pay retention bonus for medical officers below grade O-7 who met certain criteria. Although officers of the commissioned corps were not specifically mentioned, 42 U.S.C. 210(a) states that they shall receive special pay received by commissioned medical and dental officers of the Armed Forces. (P.L. 100-456.)

October 4, 1988 – P.L. 100-471 amended the PHS act to authorize the secretary, HHS, to make grants to the states to provide drugs determined to prolong the life of individuals suffering from AIDS; \$15 million was authorized to be appropriated through March 31, 1989. (Funds appropriated for FY 1989 were transferred from NIH and other PHS agencies to pay for this program, according to transfer authority contained in P.L. 100-436.)

October 28, 1988 – The National Deafness and Other Communication Disorders Act of 1988 established that institute at NIH and renamed NINCDS the National Institute of Neurological Disorders and Stroke. The legislation included a program, a data system and information clearinghouse, centers, and an advisory board, as well as a Deafness and Other Communication Disorders Interagency Coordinating Committee, to be chaired by the director of NIH or designee. (P.L. 100-553.)

November 4, 1988 – Title I of the Health Omnibus Programs Extension of 1988 (HOPE), the

National Institute on Deafness and Other Communication Disorders and Health Research Extension Act of 1988, established the NIDCD and reauthorized expiring programs of NIH for 2 years. Since the new institute had already been established by P.L. 100-553, the provision in this bill is not valid. (P.L. 100-607)

A National Center for Biotechnology Information was established in the National Library of Medicine; the provision for VA pay for nurses and allied health professionals was reiterated; NCI, NHLBI, and NRSA programs were reauthorized; responsibility for the primary care training program was shifted to HRSA; the Interagency Technical Committee was abolished; the Alzheimer's disease provisions of P.L. 99-660 were shifted to the NIA section of the PHS act; the moratorium on fetal research was extended through November 4, 1990; funds were appropriated for the Biomedical Ethics Advisory Board and a report specified; the secretary was directed to consult with the director, NIH, on establishment of a National Commission on Sleep Disorders, which would include among the ex officio members the directors of NINCDS, NHLBI, NIMH, NIA, and NICHD, with a report and a plan required. Finally, the bill extended confidentiality provisions to subjects of all biomedical, behavioral, clinical, or other research, including research on mental health.

Title II, "Programs with Respect to Acquired Immune Deficiency Syndrome," laid the foundation for a Federal policy on AIDS. In addition to provisions for AIDS research, the bill included provisions for information dissemination, education, prevention, anonymous testing, and establishment of a National Commission on AIDS. The review process for AIDS-related grants was expedited, provision was made for priority requests for personnel and administrative support, a clinical research review committee was established within NIAID, the AIDS outpatient capacity at the Clinical Center was doubled, community-based clinical trials were mandated, awards for international clinical research were authorized, research centers were supported, and information services were expanded. An Office of AIDS Research was established within OD. Title VI, the Health Professions Reauthorization Act of 1988, established a loan repayment program for scientists who agree to conduct AIDS research while employed at NIH. (P.L. 100-607.)

November 21, 1989 – Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1990, provided for the purchase of an advanced design supercomputer and named four NIH buildings for members of Congress. (P. L. 101-166)

November 29, 1989 – An act to provide for the construction of biomedical facilities in order to ensure a continued supply of specialized strains of mice essential to biomedical research in the United States, and for other purposes, provided authority to make construction grants for this purpose. (P.L. 100-190)

1990

August 18, 1990 – Ryan White Comprehensive AIDS Resources Emergency Act of 1990, authorized NIH to make demonstration grants to community health centers and other entities providing primary health care and servicing a significant number of pediatric patients and pregnant women with HIV disease. Awardees were to provide clinical data to NIH for evaluation. (P.L. 101-381)

November 5, 1990 – Omnibus Budget Reconciliation Act of Response, Compensation, and Liability Act of 1980 (under which NIEHS operates some programs) and called on the secretary, with NCI, to review periodically the appropriate frequency for performing screening mammography.

Treasury, Postal Service and General Government Appropriations Act, 1991, established the PHS senior biomedical research service. (P.L. 101-509)

Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1991, provided for the first time, a 1 percent NIH director's transfer authority for high-priority activities and capped the NIH contribution for salaries for individuals receiving

extramural funding. (P.L. 101-517)

November 15, 1990 – Clean Air Act Amendments of 1990, required NIEHS to conduct a study of mercury exposure; to be available, with NCI, for membership on a panel for the Mickey Leland Urban Air Toxics Research Center and an inter-agency task force on air pollution; and authorized an NIEHS program of basic research on human health risks from air pollutants. (P.L. 101-549)

Home Health Care and Alzheimer's Disease Amendments of 1990, broadened the authority for Alzheimer's disease research centers and authorized Claude D. Pepper Older Americans Independence Centers grants. (P.L. 101-557)

November 16, 1990 – The NIH Amendments of 1990, had two purposes: it authorized a nonprofit organization the National Foundation for Biomedical Research (membership amended by P.L. 102-170) and created NICHD's National Center for Medical Rehabilitation Research. (P.L. 101-613)

Hazardous Materials Transportation Uniform Safety Act of 1990, authorized NIEHS to provide grants for the training and education of workers who are or may be engaged in activities related to hazardous waste removal, containment or emergency response. (P.L. 101-615)

Transplant Amendments of 1990, reauthorized and amended the PHS act as it concerns the National Bone Marrow Donor Registry in the NHLBI and called for the establishment of national standards and procedures. (P.L. 101-616)

August 14, 1991 – Terry Bein Community Based AIDS Research Initiative Act of 1991, authorized this initiative in the PHS act and NIAID. (P.L. 102-96)

November 26, 1991 – Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1992, established NCI's Matsunaga-Conte Prostate Cancer Research Center, a women's health study, and provided authority to transfer funds to emergency activities. (P.L. 102-170)

December 9, 1991 – The High Performance Computing Act of 1991, authorized Federal agencies such as NIH to allow recipients of research grant funds to pay for computer networking expenses. (P.L. 102-194)

February 4, 1992 – The American Technology Preeminence Act of 1991 gave authority to the directors of Federal laboratories (NIH) to give research equipment that is excess to the needs of the laboratory to an educational institution or nonprofit organization for the conduct of technical and scientific education and research activities (P.L. 102-245)

July 10, 1992 – The Alcohol, Drug Abuse, and Mental Health (ADAMHA) Reorganization Act, amended by the PHS act to provide for the incorporation of the three ADAMHA research institutes – NIMH, NIAAA, and NIDA – into the NIH as of October 1, 1992. A new PHS act section 409 was added and defined "health services research" as research endeavors that study the impact of organization, financing, and management of health services of the quality, cost, access to and outcomes of care. This is an entirely new programmatic undertaking for NIH and these three new institutes. Of particular interest are provisions that authorize a bypass budget for these three institutes for FY 1994 and 1995. (P.L. 102-321)

October 13, 1992 – The DES Education and Research Amendments of 1992, require the director, NIH, to establish a program for the conduct and support of research and training, dissemination of health information, and other programs with respect to the diagnosis and treatment of conditions associated with exposure to DES. (P.L. 102-409)

The Agency for Health Care Policy and Research Reauthorization Act of 1992, requires that the NLM establish an information center on health service research, and on selected technology

assessments and clinical practice guidelines produced by AHCPR and other public and private sources. The AHCPR administrator, in consultation with the NLM director, is required to develop and publish criteria for the inclusion of practice guidelines and technology assessments in the information center database. (P.L. 102-410)

October 24, 1992 – The Cancer Registries Act requires the establishment of a national program of cancer registries, with the overall goal being the assurance of minimal standards for quality and completeness of (cancer) case information. Provisions also require the DHHS secretary, acting through the NCI director, to conduct a study for the purpose of determining the factors contributing to the fact that breast cancer mortality rates in 9 states and the District of Columbia are elevated compared to rates in the other 43 states. (P.L. 102-515)

The Energy Policy Act of 1992 authorizes electric and magnetic fields research and public information activities by the NIEHS director. (P.L. 102-486)

October 26, 1992 – The Preventive Health Amendments of 1992 provide authorities regarding the coordination of Federal programs related to preventable cases of infertility arising as a result of sexually transmitted diseases; also delineates coordination between the director, CDC, and director, NIH. (P.L. 102-531)

October 28, 1992 – The Small Business Innovation Research and Development and Enhancement Act of 1992 reauthorizes the SBIR program through September 30, 2000, and increases set aside percentages for each Federal agency with an extramural budget for research and development in excess of \$100 million in FY 1992 (1.25 percent) upward to 2.5 percent by 1997 and onward. Legislation also requires enhancement of agency outreach efforts to increase participation of women-owned and socially and economically disadvantaged small business concerns, and tracking of awards to document their participation in the program. (P.L. 102-564)

The Housing and Community Development Act of 1992 requires the secretary, HHS, acting through the director, CDC, and director, NIEHS, to jointly conduct a study of the sources of lead exposure in children who have elevated blood lead levels (or other indicators of elevated lead body burden) as defined by the director, CDC. (P.L. 102-550)

November 4, 1992 – The National Aeronautics and Space Administration (NASA) Authorization Act includes provisions offered as an amendment requiring NIH and NASA to jointly establish a working group, with equal representation from NASA and NIH, to coordinate biomedical research activities in areas where microgravity environment may contribute to significant progress in the understanding and treatment of diseases and other medical conditions; establishment of a joint program of biomedical research grants in the above described areas, where such research requires access to a microgravity environment, and annual issuance of joint research opportunity announcements; creation of a joint program of graduate research fellowships in biomedical research; and establishment and submission of a plan for the "conduct of joint biomedical research activities by the republics of the former Soviet Union and the United States." (P.L. 102-588)

June 10, 1993 – The NIH Revitalization Act of 1993 reauthorized certain expiring authorities of the NIH; mandated establishment of the Office of Research Integrity in DHHS; lifted the moratorium on human fetal tissue transplantation research; mandated inclusion of women and minorities in clinical research protocols; created in statute the Office of Alternative Medicine, the Office of Research on Women's Health, the Office of Research on Minority Health, the Office of Biobehavioral and Social Sciences Research, and the National Center for Human Genome Research; mandated establishment of an intramural laboratory and clinical research program on obstetrics and gynecology within NICHD and the National Center on Sleep Disorders Research in NHLBI; codified in statute the establishment of the Office of AIDS Research, and strengthened and expanded its authorities, including authorizing OAR receipt of all appropriated AIDS funds for distribution to the ICs; authorized the establishment of an NIH director's discretionary fund; provided the director, NIH, with extramural construction authority; required from extramural construction funds a \$5 million set aside for Centers of Excellence; mandated establishment of the IDeA program; required the NCI to

conduct the Long Island breast cancer study; authorized establishment of scholarship and loan repayment programs for individuals from disadvantaged backgrounds; changed the designation from center to institute for NINR and from division to center for the Division of Blood Resources, NHLBI; and provided other new NIH authorities and directives. (P.L. 103-43)

August 3, 1993 – The Government Performance and Results Act of 1993 seeks to curb fraud waste and mismanagement in the operation of the Federal Government by establishing performance standards. (P.L. 103-62)

December 14, 1993 – The Preventive Health Amendments of 1993 required the director, NIAID, to conduct or support research and research training regarding the cause, early detection, prevention and treatment of tuberculosis, and authorized to be appropriated \$50 million for FY 1994 and such sums as necessary for FYs 1995-98. (P.L. 103-183)

September 30, 1994 – The Department of Labor, HHS, and Education Appropriations Act, 1995, provided for the first time a consolidated appropriation for NIH AIDS research to the Office of AIDS Research. (P.L. 103-333)

October 25, 1994 – The Dietary Supplement Health and Education Act of 1993 mandated establishment of an Office of Dietary Supplements within NIH to conduct and coordinate NIH research relating to dietary supplements and the extent to which their use reduces the risk of certain diseases. (P.L. 103-417)

May 22, 1995 – The Paperwork Reduction Act of 1995 amends the U.S. Code to reduce by 5 percent the Federal paperwork burdens imposed on individuals, small businesses, state and local governments, education and nonprofit institutions and Federal contractors; also had the effect of establishing in statute the NIH Office of Information Resources Management. (P.L. 104-13)

December 21, 1995 – The Federal Reports Elimination and Sunset Act of 1995 provides for improvement of the efficiency of agency operations by reducing staff time and resources spent on producing "unnecessary" reports to Congress. (P.L. 104-66)

November 1, 1995 – The Biotechnology Process Patents Protection Act of 1995 strengthens patent protection and clarifies the circumstances under which a patent using biotechnological processes can be issued; allows U.S. researchers to enforce their patents claiming a certain starting material against the unfair importation of products made overseas using such material; and stops international theft of intellectual property; and makes U.S. patent law consistent with that of the Europeans and the Japanese. (P.L. 104-41)

January 26, 1996 – The Balanced Budget Downpayment Act I, a continuing resolution, contained an amendment prohibiting the use of NIH funds for human embryo research; and cited NIH's FY 1996 funding in P.L. 104-91, such that the prohibition would continue for the duration of the FY 1996 funding year. (P.L. 104-99)

March 7, 1996 – The National Technology Transfer and Advancement act of 1995 amended the Stevenson-Wydler Technology Innovation Act of 1980 with respect to reinvention made under Cooperative Research and Development Agreements; addressed the assignment of intellectual property rights and the use and deregulation of royalty income. (P.L. 104-113)

April 24, 1996 – The Antiterrorism and Effective Death Penalty Act of 1996 required that the Secretary, HHS, establish safety procedures for use of biological agents, training in handling and proper laboratory containment, safeguards to prevent their use for criminal purposes, and procedures to protect the public safety. The act provided, however, that the Secretary must ensure availability of biological agents for research purposes. (P.L. 104-132)

May 20, 1996 – The Ryan White CARE Reauthorization Act revised and extended authorization of

the 1990 act, which provided for care and services for persons living with HIV/AIDS. Title IV provisions require the administrator, HRSA, to consult with the director, NIH, in carrying out a grants program to provide health care and opportunities for women, infants, children, and youth to participate as voluntary subjects of clinical research on HIV disease that is of potential benefit to them. (P.L. 104-146)

July 29, 1996 – The Traumatic Brain Injury Act amended the PHS Act to provide for the conduct of expanded studies and establishment of innovative programs with respect to traumatic brain injury. The act authorizes the Secretary, acting through the director, NIH, to award grants or contracts for the conduct of basic and applied research regarding traumatic brain injury. (P.L. 104-166)

August 6, 1996 – The Safe Drinking Water Act amendments reauthorized the Safe Drinking Water Act, toughened standards and required the Environmental Protection Agency to consult with NIH and the CDC in announcing an interim national primary drinking water regulation for a contaminant in the case of an urgent threat to public health. (P.L. 104-182)

October 2, 1996 – The Electronic Freedom of Information Act established the right of the public to obtain access to Agency records, including electronically stored documents, and requires Federal agencies to make available certain Agency information to the public for inspection and copying. (P.L. 104-231)

October 18, 1996 – The General Accounting Office Management Reform Act amended the PHS Act to limit the amount NIH may obligate for administrative expenses each fiscal year and repealed a requirement that the U.S. Comptroller General conduct, audit, and report to the Congress regarding the National Foundation for Biomedical Research. (P.L. 104-316)

September 30, 1996 – The FY 1997 Labor, HHS, and Education Appropriations Act continued the prohibition on use of NIH funds for human embryo research. The act provided for construction of the new Mark O. Hatfield Clinical Research Center. (P.L. 104-208)

July 3, 1997 – Section 2118 of the Energy Policy Act of 1992 was amended to extend the Electric and Magnetic Fields Research and Public Information Dissemination Program, a joint U.S. Department of Energy and NIEHS venture, for 1 year. (P.L. 105-23)

August 5, 1997 – The Balanced Budget Act authorized a \$150 million increase for research on the prevention and care of type-1 diabetes. (P.L.105-33)

November 21, 1997 – The Food and Drug Administration Regulatory Modernization Act of 1997 directed NIH, in coordination with the CDC, to develop and maintain a database and information service that provides centralized information on research, treatment, detection, and prevention activities related to serious or life-threatening diseases. The act also directed NIH, the FDA, and medical and scientific societies to identify published and unpublished studies by clinicians and researchers that may support a supplemental application for a licensed product and to encourage manufacturers to submit a supplemental application or to conduct further research to support a supplemental application. (P.L. 105-115)

December 2, 1997 – The Small Business Reauthorization Act, reauthorized the Small Business Technology Transfer (STTR) program for 4 years and required that the STTR program information be submitted as a part of Federal agency performance plans and be made available to the Congress. (P.L. 105-135)

December 17, 1997 – The Federal Advisory Committee Act Amendment included provisions that permit the public to attend taxpayer-funded advisory committee meetings and receive minutes and other documents prepared for or by such committees. (P.L. 105-153)

June 23, 1998 – The Agricultural Research, Extension, and Education Reform Act of 1998 required

the Secretary, U.S. Department of Agriculture, to establish a Food Safety Research Information Office whose activities are carried out in cooperation with the NIH, the FDA, CDC, and public and private institutions. (P.L. 105-185)

July 16, 1998 – The National Marrow Donor Program was reauthorized. (P.L. 105-196)

August 7, 1998 – The Workforce Investment Partnership Act of 1997 is omnibus legislation that created in statute an Interagency Committee on Disability Research whose membership includes the directors of NIH and NIMH. (P.L. 105-220)

October 9, 1998 – The Mammography Quality Standards Reauthorization Act reauthorized through FY 2002 such sums as may be necessary for the award of grants for breast cancer screening surveillance research. (P.L. 105-248)

October 19, 1998 – The Federal Employees Health Care Protection Act of 1998 contained a provision to raise the cap from \$20,000 to \$30,000 for the Physician's Comparability Allowance (PCA). The PCA is subject to "applicable limitations," including aggregate compensation limitation. (P.L. 105-266)

October 21, 1998 – The Appropriations for the Department of Veterans Affairs and Housing and Urban Development for FY 1999 provided appropriations for the NIEHS Superfund Worker Training Program and for the NIEHS Superfund Research Program. (P.L. 105-276)

October 21, 1998 – FY 1999 Treasury and General Government Appropriations prohibited interagency financing of commissions, councils, committees, or similar groups. Section 622 prohibited Federal agencies from purchasing information technology that is not Year 2000 compliant unless the agency's chief information officer determines that noncompliance would be necessary to the function and operation of the agency.

October 21, 1998 – The Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, created in statute at NIH the National Center for Complementary and Alternative Medicine; renamed the NIDR as the National Institute of Dental and Craniofacial Research; and named two new NIH buildings after retiring members of Congress: 1) the Louis Stokes Laboratories and 2) the Dale and Betty Bumpers Vaccine Research Facility.

The act continued human embryo research prohibition, the NIH director's transfer authorities, and third-party payment authority for the NIH Clinical Center. In addition, permanent authority was provided to NIH for transit subsidies for non-full-time equivalent bearing positions, including visiting fellows, trainees, and volunteers. General provisions were provided for prohibition on the use of funds for programs for sterile needle distribution; and a prohibition on the use of funds for promoting legalization of controlled substances, except where there is evidence of therapeutic advantage or that federally sponsored clinical trials are being conducted to determine advantage.

This act authorized NICHD to be represented on a peer review panel established by the Secretary of Education to review applications from the states for scientifically based reading research activities.

Provisions included amendment of OMB Circular A-110, requiring Federal funding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act.

The director of the Office of National Drug Control Policy was directed to consult with the directors of appropriate NIH institutes to establish criteria for evaluation of substance abuse treatment and prevention programs.

The conference report included the following:

- Directive language for the NCI on prostate cancer research.
- The NIDDK and other ICs were urged to expand funding for juvenile diabetes.
- The NIEHS and ORMH would enhance support for environmental health effects/minority health centers; NIEHS is to work with NIOSH on the national occupational research agenda (NORA).
- NIA is to launch a full-scale prevention initiative for Alzheimer's disease and is to work with NIOSH on NORA.
- The NIAMS is to expand research on Osteogenesis Imperfecta.
- The Office of Rare Diseases is to develop an information program on biological samples and human cell and tissue banks available for research purposes.
- The Office of Behavioral and Social Sciences Research is urged to establish two to five mind/body centers.
- NIH is to focus resources on the cause and treatment for Parkinson's disease.
- NIH is to enhance research on Multiple Sclerosis and other autoimmune disorders. (P.L. 105-78)

October 28, 1998 – The Next Generation Internet Research Act of 1998 amended the High-Performance Computing Act of 1991 to authorize Government-funded research into high-capacity, high-speed computer networks. (P.L. 105-305)

October 31, 1998 – The Women's Health Research and Prevention Amendments of 1998 extended and/or amended various NIH authorities related to women's health research, including: the drug DES (diethylstilbestrol); osteoporosis, Paget's disease and related disorders; breast, ovarian and related cancers; heart attack, stroke, and other cardiovascular diseases; aging processes; and the Office of Research on Women's Health. (P.L. 105-340)

November 10, 1998 – The Federal Reports Elimination Act of 1998 provided for the elimination of the following reports of particular interest to NIH: Report of the Council on Alzheimer's Disease; Report on the U.S.-Japan Cooperative Medical Science Program; Report of the Interagency Coordinating Committee on Arthritis and Musculoskeletal and Skin Diseases; Report on Family Planning and Population Research; Report of the NICHD Associate Director for Prevention; Report on Health Services Research; Annual Reports of the National Diabetes Advisory Board, National Digestive Diseases Advisory Board, and National Kidney and Urologic Diseases Advisory Board; Public Health Service Report; Annual Report on Disease Prevention; and Annual Report on Administrative Expenses. (P.L. 105-362)

November 13, 1998 – The Health Professions Education Partnership Act reauthorized and consolidated health professions, nursing, and minority and disadvantaged health education programs within the Department of Health and Human Services. The act provided additional research training and Title 38 appointment authorities for the NIH director; reauthorized the NIH AIDS loan repayment program (LRP); and increased the maximum annual loan repayment from \$20,000 to \$35,000 for this and other NIH LRPs; authorized tax relief benefits for participants in the NIH Clinical Researchers from Disadvantaged Backgrounds LRP; and made discretionary the National Center for Research Resources director's authority for construction awards to the regional primate research centers and reduced the amount that may be reserved from \$5.0 million to \$2.5 million. (P.L. 105-392)

November 20, 1999 – Federal Financial Assistance Management Improvement Act of 1999 required agencies to develop plans to streamline grant administration activities. OMB was directed to 1) develop a common application, or set of common applications, for applying for Federal assistance; 2) develop a common system, including electronic processes, for grant administration activities; and 3) develop uniform administrative rules for Federal financial assistance programs across different agencies. (P.L. 106-107)

November 29, 1999 – Omnibus Appropriations for NIH, Fiscal Year 2000, provided NIH with an

increase of \$2.3 billion over FY 1999. This legislation also included the Newborn and Infant Screening and Intervention Act which directed the National Institute on Deafness and Other Communication Disorders (NIDCD) to carry out a program of research on the efficacy of new screening techniques and technology, including clinical trials of screening methods, studies on the efficacy of intervention, and related basic and applied research on hearing loss in newborns. (P.L. 106-113)

December 6, 1999 – Healthcare Research and Quality Act reauthorized and renamed the Agency for Health Care Policy and Research as the Agency for Healthcare Research and Quality (AHRQ). Provisions required the AHRQ Director, to promote innovation in evidence-based clinical practice and healthcare technologies to consult with the NIH Director and work with the National Library of Medicine to develop an electronic clearinghouse of currently available assessments and those in progress. The NIH Director will serve on the AHRQ Advisory Council as an ex officio member. (P.L. 106-129)

2000

June 30, 2000 – The Electronic Signatures in Global and National Commerce Act mandated that electronic contracts with electronic signatures have the same legal force as paper contracts. (P.L. 106-229).

July 10, 2000 – The Radiation Exposure Compensation Act (RECA) Amendments of 2000 amended the Public Health Service Act to establish a grant program to States for education, prevention, and early detection of radiogenic cancers and diseases. Entities eligible to receive such grants include National Cancer Institute-designated cancer centers. The competitive grants would be made by the Secretary of Health and Human Services, acting through the Administrator of the Health Resources and Services Administration, in consultation with the Directors of the National Institutes of Health and Indian Health Service. (P.L. 106-245)

July 13, 2000 – The Emergency Supplemental Act, Fiscal Year 2000, repealed Section 216 of P.L. 106-113, the Omnibus Consolidated Appropriations Act, which funded the NIH for fiscal year (FY) 2000. Section 216 of that Act specified that \$3 billion of the funds appropriated for NIH were not available for obligation until September 29, 2000, and would not be available for obligation until October 15, 2000. This provision was repealed, thus releasing the funds for use prior to September 29, 2000. (P.L. 106-246)

July 28, 2000 – The Semipostal Authorization Act amended the Postal Service Reorganization Act to extend the authority to issue semipostal stamps for breast cancer research until July 29, 2002. Seventy percent of the profits of this stamp go to the NIH to fund breast cancer research and thirty percent go to the U.S. Department of Defense for its breast cancer research program. Appropriations to NIH was not affected by any proceeds received from the sale of semipostal stamps. (P.L. 106-253)

October 17, 2000 – The Children's Health Act of 2000 authorized Federal programs for research and other activities related to autism, Fragile X, juvenile arthritis, juvenile diabetes, asthma, hearing loss, epilepsy, traumatic brain injuries, childhood skeletal malignancies, muscular dystrophy, autoimmune diseases, birth defects and genetic mental impairment, among other conditions. The bill also required an NIH pediatric research initiative within the Office of the Director, NIH, with provisions addressing loan repayment for pediatric researchers and pediatric research human subject protections. (P.L. 106-310)

October 17, 2000 – The American Competitiveness in the 21st Century Act of 2000 increased the cap on the number of H1-B visas from 115,000 to 195,000 each year for the next 3 years. The legislation eliminated the cap on H1-B visas for government, academic, non-profit and affiliated workers. (P.L. 106-313)

October 20, 2000 – The Ryan White CARE Act Amendments of 2000 provisions required an NIH review of the distribution and availability of ongoing and appropriate HIV/AIDS research projects to existing Ryan White sites for the purpose of enhancing and expanding voluntary access to HIV-related research, particularly in communities underserved by such projects. In addition, the NIH is required to conduct research on development of rapid diagnostic test kits. (P.L. 106-345)

November 1, 2000 – The Technology Transfer Commercialization Act of 1999 is intended to "improve the ability of Federal agencies to license Federally-owned inventions." (P.L. 106-404)

November 6, 2000 – The Needlestick Safety and Prevention Act required changes in the blood-borne pathogens standards in effect under the Occupational Safety and Health Act of 1970 to protect workers whose occupations expose them to pathogens such as HIV. Employers are required to use needles and other medical devices that have built-in safety mechanisms to reduce accidental punctures and to keep a log of needlestick injuries that would protect confidentiality of injured employees. (P.L. 106-430)

November 13, 2000 – The Older Americans Act of 2000 required a White House Conference on Aging to be convened no later than December 31, 2005, to make fundamental policy recommendations regarding programs that are important to older individuals, and to the families and communities of such individuals. The Conference is to be planned and conducted under the direction of the Secretary, in cooperation with other federal agencies, including the Director of the National Institute on Aging. H.R. 782 will now proceed to the Senate for consideration. The legislation reauthorizes and amends the Older American's Act of 1965 and the Older Americans Act Amendments of 1987. (P.L. 106-501)

November 13, 2000 – The Public Health Improvement Act of 2000 is a compilation of bills which amended the Public Health Service Act and provided new authorities to NIH and other Public Health Service agencies, or placed in statute ongoing activities or programs. This law provided the following: 1) established in statute the National Center for Research Resources (NCRR's) general clinical research centers, the NIH Career Awards in Patient-Oriented Research, which include the Mentored Patient-Oriented Research Career Development Award (K23), the Mid-Career Investigator Award in Patient-Oriented Research (K24), and the Clinical Research Curriculum Award (K30); 2) required the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) to expand and intensify research and related activities regarding lupus; 3) substantially increased the authorization for NIH extramural facilities construction and authorized \$100 million to allow the continued operation of NCRR's Shared Instrumentation Grant Program; 4) established in statute an extramural clinical loan repayment program for qualified health professionals who agree to conduct clinical research; 5) created in statute the Alzheimer's Disease Clinical Research and Training program within the National Institute on Aging (NIA); 6) extended the current authority to conduct basic and clinical research in combating prostate cancer research at the National Cancer Institute; 7) directed NIH to evaluate the effectiveness of screening strategies; and 8) included a technical amendment to the Children's Health Act of 2000 (Public Law 106-310) which corrects an inaccurate citation to a provision in the Code of Federal Regulations. (P.L. 106-505)

November 22, 2000 – The Minority Health and Health Disparities Research and Education Act of 2000 created in statute a National Center on Minority Health and Health Disparities at the NIH to coordinate: 1) health disparities research performed or supported by NIH, 2) a grant program through the new Center to further biomedical and behavioral research education and training, 3) an endowment program to facilitate minority and other health disparities research at centers of excellence, and 4) a loan repayment program to train members of minority or other health disparities populations as biomedical research professionals. (P.L. 106-525)

December 19, 2000 – The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) Authorization Act of 2000 codifies the existing ICCVAM as a permanent standing committee to be administered by the National Institute on Environmental Health Sciences. The statute requires the ICCVAM to establish, wherever feasible, guidelines, recommendations, and regulations that promote the regulatory acceptance of new or revised scientifically valid toxicological

tests that protect human and animal health and the environment while reducing animal tests and ensuring human safety and product effectiveness. (P.L. 106-545)

December 20, 2000 – The Chimpanzee Health Improvement, Maintenance, and Protection Act requires NIH to enter into a contract with a nonprofit private entity for the purpose of operating a sanctuary system for the long-term care of chimpanzees that are no longer needed in research conducted or supported by the NIH, the Food and Drug Administration, and other Federal agencies. The law provides for standards for permanent retirement of chimpanzees into the system, including prohibiting using sanctuary chimpanzees for research except in specified circumstances. (P.L. 106-551)

December 21, 2000 – The Consolidated Appropriations Act, 2001, provides funding for the U.S. Departments of Labor, Health and Human Services (HHS) and Education; the legislative branch; and the Treasury and Postal Service, and H.R. 5667, the Small Business Reauthorization Act. For the NIH this law provides an appropriation of a \$2.523 billion, or 14 percent increase over fiscal year 2000. Specific provisions of the law: 1) provides \$47.3 million within Buildings and Facilities for the National Neuroscience Research Center, to be named the John Edward Porter Neurosciences Research Center; 2) permits the Director of NIH to enter into and administer a longterm lease for facilities for the purpose of providing laboratory, office and other space for biomedical and behavioral research at the Bayview Campus in Baltimore, Maryland; 3) expands the intramural loan repayment program for clinical researchers from disadvantaged backgrounds to the extramural community; and 4) raises the salary cap for extramural investigators to Executive Level I from Level II. (P.L. 106-554)

December 28, 2000 – The Federal Physicians Comparability Allowance Amendments of 2000 makes physician comparability allowances a permanent authority and requires the allowances to be treated as part of basic pay for retirement purposes. (P.L. 106-571)

December 29, 2000 – The National Institute of Biomedical Imaging and Bioengineering Establishment Act amends the Public Health Service Act to create at NIH the National Institute of Biomedical Imaging and Bioengineering. The statute authorizes an amount equal to (plus inflation) the amount currently spent by NIH Institutes for imaging and engineering programs. In establishing the Institute, the Director of NIH is authorized to transfer personnel, use appropriate facilities to house the new Institute, and obtain administrative support from other agencies of NIH. The Institute is required to have a 12-member advisory council, and prepare a plan to address the consolidation and coordination of NIH biomedical imaging and engineering programs, as well as related activities of other Federal agencies. (P.L. 106-580)

May 24, 2001 – The Animal Disease Risk Assessment, Prevention and Control Act of 2001 mandates that the Secretary of Agriculture submit a final report to Congress on plans by Federal agencies (including the National Institutes of Health and the Agriculture Research Service and Cooperative State Research, Education, and Extension Service of the U.S. Department of Agriculture) to carry out in partnership with the private sector 1) research programs into the causes and mechanisms of transmission of foot and mouth disease and bovine spongiform encephalopathy (BSE), variant Creutzfeldt-Jacob disease, and related disease, and 2) diagnostic tools and preventive and therapeutic agents needed for foot and mouth disease, BSE, variant Creutzfeldt-Jacob disease, and related diseases. In addition, this legislation mandates that the final report to Congress contain plans by Federal agencies (including the Centers for Disease Control and Prevention) 1) to monitor the incidence and prevalence of the transmission of foot and mouth disease, BSE, variant Creutzfeldt-Jacob disease, and related diseases in the United States; and 2) to assess the effectiveness of efforts to prevent and control the spread of foot and mouth disease, BSE, variant Creutzfeldt-Jacob disease, and related diseases in the United States. (P.L. 107-9)

July 24, 2001 – The 2001 Supplemental Appropriations Act included 1) provisions to permit the transfer of funds from the National Library of Medicine (NLM) to the National Institutes of Health (NIH) Buildings and Facilities account to complete the design phase of a new NLM facility, 2) report language to permit the new National Institute of Biomedical Imaging and Bioengineering (NIBIB) to use funds appropriated to the NIH Office of the Director (OD) for start up of the new Institute, and 3)

language directing that information requested from the Committee on Appropriations was to be transmitted "uncensored and without delay." (P.L. 107-20)

October 26, 2001 – The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (PATRIOT) Act of 2001 amends a number of titles of the United States Code in an effort to expand the Nation's ability to intercept and thwart terrorist threats. Of particular interest are amendments to Title 18 regarding possession, use, and transport of biological agents. These amendments seek to ensure that only those persons who have a lawful purpose for possessing, using, and/or transporting such agents are permitted to work with these agents, and that penalties are established for certain "restricted" individuals who are in possession of such agents. The Act also enhances the powers of the Attorney General, law enforcement officials, and the courts regarding wire, oral, and electronic communications. (P.L. 107-56)

December 18, 2001 – The Muscular Dystrophy Community Assistance Research and Education Amendments of 2001 (MD-CARE Act) amends the Public Health Service Act. Of particular interest to NIH this legislation mandates that the Director of the National Institutes of Health, in coordination with the Directors of the National Institute of Neurological Disorders and Stroke, National Institute of Arthritis and Musculoskeletal and Skin Diseases, National Institute of Child Health and Human Development, and other national research institutes, as appropriate, expand and intensify programs with respect to research and related activities concerning Duchenne, myotonic, facioscapulohumeral, and other forms of muscular dystrophy (MD). In addition, the legislation 1) requires the establishment of Muscular Dystrophy Centers of Excellence, 2) requires the Secretary of Health and Human Services (HHS) to contract with the Institute of Medicine to study centers at NIH and make recommendations when their establishment is appropriate, 3) creates a Muscular Dystrophy Interagency Coordinating Committee that is required to develop a plan for conducting and supporting research and education on MD through the national research institutes and submits a biennial report to Congress describing research activities; 4) establishes a program in which samples of tissues and genetic materials that are of use in research on MD are donated, collected, preserved, and made available for such research; 5) requires the Secretary of HHS to provide a means of public input on existing and planned MD research activities; 6) requires the Centers for Disease Control and Prevention to carry out activities with respect to Duchenne MD epidemiology. (P.L. 107-84)

January 4, 2002 – The Best Pharmaceuticals for Children Act reauthorizes the pediatric studies provision of the Food and Drug Administration Modernization and Accountability Act of 1997 to improve the safety and efficacy of pharmaceuticals for children. It continues to encourage pharmaceutical companies to conduct pediatric studies of on-patent drugs that are used in pediatric populations, but are not labeled for such use, by extending their market exclusivity. In addition, this legislation authorizes studies for "off-patent" drugs by the Federal Government or other entities with the expertise to conduct pediatric clinical trials. (P.L. 107-109)

January 10, 2002 – The Department of Defense Appropriations Act, 2002 provides funding for NIH for bioterrorism under the Emergency Supplemental Act, 2002 (which is part of this legislation). The "conferees encourage the National Institute of Allergy and Infectious Diseases (NIAID) to conduct research on safer alternatives to the existing smallpox vaccine, such as an inactivated smallpox virus." In addition, funds are provided for the construction of a level-4 biosafety laboratory and related infrastructure costs at NIAID and for improving laboratory security at CDC and NIH. The bill also includes funds for the National Institute of Environmental Health Sciences (NIEHS) "for carrying out under current authorities, worker training, research, and education activities" in response to the September 11 terrorist attacks. (P.L. 107-117)

May 14, 2002 – The Hematological Cancer Research Investment and Education Act, amends the Public Health Service Act to require 1) the Director of the National Institutes of Health, through the National Cancer Institute, to expand and coordinate blood cancer research programs, particularly with respect to leukemia, lymphoma, and multiple myeloma (the Joe Moakley Research Excellence Program); and 2) the Secretary of Health and Human Services to establish a related education program for patients and the general public (the Geraldine Ferraro Cancer Education Program). (P.

L. 107-172)

June 12, 2002 – The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 amends Section 319 of the Public Health Service Act to strengthen protections related to public health. The Act requires the Secretary of Health and Human Services (HHS), in coordination with appropriate Federal department and agency officials, to establish a joint interdepartmental working group on preparedness for acts of bioterrorism. Among its activities, this group is charged with providing consultations on, assistance in, and recommendations regarding provision of appropriate safety and health training; coordination and prioritization of countermeasures to treat, prevent, or identify exposures to biological agents; and research on pathogens likely to be used in a biological threat or attack on the civilian population. (P.L. 107-188)

August 2, 2002 – The Supplemental Appropriations for FY 2002 bill names in statute the National Research Service Awards (NRSA) the Ruth L. Kirschstein National Research Service Awards. (P.L. 107-206)

October 26, 2002 – The Medical Device User Fee and Modernization Act of 2002 amends Section 215 of the Public Health Service Act to authorize the Director of NIH to conduct or support research to examine the long-term health implications of gel and saline-filled breast implants. This authorization includes studies to 1) develop and examine techniques to measure concentrations of silicone in body fluids and tissues, and 2) track silicone breast implant recipients. Within 6 months of enactment, the Director of NIH is required to submit a report to Congress describing the status of research on breast implants being conducted or supported by the Agency. (P.L. 107-250)

October 26, 2002 – The Health Care Safety Net Amendments, repeals the requirement for the Health Resources and Services Administration loan repayment program (LRP) reporting requirements, which also repeals the National Institutes of Health LRP reporting requirements, which were mandated under the National Health Service (NHS) authorities. Specifically, this repeals Section 338B(i) of the Public Health Service Act, which required an annual report to Congress on the NHS Corps Loan Repayment Program. (P.L. 107-251)

November 2, 2002 – The 21st Century Department of Justice Appropriations Authorization Act contains a provision that amends Section 464N of the Public Health Service Act addressing drug abuse and addiction research. The law provides that the Director of NIDA may make grants or enter into cooperative agreements to expand the current and ongoing interdisciplinary research and clinical trials with treatment centers of the National Drug Abuse Treatment Clinical Trials Network that relate to drug abuse and addiction, including related biomedical, behavioral, and social issues. The law mandates that the Director of NIDA shall promptly disseminate research results to Federal, State, and local entities involved in combating drug abuse and addiction. The law also requires NIDA to conduct a study of methamphetamine treatment. (P.L. 107-273)

November 6, 2002 – The Rare Diseases Act provides statutory authorization for the existing NIH Office of Rare Diseases (ORD). The measure requires the Director of the Office of Rare Diseases to recommend an agenda for research on rare diseases, promote coordination and cooperation among NIH Institutes and Centers, promote sufficient allocation of NIH resources related to rare diseases, promote the establishment of a centralized rare diseases information clearinghouse, prepare a biennial report of rare disease research activities and opportunities, prepare the annual report of the Director of NIH to Congress on rare disease research, and serve as the principal advisor on orphan diseases to the Director of NIH. In addition, the legislation establishes regional Centers of Excellence on Rare Diseases. (P.L. 107-280)

November 25, 2002 – The Homeland Security Act of 2002 establishes a new Executive Branch agency known as the U.S. Department of Homeland Security (DHS). Among its research provisions, the Act: 1) establishes within DHS a Directorate of Science and Technology, to conduct basic and applied research, development, demonstration, testing, and evaluation activities that are relevant to any or all elements of DHS with the exception of human health-related research and development activities; 2) requires the Secretary of HHS to set priorities, goals, objectives, and policies and to

develop a coordinated strategy for these activities in collaboration with the Secretary of Homeland Security; and 3) authorizes the Secretary of Homeland Security to draw upon the expertise of any Federally-supported laboratory, and to establish a headquarters laboratory and additional laboratory units for the Department at any laboratory or site. The Act also includes provisions regarding Federal agency information security protections; acquisitions and procurement improvements; permanent extension, revision, and expansion of authorities for use of voluntary separation incentive pay and voluntary early retirement; and other authorities relevant to human resources management. (P.L. 107-296)

December 18, 2002 – The Public Health Service Amendment on Diabetes amends Section 319 of the Public Health Service Act to renew funding for the special diabetes programs for Type 1 diabetes research, and also the parallel services program for diabetes in Native Americans, at \$150 million for each of the FYs 2004 through 2008. This measure provides additional funding separate from the regular appropriations process for the special diabetes programs for Type 1 diabetes research at NIH. (P.L. 107-360)

May 27, 2003 – The United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 has the following provisions: 1) requires the President to establish a comprehensive, integrated 5-year strategy to combat global HIV/AIDS, including specific objectives, approaches and strategies; 2) assigns priorities for relevant executive branch agencies; 3) improves coordination among such agencies; and 4) projects general levels of resources needed to achieve the stated goals. This legislation also requires the President to establish a position of HIV/AIDS Response Coordinator at the U.S. Department of State, who would have primary responsibility for oversight and coordination of all U.S. international activities to combat the HIV/AIDS pandemic. (P.L. 108-25)

August 15, 2003 – The Mosquito Abatement for Safety and Health Act authorizes grants through the Centers for Disease Control and Prevention for mosquito control programs to prevent mosquito-borne diseases. This legislation requires the Director of the National Institute of Environmental Health Sciences to conduct or support research on methods of controlling the population of insects and vermin that transmit dangerous, diseases to humans. (P.L. 108-75)

December 8, 2003 – The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 requires NIDDK to conduct a clinical investigation of pancreatic islet cell transplantation. (P.L. 108-173)

January 23, 2004 – The Omnibus Appropriations for FY 2004, contains the following two provisions: 1) provides flexible research authority for the NIH Director to enter into transactions (other than contracts, cooperative agreements, or grants) to carry out research in support of the NIH Roadmap Initiative of the Director on a pilot basis; and 2) designates the NIH Muscular Dystrophy Centers as the Senator Paul D. Wellstone Muscular Dystrophy Cooperative Research Centers. (P.L. 108-199)

July 21, 2004 – The Project Bioshield Act of 2004 authorizes NIAID to award grants or contracts to public and nonprofit private entities to expand, remodel, renovate, or alter existing research facilities or construct new research facilities. (P.L. 108-276)

August 2, 2004 – The Minor Use and Minor Species Animal Health Act of 2004 requires NIH to convene an ad hoc panel of nationally known experts in the fields of allergy and immunology to review current basic and clinical research activities related to food allergies. The panel is to make recommendations to the Secretary regarding the enhancement and coordination of food allergies research not later than 1 year after the date of enactment of the Act. (P.L. 108-282)

October 25, 2004 – The Pancreatic Islet Cell Transplantation Act of 2004 requires the Diabetes Mellitus Interagency Coordinating Committee to include in its annual report an assessment of the Federal activities and programs related to pancreatic islet cell transplantation, which shall address: 1) the adequacy of funding; 2) policies and regulations affecting the supply of pancreata; 3) the effect of xenotransplantation; 4) the effect of the United Network for Organ Sharing policies; 5) the

existing mechanisms to collect and coordinate outcome data from trials; 6) implementation of multi-agency clinical investigations; and 7) recommendations for legislation and administrative actions to increase the supply of pancreata. (P.L. 108-362)

For more information on legislation affecting NIH, go to <http://olpa.od.nih.gov/legislation/>.

This page was last reviewed on August 17, 2005 .

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National Institutes of Health (NIH)
9000 Rockville Pike
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The NIH Almanac – Historical Data

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NIH Director Elias A. Zerhouni, M.D.



NIH Director, Elias A. Zerhouni, M.D., leads the nation's medical research agency and oversees the NIH's 27 Institutes and Centers with more than 17,000 employees and a fiscal year 2004 budget of over \$28 billion. [Read Dr. Zerhouni's bio](#)

Chronology of NIH Directors

Name	In Office from	To
Joseph J. Kinyoun ¹	August 1887	April 30, 1899
Milton J. Rosenau	May 1, 1899	September 30, 1909
John F. Anderson	October 1, 1909	November 19, 1915
George W. McCoy ²	November 20, 1915 May 26, 1930	May 25, 1930 Jan. 31, 1937
Lewis R. Thompson	February 1, 1937	January 31, 1942
Rolla E. Dyer ³	February 1, 1942 June 16, 1948	June 15, 1948 September 30, 1950
William H. Sebrell, Jr.	October 1, 1950	July 31, 1955
James A. Shannon	August 1, 1955	August 31, 1968
Robert Q. Marston	September 1, 1968	January 21, 1973
Robert S. Stone	May 29, 1973	January 31, 1975
Donald S. Fredrickson	July 1, 1975	June 30, 1981
James B. Wyngaarden	April 29, 1982	July 31, 1989
Bernadine Healy	April 9, 1991	June 30, 1993
Harold E. Varmus	November 23, 1993	December 31, 1999
Elias A. Zerhouni	May 2, 2002	Present

¹ Director, Hygienic Laboratory.

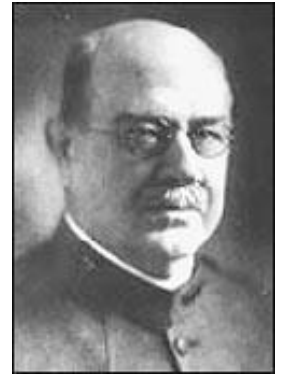
² Director, National Institute of Health.

³ Director, National Institutes of Health.

Biographical Sketches

Joseph James Kinyoun, M.D.

Founder and director of the Hygienic Laboratory, Dr. Joseph J. Kinyoun introduced scientific research into the Marine Hospital Service. His interest in bacteriology and his isolation of the cholera organism laid the groundwork for the present health research program of NIH.



Dr. Kinyoun received his M.D. degree from New York University in 1882 and did postgraduate work in Europe under the German bacteriologist, Robert Koch.

Dr. Kinyoun joined the Marine Hospital Service in 1886. In a one-room laboratory on Staten Island, N.Y., he applied new techniques he had learned in Europe, enabling him to isolate the organism that causes cholera. The Hygienic Laboratory was established in August 1887 and Dr. Kinyoun served as its director until April 30, 1899.

During his government career, Dr. Kinyoun designed the Kinyoun-Francis sterilizer, a shipboard disinfecting apparatus. In 1903 he retired from public service and, after working in private industry and as a professor at the George Washington University, he became a bacteriologist in the District of Columbia Health Department.

Milton Joseph Rosenau, M.D.

As second director of the Hygienic Laboratory, Dr. Milton J. Rosenau was responsible for expanding its scope of investigations.



After receiving his M.D. from the University of Pennsylvania, he did postgraduate work in Europe in the field of sanitation and public health.

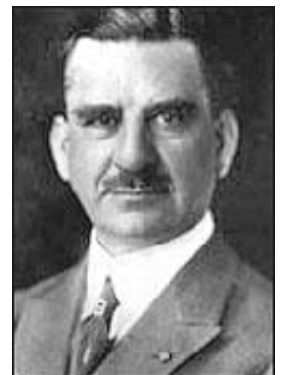
In 1890 he received his commission in the Marine Hospital Service. He became director of the Hygienic Laboratory on May 1, 1899.

A pioneer in the study of anaphylaxis, he also conducted research on yellow fever, malaria, typhoid fever, poliomyelitis, disinfectants, and the pasteurization of milk. His *Preventive Medicine and Hygiene* is a standard text for students of public health.

On September 30, 1909, Dr. Rosenau resigned from government service to join the staff of Harvard Medical School. In 1936 he went to the University of North Carolina where he served as director of the Public Health School.

John F. Anderson, M.D.

Dr. John F. Anderson, third director of the Hygienic Laboratory, was among the early scientists who made the Laboratory well-known in scientific circles.



After receiving his M.D. degree at the University of Virginia, he went abroad to study bacteriology. Upon returning in 1898, he joined the Marine Hospital Service and on October 1, 1909, succeeded Dr. Rosenau as director of the Hygienic Laboratory.

Throughout his career in the service, he was actively engaged in research. He studied serum and vaccine therapy, immunology, cholera, typhus, poliomyelitis, and public health and sanitation problems. He worked with Dr. Rosenau on hyper-susceptibility, anaphylaxis, and tuberculosis, and with Dr. Joseph Goldberger on the transmission of measles to monkeys, providing science with an experimental animal for that disease.

Dr. Anderson served as director of the Hygienic Laboratory until November 19, 1915, when he resigned to become director of the Research and Biological Laboratories and later vice president of E. R. Squibb & Sons.

George Walter McCoy, M.D.

Dr. George W. McCoy was, during his lifetime, the Nation's greatest authority on leprosy. For his many contributions to public health, he won the Sedgwick Memorial Medal of the American Public Health Association in 1921.



He entered the Marine Hospital Service in 1900 after graduating from the University of Pennsylvania Medical School.

During his first assignment at the Marine hospital in San Francisco, he became interested in leprosy. While heading the U.S. Plague Laboratory in San Francisco from 1908 to 1911, he discovered that the California ground squirrel was responsible for the spread of the organism causing tularemia.

On November 20, 1915, he became fourth director of the Hygienic Laboratory, renamed "National Institute of Health" in 1930. During this period he conducted important studies in influenza, poliomyelitis, smallpox, tularemia, amoebic dysentery, and pneumonia. Dr. McCoy served as director until January 31, 1937.

After conducting a nationwide survey on leprosy, Dr. McCoy retired from PHS on June 30, 1938, and joined the staff of Louisiana State University in New Orleans.

Lewis Ryers Thompson, M.D.

Dr. Lewis R. Thompson was intensely interested in research on industrial health problems and on problems of stream pollution.



He joined PHS in 1910, having graduated from Louisville Medical College. After becoming chief of the Division of Scientific Research in 1930, he administered field investigations of stream pollution, malaria, cancer, nutritional diseases, child hygiene, milk, dental problems, and industrial hygiene. When the division was merged with NIH, Dr. Thompson became director on February 1, 1937.

Dr. Thompson was largely responsible for securing the present-day site of NIH and for securing appropriations for the construction of the first six buildings. He served as director until January 31, 1942, and after retiring from PHS in 1947 became a scientific director of the international health division of the Rockefeller Foundation.

Rolla Eugene Dyer, M.D.

Dr. Rolla E. Dyer's major research contributions were in the field of infectious diseases; in particular, endemic typhus. He demonstrated how endemic typhus is spread and helped develop a vaccine to protect against the disease.



Dr. Dyer received his M.D. from the University of Texas and joined PHS in 1916.

His first assignment involved fieldwork on bubonic plague in New Orleans.

Five years later he joined the staff of the Hygienic Laboratory, became chief of the Division of Infectious Diseases in 1936, and director of NIH in 1942.

As director, Dr. Dyer organized the Division of Research Grants, assisted in planning the Clinical Center, and helped establish three new institutes: the National Heart Institute, the National Institute of Dental Research, and the National Institute of Mental Health.

After retiring from active duty on September 30, 1950, Dr. Dyer served as a member of the scientific board of directors of the international health division of the Rockefeller Foundation.

William Henry Sebrell, Jr., M.D.

A leading international authority on nutrition, Dr. William H. Sebrell first recognized and described the dietary deficiency disease, ariboflavinosis, and made significant contributions to knowledge of dietary needs and deficiencies.

Dr. Sebrell received his M.D. degree from the University of Virginia and joined PHS in 1926.

He began his research career under Dr. Joseph Goldberger who demonstrated that pellagra is a deficiency disease. During the 1930's, Dr. Sebrell made many important contributions to our knowledge of the anemias and the role of diet in cirrhosis of the liver.

During World War II, Dr. Sebrell was codirector of the National Nutrition Program which coordinated activities of all state agencies working in the field of nutrition. This program aided food production and the maintenance of civilian health during the war years.

In 1948 he became director of the Experimental Biology and Medicine Institute, and on October 1, 1950, was appointed director of NIH. He held this post until his retirement on July 31, 1955.

Dr. Sebrell helped formulate the first international standards of nutrition for the League of Nations, and pioneered the growing acceptance of scientific nutrition as a regular function of modern state and local health departments.

James A. Shannon, M.D.

Dr. James A. Shannon, widely recognized in the scientific world for his original research in kidney function, chemotherapy, and malaria, has throughout his career, been devoted to medical research, teaching, and public service.

He received his M.D. in 1929 and a Ph.D. in physiology in 1935 from New York University.

Following his internship at Bellevue Hospital in New York, Dr. Shannon taught in the department of physiology at New York University College of Medicine from 1931 to 1941, and directed research at the university's Goldwater Memorial Hospital from 1940 to 1945.

During periods of leave, he served as guest investigator at the physiological laboratory, University of Cambridge, England, and as a member of the staff of the Marine Biological Laboratory at Woods Hole, Mass.



During World War II, Dr. Shannon played a prominent part in malaria research activities of the National Research Council and was consultant on tropical diseases to the secretary of war. In recognition of this work, he received the Presidential Medal for Merit, the highest award at that time for civilian service in government.

Before joining PHS in 1949, he was director of the Squibb Institute for Medical Research (1946-49), and special consultant to the PHS Surgeon General.

Dr. Shannon then served as associate director in charge of research in the National Heart Institute until 1952. After holding the post of associate director, NIH, for 3 years, he became its director on August 1, 1955.

Among his many honors were the Public Welfare Medal of the National Academy of Sciences for "eminence in the application of science to the public welfare" (1962), the Rockefeller Public Service Award for Science, Technology, or Engineering (1964), and the Presidential Distinguished Federal Civilian Service Award (1966).

On retiring as NIH director (August 31, 1968), Dr. Shannon joined the NAS as special advisor to the president. In February 1970 he became professor and special assistant to the president, Rockefeller University. He retired from those positions in 1975.

Robert Q. Marston, M.D.

Dr. Robert Quarles Marston became director of NIH on September 1, 1968, after serving for 5 months as administrator of the Health Services and Mental Health Administration.

He received his B.S. degree in 1943 from the Virginia Military Institute, and his M.D. from the Medical College of Virginia in 1947. As a Rhodes scholar, he worked for the next 2 years with Nobel prizewinner Howard Florey at Oxford University, Oxford, England, earning a B.Sc. from that institution in 1949.



After an internship at Johns Hopkins Hospital and a year's residency at Vanderbilt University Hospital in Nashville, Tenn., he was stationed at NIH from 1951 to 1953 as a member of the Armed Forces Special Weapons Project, conducting research on the role of infection after whole body irradiation. He completed his residency at the Medical College of Virginia in Richmond the following year.

While a Markle fellow, he served as assistant professor of medicine at the Medical College of Virginia from 1954 to 1957, and as assistant professor of bacteriology and immunology at the University of Minnesota in Minneapolis for 1 year. He returned to the Medical College of Virginia in 1959 as associate professor of medicine and assistant dean in charge of student affairs.

In 1961, Dr. Marston became director of the University of Mississippi Medical Center and dean of the School of Medicine in Jackson, Miss., and was appointed vice chancellor there in 1965.

He became an associate director of NIH and director of the newly created Division of Regional Medical Programs on February 1, 1966.

On April 1, 1968, Dr. Marston was named administrator of the Health Services and Mental Health Administration, under a departmental reorganization.

He became acting director of the National Institute of Neurological Diseases and Stroke on January 21, 1973. He left the Federal service in April 1973 to become a scholar-in-residence at the University of Virginia. He also was named the first distinguished fellow of the Institute of Medicine, NAS.

On January 11, 1974, Dr. Marston was named president of the University of Florida at Gainesville, a position he held until 1984, after which he sat on the governing board of Virginia Military Institute while continuing his work with graduate students at the University. He retired in the late 1980's.

Robert S. Stone, M.D.

Dr. Robert S. Stone, former vice president for health services and dean of the school of medicine at the University of New Mexico, became director of NIH on May 29, 1973.



He received his B.A. in 1942 from Brooklyn College and his M.D. from the State University of New York College of Medicine in 1950. Dr. Stone was an instructor in pathology at Columbia University College of Physicians and Surgeons from 1950 to 1952.

Following his 1950-1952 internship and assistant residency in pathology at New York's Presbyterian Hospital, Dr. Stone moved to Los Angeles and joined the faculty of UCLA's School of Medicine, department of pathology.

From 1957 to 1959 as part of his academic duties he was deputy coroner at Los Angeles County, and for several years was pathologist for the Los Angeles Shriners Hospital for Crippled Children.

While on sabbatical as a visiting scientist at the Rockefeller Institute in 1959, he was credited with demonstrating by electron microscopy that the Shope papilloma virus of rabbits could be found in mature skin cells, but was undetectable, although presumed present, in younger growing cells.

Based on his observation of autopsies of atomic bomb victims in Hiroshima, Japan, Dr. Stone was one of the first researchers to suggest that radiation exposure increases the incidence of certain known diseases rather than creating new types. He served as chief of research in pathology for the Atomic Bomb Casualty Commission from 1959 to 1960.

He contributed to the concept of developing a method control population to study the normal incidence of various diseases for comparison, as was subsequently done.

It was as a result of this work and his continuing interest that he was appointed to the NAS Advisory Committee on the Atomic Bomb Casualty Commission.

Dr. Stone joined the University of New Mexico School of Medicine as chairman of the department of pathology in 1963, and became dean of the school in 1968. Prior to his appointment as NIH director, he took a year's leave from the university and was a visiting professor at the Sloan School of Management, MIT.

He became dean of the School of Medicine of the University of Oregon Health Sciences Center and vice president of the Health Sciences Center in August 1975. In August of 1978, he was appointed dean of the College of Medicine at Texas A & M University in August of 1978.

Donald S. Fredrickson, M.D.

Dr. Donald S. Fredrickson, internationally known authority on lipid metabolism and its disorders, became NIH director on July 1, 1975. Immediately prior to this appointment, he had served for 1 year (1974-1975) as president of the Institute of Medicine, NAS.



His association with NIH, however, spanned more than two decades beginning in 1953 when he joined the scientific staff of the then National Heart Institute (renamed the National Heart, Lung, and Blood Institute in 1976) as a clinical associate.

During his research career in the Federal service, Dr. Fredrickson held numerous positions at NIH, several in the heart institute simultaneously. From 1955 to 1961 he was a member of the Laboratory of Cellular Physiology and Metabolism. He then served as clinical director (1961-1966), while continuing his research as head of the section of molecular diseases, Laboratory of Metabolism (1962-1966). He was appointed institute director in 1966, serving in that capacity until 1968. He combined this executive responsibility with research as chief of the Molecular Diseases Branch (1966-1974), and as director of intramural research (1969-1974).

His earliest research interests centered on the metabolism of sterols. Later he focused on the structure of the plasma lipoproteins, their importance in the transport of fats, and the genetic factors regulating their metabolism and concentration in blood. It was during this period that he discovered two new genetic disorders: Tangier disease (absence of high density lipoproteins) and cholesteryl ester storage disease, a lysosomal enzyme deficiency.

In 1965 he and his coworkers introduced a system for identifying and classifying blood-lipid abnormalities on the basis of plasma lipoprotein patterns. From this work came recognition of new monogenic causes of hyperlipidemia: type 3 and type 5 hyperlipoproteinemia and what is called familial hypertriglyceridemia. The system received prompt acceptance by the WHO and is now used widely by laboratories around the world.

Research findings of Dr. Fredrickson and colleagues have also included the discovery of several previously unknown apolipo-proteins, and new knowledge including descriptions concerning the structure and function of various apoproteins.

He received both his B.S. (1946) and M.D. (1949) from the University of Michigan, and was certified by the American Board of Internal Medicine in 1957. He did postgraduate work at Peter Bent Brigham and Massachusetts General Hospitals and the Harvard Medical School prior to coming to NIH in 1953.

Dr. Fredrickson was a member of numerous professional societies in addition to the NAS and the American Academy of Arts and Sciences.

He resigned as NIH director on June 30, 1981 and returned to the NAS as a visiting scholar. In 1983 he joined the Howard Hughes Medical Institute (HHMI) as vice president, and became president and CEO in 1984. In 1987 he left HHMI and became a scholar at the National Library of Medicine.

James B. Wyngaarden, M.D.

Dr. James B. Wyngaarden, an internationally recognized authority on the regulation of purine biosynthesis and the genetics of gout, and a nationally respected advisor on various aspects of the administration of biomedical research, became the 12th director on April 30, 1982. Immediately prior to his appointment, he was professor and chairman of the department of medicine at Duke University School of Medicine, a position he had held since 1967.



He has had a long association with the NIH. From 1953 to 1954, he was a research associate in the Laboratory of Chemical Pharmacology of the then National Heart Institute, and from 1954 to 1956, he was a clinical associate at the then National Institute of Arthritis and Metabolic Diseases. After leaving in 1956 to become associate professor at the Duke University School of Medicine, he continued an association with NIH. He has held grants from several NIH components.

Dr. Wyngaarden has been active on various NIH study groups, evaluation committees, and review panels over the years, including a term with the board of scientific counselors of the then NIAMD (1971-1974). He also served as a consultant to the NIH as a member of study sections (1958-1960; 1967-1969).

He has also served as advisor to the broader scientific community as a member of the National Academy of Sciences since 1974, and was active from 1975 to 1982 on an NAS committee set up to study the Nation's overall need for biomedical and behavioral researchers; consultant for the President's Office of Science and Technology (1966-1972), a member of the President's Science Advisory Committee (1972-1973), and a member of the U.S. Atomic Energy Commission's Advisory Committee on Biology and Medicine.

Dr. Wyngaarden is the coauthor of *Cecil Textbook of Medicine*. In collaboration with former NIH director, Dr. Fredrickson, and others, he edited *The Metabolic Basis of Inherited Disease*. The original work was published in 1960.

He attended Calvin College there, and Western Michigan University in 1943-1944. In 1948 he graduated first in his class from the University of Michigan Medical School.

Dr. Wyngaarden trained in internal medicine at the Massachusetts General Hospital and did postdoctoral work at the Public Health Research Institute of the City of New York, under the direction of Dr. DeWitt Stetten, Jr., former NIGMS director. After serving as research associate at NIH from 1953 to 1956, he went to Duke and in 1959 became director of the medical research training program there as well as associate professor of medicine and biochemistry. In 1961 he became professor of medicine and associate professor of biochemistry.

In 1963 and 1964, he was a visiting scientist at the Institute de Biologie-Physiocochemie in Paris. Shortly after his return to this country, he left Duke to become professor and chairman of the department of medicine and professor of biochemistry at the University of Pennsylvania. He returned to Duke in 1967.

Dr. Wyngaarden has received many honorary degrees: University of Michigan (D.Sc., 1980), Medical College of Ohio (D.Sc., 1984), University of Illinois at Chicago (D.Sc., 1985), George Washington University (D.Sc., 1986), and Tel Aviv University (Ph.D., 1987).

He is a diplomate of the American Board of Internal Medicine. He has served on editorial boards of numerous professional publications.

Dr. Wyngaarden is a member of a number of professional societies including the NAS Institute of Medicine, the American Academy of Arts and Sciences, the American Society for Clinical

Investigation, and is a past president of the Association of American Physicians. He is a fellow of the Royal College of Physicians of London and was elected to the Royal Academy of Sciences of Sweden in 1987.

Bernadine Healy, M.D.

Dr. Bernadine Healy became NIH director in April 1991. Shortly after her appointment, she launched the NIH Women's Health Initiative, a \$500 million effort to study the causes, prevention, and cures of diseases that affect women. She also established the Shannon Award, grants designed to foster creative, innovative approaches in biomedical research and keep talented scientists in a competitive system.



Prior to her appointment, she was chairman of the Research Institute of the Cleveland Clinic Foundation, where she directed the research programs of nine departments including efforts in cardiovascular disease, neurobiology, immunology, cancer, artificial organs, and molecular biology. From her appointment in November 1985, she also served as a staff member of the clinic's department of cardiology.

In February 1984, Dr. Healy became deputy director of the Office of Science and Technology Policy at the White House. Her appointment, made by President Reagan and confirmed by the Senate in June of 1984, involved her heavily in life science and regulatory issues at the Federal level. She served as chairman of the White House Cabinet Working Group on Biotechnology, was executive secretary of the White House Science Council's Panel on the Health of Universities, and served as member of several advisory groups, including the councils of the NHLBI, NCI, as well as the White House Working Group on Health Policy and Economics. From June 1976 until February 1984, she was professor of medicine at Johns Hopkins University School of Medicine and Hospital, where she also had clinical responsibilities, directed a program in cardiovascular research, and was director of the coronary care unit. In addition to serving on the medical school faculty, she assumed the role of assistant dean for postdoctoral programs and faculty development.

Among her other professional affiliations, Dr. Healy has served on the board of governors of the American College of Cardiology and has been president of the American Federation of Clinical Research (1983-84) and was chairman of its public policy committee for several years. She was president of the American Heart Association in 1988-1989 and has served as a member of its board of directors since 1983. As AHA president, she initiated a women's minority leadership task force and a women and heart disease program that took hold in affiliates nationwide.

She is a member of the Institute of Medicine of NAS. In 1989 she was elected as a member of the board of overseers of Harvard College and has served on the board of trustees of Vassar College. She has also been chairman of the Ohio Council on Research and Economic Development, and served on several other advisory committees and boards, including the Ohio Board of Regents.

Dr. Healy has been active in several Federal advisory groups. Until her NIH appointment, she was a member of the advisory committee to the NIH director. She has been a member of the White House Science Council and chairman of the advisory panel for new developments in biotechnology of the Office of Technology Assessment of the U.S. Congress and a member of the NASA Life Sciences Strategic Planning Study Committee. In 1990 she was appointed to the President's Council of Advisers on Science and Technology (PCAST) and served as its vice chairman. She also chaired the advisory panel for basic research for the 1990s of the Office of Technology Assessment, and served on the special medical advisory committee of the Department of Veterans Affairs.

She received her bachelor's degree from Vassar College in 1965, and her M.D., cum laude, from Harvard Medical School in June 1970. She completed training in internal medicine and cardiology at Johns Hopkins School of Medicine.

Dr. Healy has written extensively in the areas of cardiovascular research and medicine, and has served on the editorial boards of numerous scientific journals.

She stepped down as director of NIH on June 30, 1993, to return to the Cleveland Clinic in Ohio. Dr. Healy was dean of the Ohio State University Medical School and President and Chief Executive Officer of the American Red Cross.

Harold E. Varmus, M.D.

Dr. Harold E. Varmus became 14th director of NIH on November 23, 1993. Winner of the Nobel Prize in 1989 for his work in cancer research, he came to NIH from the University of California, San Francisco. He is a leader in the study of cancer-causing genes called "oncogenes," and an internationally recognized authority on retroviruses, the viruses that cause AIDS and many cancers in animals.



Prior to his appointment, he was professor of microbiology, biochemistry, and biophysics, and the American Cancer Society professor of molecular virology at UCSF. He has been working at the cutting edge of modern cell and molecular biology, and has had an active relationship with NIH for about 30 years as an intramural scientist, grantee, and public advisor.

Dr. Varmus and his UCSF colleague Dr. J. Michael Bishop shared the 1989 Nobel in Physiology or Medicine for demonstrating that cancer genes (oncogenes) can arise from normal cellular genes, called proto-oncogenes. While investigating a retroviral gene, v-src, responsible for causing tumors in chickens, they discovered a nonviral src gene, very similar to v-src, present in the normal cells of birds and mammals.

In recent years his work has assumed special relevance to AIDS, through a focus on biochemical properties of HIV, and to breast cancer, through investigation of mammary tumors in mice. His research activities included grants from NCI, NIAID, NIGMS, American Cancer Society, and the Melanie Bronfman Award for Breast Cancer.

Dr. Varmus has served as chairman of the board of biology for the National Research Council, an advisor to the Congressional Caucus for Biomedical Research, a member of the joint steering committee for Public Policy of Biomedical Societies, and cochairman of the New Delegation for Biomedical Research, a coalition of leaders in the biomedical community. He directed "Winding Your Way Through DNA," a popular public symposium on recombinant DNA staged by UCSF.

Author or editor of four books and nearly 300 scientific papers, he has been elected to the Institute of Medicine, the National Academy of Sciences, and the American Academy of Arts and Sciences. His most recent book, *Genes and the Biology of Cancer*, intended for a general audience, was coauthored with Robert Weinberg for the Scientific American Library. He has edited several professional journals, and served on a variety of review and advisory boards for government, biotechnology firms, and pharmaceutical companies.

Dr. Varmus was a member of the IOM committee that advised the Department of Defense on the use of \$210 million allocated by Congress in 1992 for breast cancer research. In 1986 he chaired the subcommittee of the International Committee on the Taxonomy of Viruses that gave the AIDS virus its name, HIV.

He attended public schools in Freeport, Long Island; his father practiced family medicine and his mother was a psychiatric social worker. He is a graduate of Amherst College (B.A., 1961), where he majored in English literature and edited the school newspaper; Harvard University (M.A., 1962); and Columbia University (M.D., 1966). While in medical school, he worked for 3 months at a mission hospital in northern India.

After an internship and residency in internal medicine at Columbia-Presbyterian Hospital in New York, he served as a clinical associate for 2 years (1968-70) at the National Institute of Arthritis and Metabolic Diseases, where he did his first scientific work in the area of bacterial genetics with Dr. Ira Pastan, who is now chief of NCI's Laboratory of Molecular Biology. He came to UCSF as a postdoctoral fellow in Bishop's laboratory in 1970, initiating a long-standing collaboration to study tumor viruses, and was appointed to the faculty later that year.

He became a full professor in 1979 and an ACS research professor in 1984. Dr. Varmus left NIH in December 1999 to become the President and Chief Executive Officer of the Memorial Sloan-Kettering Cancer Center.

Elias A. Zerhouni, M.D.

NIH Director, Elias A. Zerhouni, M.D., leads the nation's medical research agency and oversees the NIH's 27 Institutes and Centers with more than 17,000 employees and a fiscal year 2004 budget of over \$28 billion. [Read Dr. Zerhouni's full biosketch](#)



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Biographical Sketch of Dr. Elias A. Zerhouni



NIH Director, Elias A. Zerhouni, M.D., leads the nation's medical research agency and oversees the NIH's 27 Institutes and Centers with more than 17,000 employees and a fiscal year 2004 budget of \$28 billion.

The NIH investigates the causes, treatments, and preventive strategies for both common and rare diseases helping to lead the way toward important medical discoveries that improve people's health and save lives. More than 80% of the NIH's funding is awarded through almost 50,000 competitive grants to more than 212,000 researchers at over 3,000 universities, medical schools, and other research institutions in every state and around the world. About 10% of the NIH's budget supports projects conducted by nearly 6,000 scientists in its own laboratories, most of which are on the NIH campus in Bethesda, MD.

Dr. Zerhouni, a well-respected leader in the field of radiology and medicine, has spent his career providing clinical, scientific, and administrative leadership. Since being named by President George W. Bush to serve as the 15th Director of the National Institutes of Health, beginning in May 2002, Dr. Zerhouni has:

Overseen the completion of the doubling of the NIH budget

The National Institutes of Health supports a thriving medical research enterprise. With the historic doubling of the NIH budget from 1998 to 2003, a record number of research grants are being awarded to scientists around the country, more young scientists are receiving training than ever before, and clinical trials — patient studies of new approaches to prevent, diagnose, and treat diseases — are receiving unprecedented support.

Initiated the NIH Roadmap for Medical Research

Launched in September 2003, the NIH Roadmap for Medical Research, a new research vision to accelerate medical discovery to improve health, focuses the attention of the biomedical research community on new pathways of discovery, research teams for the future and the re-engineering of the clinical research enterprise. It aims to accelerate the pace of discovery and speed the application of new knowledge to the development of new prevention strategies, new diagnostics and new treatments, and, ultimately, to the transfer these innovations to health care providers, and the public.

Established an NIH-wide research initiative to address the obesity epidemic

The Strategic Plan for NIH Obesity Research is a multi-dimensional research agenda that addresses one of the nation's most dramatic health challenges. In the U.S. population, recent figures show that 65 percent of adults — or 130 million people are overweight or obese. The strategic plan enhances both the development of new research in areas of greatest scientific opportunity and the coordination of obesity research across the NIH. The plan calls for interdisciplinary research teams to bridge the study of behavioral and environmental causes of obesity with the study of genetic and biologic causes.

Supported the NIH Neuroscience Blueprint

Mental illness, neurological disorders and a range of behavioral disorders are major causes of human suffering and contribute greatly to the burden of disease. These illnesses exact a cost of \$500 billion each year. NIH Directors from 17 Institutes and Centers have developed a model of strategic leadership to address several of the most

common causes of death and disability, as well as rare disorders that affect the brain, spinal cord, or nerve cells throughout the body. The blueprint leverages the abilities of the Institutes and Centers to create new resources, tackle common scientific problems, and train the next generation of neuroscientists through collaboration and leadership.

Supported the reduction of health disparities and barriers to opportunity for minority individuals

"Broadening the collaborative relationships developed through partnerships between NIH and institutions and researchers from all populations," is the focus of Dr. Zerhouni's commitment to eliminating health disparities and disparities in the burden of disease. In 2004, NIH announced the awarding of \$65.1 million to support the advancement of health disparities research. This was the most recent in a series of commitments of funds to this research. NIH has made 71 awards under the Centers of Excellence program.

Ensured public access to NIH-funded research results

February 3, 2005, Dr. Zerhouni announced an historic public access policy. For the first time, the public will have access to peer-reviewed research publications that resulted from studies funded by NIH. Dr. Zerhouni has urged maximum participation by investigators, encouraging scientists to submit their publications as soon as possible and within twelve months of publication to the archive.

Committed to earn the public's trust

Dr. Zerhouni continues to seek advice from the public through the Council of Public Representatives (COPR), a recent public trust workshop, and, more locally, through community liaison efforts. He is committed as well to producing the most scientifically-accurate, useful and accessible health information through public health campaigns, fact sheets, over the Web and through a full complement of outreach efforts with special attention to cultural competence designed to keep the public informed.

Enhanced the leadership of NIH

Since becoming the NIH Director, Dr. Zerhouni named a new NIH Deputy Director (Raynard S. Kington, M.D., Ph.D.) and directors for seven institutes and a center: National Institute of Mental Health (Thomas R. Insel, M.D.), National Institute on Alcohol Abuse and Alcoholism (Ting-Kai Li, M.D.), National Institute on Drug Abuse (Nora D. Volkow, M.D.), National Institute of Neurological Disorders and Stroke (Story C. Landis, Ph.D.), National Institute of General Medical Sciences (Jeremy M. Berg, Ph.D.), National Institute of Environmental Health Sciences and the National Toxicology Program (David A. Schwartz, M.D.), National Heart, Lung, and Blood Institute (Elizabeth G. Nabel, M.D.) and Center for Scientific Review (Antonio Scarpa, M.D., Ph.D.).

Prior to joining the NIH, Dr. Zerhouni served as executive vice-dean of Johns Hopkins University School of Medicine, chair of the Russell H. Morgan department of radiology and radiological science, and Martin Donner professor of radiology, and professor of biomedical engineering. Before that, he was vice dean for research at Johns Hopkins.

Dr. Zerhouni was born in Nedroma, Algeria and came to the United States at age 24, having earned his medical degree at the University of Algiers School of Medicine in 1975. After completing his residency in diagnostic radiology at Johns Hopkins in 1978 as chief resident, he served as assistant professor in 1979 and associate professor in 1985. Between 1981 and 1985 he was in the department of radiology at Eastern Virginia Medical School and its affiliated DePaul Hospital. In 1988, Dr. Zerhouni returned to Johns Hopkins where he was appointed director of the MRI division, and then was appointed full professor in 1992 becoming the chairman of the radiology department in January 1996.

Since 2000, he has been a member of the National Academy of Sciences' Institute of Medicine. He served on the National Cancer Institute's Board of Scientific Advisors from 1998-2002. In 1988, he was a consultant to the World Health Organization, and in 1985 he was a consultant to the White House under President Ronald Reagan.

A resident of Baltimore, he has won several awards for his research including a Gold Medal from the American

Roentgen Ray Society for CT research and two Paul Lauterbur Awards for MRI research. His research in imaging led to advances in Computerized Axial Tomography (CAT scanning) and Magnetic Resonance Imaging (MRI) that resulted in 157 peer reviewed publications and 8 patents.

Dr. Zerhouni received the honorary title Doctor Emeritus of the University of Algiers in 2005.

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The NIH Almanac – Historical Data

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Deputy Directors

[Raynard S. Kington](#), Deputy Director, NIH

[Michael Gottesman](#), Deputy Director for Intramural Research

[Norka Ruiz Bravo](#), Deputy Director for Extramural Research

[Colleen Barros](#), Deputy Director for Management

Chronology of Deputy Directors

Name	In Office from	To
C. J. Van Slyke	December 3, 1958	December 1, 1959
David E. Price	July 1, 1960	June 30, 1962
Stuart M. Sessoms	August 1, 1962	July 31, 1968
G. Burroughs Mider ¹	July 1, 1960	May 19, 1968
John. F. Sherman	November 1, 1968	March 16, 1974
Robert W. Berliner ²	February 23, 1969	September 1, 1973
Carl M. Leventhal ^{1,2}	September 1973	February 1974
DeWitt Stetten, Jr. ²	March 17, 1974	September 11, 1979
Ronald W. Lamont-Havers	August 4, 1974	September 25, 1976
Thomas E. Malone	March 24, 1977	Aug. 1, 1986
Robert Goldberger ²	September 11, 1979	June 26, 1981
Joseph E. Rall ³	July 2, 1981	June 6, 1982
Philip S. Chen, Jr. ³	June 7, 1982	March 18, 1983
William F. Raub ⁴	April 3, 1983	November 1991
Joseph E. Rall ⁵	June 1983	May 13, 1991
Katherine Bick ⁴	May 19, 1987	March 1990
John Diggs ⁴	August 1990	June 14, 1993
Lance Liotta ⁵	July 6, 1992	August 1993
Jay Moskowitz ⁶	March 1993	October 1993
John D. Mahoney	March 21, 1993	February 19, 1995
Ruth L. Kirschstein	November 1993	February 8, 2003
Michael Gottesman ⁵	November 1993	Present
Wendy Baldwin ⁴	February 1994	December 2002

Anthony Itteilag	January 7, 1996	October 2001
Yvonne Maddox (Acting)	January 1, 2000	May 18, 2002
Charles E. Leasure, Jr. ⁷	October 7, 2001	February 3, 2004
Raynard S. Kington	February 9, 2003	Present
Norka Ruiz Bravo	October 30, 2003	Present
Colleen Barros ⁸	May 30, 2004	Present

¹ Held title "Director of Laboratories and Clinics."

² For Science.

³ For Science, Acting.

⁴ For Extramural Research.

⁵ For Intramural Research.

⁶ Named by NIH director as NIH principal deputy director and NIH deputy director for Science Policy and Technology Transfer.

⁷ For Management.

⁸ Deputy Director for Management and Chief Financial Officer.

Biographical Sketches

Cassius James Van Slyke, M.D.

Dr. Van Slyke, first deputy director of NIH, served in that position from December 3, 1958, until his retirement on December 1, 1959. He received his M.D. in 1928 from the University of Minnesota and entered the PHS reserve corps that same year.

In 1932 he was commissioned in the regular corps and from 1936 to 1944 pursued a distinguished research career at the PHS Venereal Disease Research Laboratory in Staten Island, N.Y. In 1944, he was made assistant chief, Venereal Disease Division, Washington, D.C.

Dr. Van Slyke joined NIH in 1946 as chief of the newly established Research Grants Office, later renamed the Division of Research Grants, serving there until he was named director of the National Heart Institute (NHI) on August 1, 1948. He left NHI on November 30, 1952, to serve as associate director of NIH, a post he held until he was named NIH deputy director.

David E. Price, M.D.

Dr. Price earned his medical degree at the University of California School of Medicine at Berkeley in 1940, and served his internship at the PHS Hospital in San Francisco. In 1946, he received his doctorate in public health at Johns Hopkins University School of Hygiene and Public Health.

Following a tour of duty in the Venereal Disease Division, PHS, he was assigned first to the DRG as assistant to the chief (1946-47) and then to the NCI as chief of the Research Grants Branch (1947-48). He returned to DRG in 1948 as chief, a post he held until he was named NIH associate director for extramural affairs (1950-52).

After a series of key appointments in the Office of the Surgeon General, the Bureau of Medical Services and the Bureau of State Services, Dr. Price was named deputy director of NIH on July 1, 1960. Two years later, he was appointed deputy surgeon general, PHS.

He retired from the service in 1965. After his retirement, he was associated with the Ford Foundation and the American Public Health Association.

Dr. Price was director of planning of the medical institutions, the Johns Hopkins Medical Institution,

Baltimore, MD, until his retirement on July 1, 1980.

Stuart M. Sessoms, M.D.

Dr. Sessoms came to NIH in 1953 as a member of the NCI staff. From 1955 to 1957 he was assistant director of the Clinical Center. He was appointed assistant director, NCI, on January 1, 1958, prior to his appointment in November 1958 as chief of NCI's Cancer Chemotherapy National Service Center.

During this period, Dr. Sessoms also served as NCI associate director (1960), and associate director for collaborative research (1961) with responsibility for the institute's Virology Research Resources Branch, in addition to his duties at the Cancer Chemotherapy National Service Center.

He became the third NIH deputy director on August 1, 1962, serving in that capacity until his retirement July 31, 1968. On retirement, he held the rank of assistant surgeon general (rear admiral) in the PHS.

During his career at NIH, Dr. Sessoms was the recipient of two Meritorious Service Awards for his accomplishments as head of the Cancer Chemotherapy National Service Center, and for "outstanding ability and achievements in the development, operation and staffing" of the Regional Medical Programs.

He received his B.S. in pharmacy at the University of North Carolina in 1943 and his M.D. from the Medical College of Virginia in 1946.

On retiring after 25 years of government service, Dr. Sessoms joined Duke University.

On Jan. 1, 1976, he was named president of Blue Cross and Blue Shield of North Carolina.

G. Burroughs Mider, M.D.

Dr. Mider, whose career at NIH reaches back to 1939, is well-known on the campus. Just prior to transferring to the National Library of Medicine, an NIH component, in 1968, Dr. Mider had served for 8 years as NIH director of laboratories and clinics (1960-68), in which he functioned as deputy director as well.

He first came to NIH as a research fellow, NCI, in 1939. On completing the fellowship, he became an instructor in pathology and assistant professor of pathology (1941-44) at Cornell Medical College. Concurrently, he was an assistant pathologist at New York Hospital.

Then came assignments as associate professor of pathology, University of Virginia School of Medicine (1944-45) and research associate in surgery and professor of cancer research, University of Rochester School of Medicine and Dentistry (1945-52).

On returning to NIH in 1952, he became NCI associate director in charge of research. In 1960 he was appointed NIH director of laboratories and clinics. In May 1968, Dr. Mider transferred to the NLM as special assistant to the director for medical program development and evaluation. The following year he was named acting deputy director, and in 1970 became NLM deputy director.

In 1960, he was the recipient of a DHEW Distinguished Service Award. Dr. Mider retired from the Library on June 30, 1972, to become executive officer for the Universities Associated for Research and Education in Pathology, Inc., and the American Society of Experimental Pathology.

John F. Sherman, Ph.D.

Dr. Sherman was appointed deputy director of NIH on November 1, 1968, after a long career in research and research grants administration. He was designated by HEW Secretary Richardson as acting director of NIH on January 21, 1973, and served until a new director was appointed on May 29, 1973. He then returned to the position of deputy director.

He came to NIH in January 1953 as a research pharmacologist in the Laboratory of Tropical Diseases, National Microbiological Institute, which became the NIAID in 1955.

In July 1956, Dr. Sherman joined the staff of the NIAMD as assistant to the chief of extramural programs. He became assistant chief of the institute's extramural programs in August 1957, and deputy chief in October 1958.

On July 1, 1961, he was appointed associate director for extramural programs, NINDB. He rejoined the NIAMD in 1962 as associate director for extramural programs, serving in that capacity until January 1, 1964, when he was named NIH associate director for extramural programs.

Dr. Sherman received his B.S. in 1949 from Union University College of Pharmacy in Albany, N.Y., and his Ph.D. in pharmacology in 1953 from Yale University.

He is the author of numerous scientific papers and articles in his field of research. In 1971, he received a DHEW Distinguished Service Award.

Dr. Sherman left NIH in 1974 to become vice president of the Association of American Medical Colleges and director of the association's department of planning and policy development.

Robert W. Berliner, M.D.

Dr. Berliner, the first NIH deputy director for science, is an internationally renowned renal physiologist whose research in the field has contributed to understanding of the control of the excretion of sodium and potassium salts.

For 12 years (1950-62), he was chief of the Laboratory of Kidney and Electrolyte Metabolism, NHI, and from 1954 to 1968 served as the institute's director of intramural research.

In 1968, he was appointed director of laboratories and clinics, NIH. He was named to the newly created post of deputy director for science in 1969.

Prior to joining NIH in 1950, Dr. Berliner was assistant professor of medicine at Columbia University, and research associate with the New York City department of hospitals.

He received his B.S. from Yale University and his M.D. from Columbia University in 1939. He served his internship and residency at the Presbyterian Hospital and Goldwater Memorial Hospital, respectively, both in New York.

He was elected to the National Academy of Sciences in 1968. Other honors include the PHS Distinguished Service Award (1962), the Homer W. Smith Award (1965), the Modern Medicine Award for Distinguished Achievement (1969), and the American Heart Association's Research Achievement Award (1970).

Dr. Berliner left NIH to accept appointment as dean of the Yale University Medical School in September 1973.

DeWitt Stetten, Jr., M.D., Ph.D.

Dr. Stetten, an eminent medical educator and researcher in metabolic diseases, was named NIH

deputy director for science on March 17, 1974.

He received his A.B. degree from Harvard College in 1930, and his M.D. and Ph.D. from Columbia University in 1934 and 1940, respectively. From 1934 to 1937, he took his internship and residency at Bellevue Hospital in New York. Dr. Stetten then joined the staff at Columbia University for 9 years, serving successively as assistant instructor and assistant professor of biochemistry. In 1947, he was appointed assistant professor in biological chemistry at the Harvard Medical School. From 1948 to 1954, he was chief of the division of nutrition and physiology for the Public Health Research Institute of New York City.

Dr. Stetten first came to NIH in 1954 as director of the intramural research program of the National Institute of Arthritis and Metabolic Diseases. In that capacity, he directed institute programs on basic and clinical research in diabetes, vitamin deficiencies, and disorders of the blood, bone, and liver. He left NIH in 1962 to become the first dean of the Rutgers Medical School, a position he held until his return to NIH on October 1, 1970, as director of the National Institute of General Medical Sciences.

The American Diabetes Association awarded Dr. Stetten the Banting Medal in 1957. In 1963, he delivered the 22nd annual NIH Lecture on the "History and Natural History of Gout."

Among his many honors were the DHEW Superior Service Honor Award (1973) and the DHEW Distinguished Service Award (1977). He also received honorary D.Sc. degrees from Washington University (1974), and from the College of Medicine and Dentistry of New Jersey (1976).

Author of more than 100 original papers in his field of research, and coauthor of the early editions of the textbook, *Principles of Biochemistry*, Dr. Stetten served on the editorial boards of numerous scientific and medical journals. He was president of the Foundation for Advanced Education in the Sciences (1972-74), and was a member of the National Academy of Sciences and the NAS Council. He was president of the Society for Experimental Biology and Medicine, 1977-79.

Dr. Stetten was named senior scientific advisor to the NIH director in September 1979.

Ronald W. Lamont-Havers, M.D.

Dr. Lamont-Havers, internationally known rheumatologist, was appointed deputy director of NIH on August 4, 1974, after serving in an acting capacity since May 20.

Prior to this appointment, he had been deputy director of the National Institute of Arthritis, Metabolism, and Digestive Diseases (1972-74), and NIH associate director for extramural research and training for 4 years (1968-72).

He received his B.A. in 1942 from the University of British Columbia, Canada, and M.D. in 1946 from the University of Toronto. He took staff and residency training (1946-48) at the Vancouver General Hospital, and residency in internal medicine (1949-51) at the Queen Mary Veterans Hospital in Montreal. From 1951 to 1953, he was a fellow of the Canadian Arthritis and Rheumatism Society at Columbia Presbyterian Hospital, College of Physicians and Surgeons, Columbia University. He also received a diploma in internal medicine in 1953 from McGill University.

He came to NIH in 1964 as associate director for extramural programs, NIAMD. From 1955 to 1964 he was national medical director of the Arthritis Foundation and an instructor in medicine, College of Physicians and Surgeons, Columbia University. Previously, he served as medical director of the Canadian Arthritis and Rheumatism Society, British Columbia division, Vancouver, from 1953 to 1955, and as associate medical director, Student Health Service, University of British Columbia (1948-49).

Dr. Lamont-Havers, author or coauthor of numerous papers on arthritis and rheumatism, was

honored in June 1973 with a DHEW Superior Service Award.

He left NIH in September 1976 to become deputy for research policy and administration to the general director, Massachusetts General Hospital, Boston.

Thomas E. Malone, Ph.D.

Dr. Malone, whose career at the NIH began in 1962, was named the sixth deputy director of NIH in March 1977.

He earned his B.S. and M.S. degrees from North Carolina Central University in 1948 and 1949 respectively, and his Ph.D. from Harvard University in 1952. During the period 1950-52 he held a teaching fellowship at Harvard University.

Dr. Malone was professor of zoology at N.C. Central University in Durham from 1952 to 1958. He left that position to accept a postdoctoral fellowship of the NAS National Research Council, serving as a resident research associate at Argonne National Laboratory from 1958 to 1959. He subsequently served on the faculty at Loyola University in Chicago until joining the NIH staff in 1962.

He came to NIH as a member of the Grants Associates Program. After completing a year's training, he joined the staff of the National Institute of Dental Research in 1963, serving in several capacities - from 1963 to 1964 he was assistant chief of the research grants section; 1964 to 1966, deputy chief, extramural programs; and 1966 to 1967, chief, periodontal diseases and soft tissue studies, extramural programs.

In 1967 Dr. Malone accepted a position as professor and chairman of the department of biology at the American University of Beirut, Lebanon. He returned to NIDR in 1969, where he was associate director for extramural programs until 1972 when he was appointed NIH associate director for extramural research and training, a position which he held until his appointment as deputy director of NIH.

He is a member of the Institute of Medicine and of numerous other professional organizations in health research and administration.

In June of 1971 Dr. Malone received the DHEW Superior Service Award and was honored in April 1974 with the DHEW Distinguished Service Award. In October 1975 the American College of Dentists presented him with a Certificate of Merit. He received a Senior Executive Service Presidential Merit Award in 1980 and a Senior Executive Service Presidential Distinguished Executive Rank Award in 1983.

He served as a member of the U.S. Delegation to the 31st through 35th World Health Assemblies and has participated in numerous other international health activities.

Upon the resignation of Dr. Fredrickson, Dr. Malone was named acting NIH director until the appointment of Dr. Wyngaarden.

Robert Goldberger, M.D.

A highly regarded scientist in biomedical research, Dr. Goldberger became NIH deputy director for science in September 1979.

After receiving his A.B. degree from Harvard College in 1954, he attended the New York University Medical School, where he obtained an M.D. in 1958. He interned at Mt. Sinai Hospital in New York, and then spent 2 years as a post- doctoral fellow at the University of Wisconsin's Institute for

Enzyme Research. He came to the NIH as a research associate in the National Heart Institute in 1961, working with Dr. C. B. Anfinsen on the mechanism by which newly synthesized polypeptide chains attain three-dimensional structures characteristic of native proteins. In 1963 he was a visiting scientist at the Weizmann Institute of Science.

Dr. Goldberger served as a biochemist in the Laboratory of Chemical Biology, NIAMD, from 1963 to 1966, when he became chief of that laboratory's Biosynthesis and Control Section. He worked on regulation of gene expression in bacteria.

In 1973 he moved to the NCI's Division of Cancer Biology and Diagnosis, where, as chief of the cellular regulation section, he worked on hormonal regulation of gene expression in avian liver.

Dr. Goldberger has written one book on biochemistry and has edited a multivolume treatise on biological regulation. From 1970 to 1971 he served as president of NIH's Inter-Assembly Council of the Assemblies of Scientists. He received the Superior Service Award, DHEW, in 1973 and the Meritorious Service Medal, USPHS, in 1977.

At the end of June 1981, he left NIH to accept a dual position as provost of Columbia University and vice president for health sciences, and as a professor of chemistry.

William F. Raub, Ph.D.

Dr. Raub was appointed deputy director in August 1986. Since June 1983, he had served as deputy director for extramural research and training coordinating the development and implementation of policies affecting extramural programs.

Upon the resignation of Dr. Wyngaarden, July 31, 1989, Dr. Raub was named acting NIH director.

He was NIH associate director for extramural research and training previous to this appointment. He has served as associate director, National Eye Institute (1975-78), and chief, Biotechnology Resources Branch, Division of Research Resources (1969-75). He joined NIH in 1966.

Dr. Raub led the effort to develop the PROPHET system, a national computer resource for pharmacologists and others who study chemical/biological interactions. PROPHET is the most nearly comprehensive set of information-handling tools for this area of science ever to be presented in a unified system, and offered as a service to the biomedical community.

A graduate of Wilkes College in Wilkes-Barre, Pa., in 1961, he received his Ph.D. in 1965 from the University of Pennsylvania.

Joseph E. Rall, M.D., Ph.D.

Dr. Rall was appointed deputy director for intramural research in June 1983. He advised the NIH director on general scientific matters and intramural research policies and coordinated the intramural research program.

With NIH since 1955, he was director of the division of intramural research at the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases for more than 20 years.

Dr. Rall received his M.D. from Northwestern University School of Medicine (1945) and Ph.D. from the University of Minnesota (1952). He received honorary degrees from North Central College, (1966), the Free University of Brussels (1975), and the University of Naples (1985). He was elected to the NAS in 1980 and to the American Academy of Arts and Sciences in 1985. In 1988 he was invited to become a member of the scientific advisory committee for the International Human Frontier Science Program.

A member of many organizations and the coauthor of more than 160 scientific articles, his research involves thyroid hormones, iodine metabolism, and thyroid diseases.

In addition to the Van Meter Prize (1950) and the Robert Williams Distinguished Leadership Award of the Endocrine Society (1983), Dr. Rall has received the Arthur S. Flemming Award (1959), the DHHS Superior Service Award (1965), and the Distinguished Service Award (1968).

Katherine L. Bick, Ph.D.

Dr. Bick was named NIH deputy director for extramural research in April 1987. As a principal advisor to the NIH director, she coordinated the development and implementation of policies affecting NIH extramural programs.

She joined NIH in 1976 as a scientist administrator in the Neurological Disorders Program, NINCDS. In September 1983 she was appointed NINCDS deputy director, after serving in an acting capacity since February 1981. While in this position she received a PHS Special Achievement Award for sustained superior work performance.

Dr. Bick received her undergraduate degree from Acadia University, Nova Scotia, and earned her Ph.D. from Brown University. She has held academic positions at Georgetown University and California State University, Northridge, and research positions at the UCLA School of Medicine and the University of Western Ontario.

Among her many honors are the PHS Superior Service Award (1986), Senior Executive Service Bonus Award for Performance (1984-88), and the NIH Director's Award (1977). In 1989 she received a Presidential Senior Rank Award.

Dr. Bick left NIH in April 1990.

John W. Diggs, Ph.D.

Dr. Diggs was appointed NIH deputy director for extramural research on July 29, 1990. He had been director of the NIAID Division of Extramural Activities since 1982.

A biology major at Lane College in Jackson, Tenn., he earned his M.S. (1969) and Ph.D. (1972) in physiology from Howard University. His postdoctoral work included serving as a senior research physiologist at Walter Reed Army Institute of Research.

Dr. Diggs joined NINDS in 1974 as a health scientist administrator and received the institute's Special Achievement Award in 1979. He received the NIH Director's Award in 1985, the Presidential Meritorious Executive Rank Award in 1987, and the PHS Superior Service Award in 1990.

Included in his other honors are the Super Achiever in Science Award of Lane College National Alumni (1989), Merit Award of the District of Columbia General Hospital (1989), Outstanding Service Award of Montgomery County Department of Health (1989), Outstanding Service Award of Maryland Congress of Parents and Teachers, Inc. (1989), the Distinguished Senior Professional Award from the International Professional Management Association (1986), and Howard's Distinguished Alumni Award (1979).

He served the NIH until 1993.

Lance A. Liotta, Ph.D., M.D.

Dr. Liotta was named NIH deputy director for intramural research and training on July 6, 1992. He joined the Office of the Director after simultaneously serving since 1982 in three NCI Laboratory of

Pathology positions: chief, tumor invasion and metastases section; lab chief; and codirector, Anatomic Pathology Residency Program.

He earned his A.B. degree in general science and biology from Hiram College in Ohio, followed by his Ph.D. in biomedical engineering and biomathematics from Case Western Reserve University. In 1976 he earned his M.D. from Case Western and joined NIH as a PHS resident physician in the NCI Laboratory of Pathology.

Dr. Liotta has devoted his career to the study of cancer invasion and metastasis, the major cause of cancer treatment failure. He was one of the first scientists to investigate this process at the molecular level. In 1975 he proposed that tumor cell attachment and degradation of the basement membrane (a collagenous sheath that surrounds epithelial ducts, blood vessels and nerves, and separates tissue compartments) was crucial to invasion and metastasis.

He found that disruption of the basement membrane is the general hallmark of the transition from in situ to invasive cancer for all human epithelial cancers. He discovered metallo-proteinases produced by tumor cells that degrade the metastasis; TIMP-2 (Dr. William Stetler-Stevenson), a new protein that inhibits invasion and angiogenesis; laminin-binding proteins (Dr. Mark Sobel) that mediate tumor cell attachment; and autotaxin (Dr. Mary Stracke), a protein that profoundly stimulates motility.

Dr. Liotta's group also developed the first synthetic compound (CAI) (Dr. Elise Kohn) that blocks cancer metastasis growth by inhibiting selected signal transduction pathways. CAI has now entered clinical phase I trials under support from the Division of Cancer Treatment.

He is a member of the International Metastasis Research Society, American Association for Cancer Research, American Association of Pathologists, American Society of Cell Biology, American Society for Clinical Investigation, and the International Academy of Pathology.

Dr. Liotta has received numerous awards including three PHS Commissioned Corps Medals, the Arthur S. Flemming Award, the Warner Lambert/Parke Davis Award, the Josef Steiner Prize, and the Lil Gruber Research Award. He holds more than 30 patents for his work.

Jay Moskowitz, Ph.D.

Dr. Moskowitz was named by the NIH director as NIH principal deputy director and NIH deputy director for science policy and technology transfer in March 1993. He voluntarily resigned in October 1993.

In October 1993, Dr. Moskowitz became deputy director of the National Institute on Deafness and Other Communication Disorders (NIDCD) and acting director of NIDCD's Division of Intramural Research. He earlier served as founding and acting director of NIDCD, which was established in 1988.

Dr. Moskowitz joined NIH in 1969 as a postdoctoral pharmacology research associate with the National Institute of General Medical Sciences. In 1971 he became a grants associate with the Division of Research Grants.

From 1972 to 1986, Dr. Moskowitz held several administrative positions with the National Heart, Lung, and Blood Institute (NHLBI). As acting chief of the Special Programs and Resources Branch, NHLBI, he was responsible for planning and developing the Young Investigator Pulmonary Research Grant Program.

From 1986 to 1987, Dr. Moskowitz was NIH associate director for program planning and evaluation and executive director of the NIH Centennial Observance. From 1987 to 1993, Dr. Moskowitz was NIH associate director for science policy and legislation.

A graduate of Queens College, City University of New York, Dr. Moskowitz received his Ph.D. in 1969 from Brown University. He is the recipient of numerous honors and awards, including the NIH Director's Award in 1987, the PHS Superior Service Award in 1980, the Senior Executive Service Meritorious Executive Rank Award in 1989, and the DHHS Distinguished Service Award in 1991.

Dr. Moskowitz left NIH in 1995. He became senior associate dean (science and technology) and professor of public health sciences at the Wake Forest University School of Medicine in Winston-Salem, North Carolina, and in 2002 was appointed associate vice president for health sciences research and professor of health policy and administration and vice dean for research and professor of medicine at Penn State College of Medicine.

John D. Mahoney

Mr. Mahoney was named NIH deputy director for management on March 21, 1993. He became senior advisor to the NIH director on August 7, 1994.

Mr. Mahoney began his career in the U.S. Public Health Service in 1970 as a budget analyst for the National Institute of Mental Health. From 1972 to 1979, he held several positions in financial and budget management with the Alcohol, Drug Abuse and Mental Health Administration. From 1979 to 1984, he was chief of the Budget Branch in the Office of the Assistant Secretary for Health. In this position he was responsible for planning and coordinating budget estimates for programs of the agencies of the U.S. Public Health Service, including NIH.

From 1984 to 1986, Mr. Mahoney was director of the Office of Financial Management and Administrative Systems for the Health Care Financing Administration.

In 1986, Mr. Mahoney was named NIH associate director for administration, responsible for advising the NIH director on administrative matters and for developing and implementing administrative policies in support of NIH's research mission. He held that position until 1993. Mr. Mahoney was also acting deputy assistant secretary for health operations from 1990 to 1991.

Mr. Mahoney earned a B.A. and M.B.A. from the University of Maryland. He has received numerous awards including the Presidential Rank Award for Meritorious Service in 1990 and 1996; the General Services Administration, Excellence in Administration, Certificate of Merit in 1992; the Department's Distinguished Service Award and the PHS Special Achievement Award in 1990; the Secretary's Award for Exceptional Achievement in 1983; and the PHS Superior Service Award in 1982.

Mr. Mahoney became the deputy administrator, Health Resources and Services Administration, on February 19, 1995, and retired from federal service on December 31, 1996. Since that time he has been an independent consultant to various agencies of the Department of Health and Human Services and nonprofit organizations.

Ruth Kirschstein, M.D.

Dr. Ruth L. Kirschstein served as the NIH Deputy Director until February 8, 2003. She also served as NIH Deputy Director between November 1993 and December 1999. On January 1, 2002, Dr. Kirschstein was named Acting Director, NIH, and continued to serve in that role (technically called Principal Deputy Director) until May 20, 2002. She also served as Acting Director, NIH between July 1993 and November 1993.

Dr. Kirschstein received a B.A. degree magna cum laude in 1947 from Long Island University. She went on to earn her M.D. in 1951 from Tulane University School of Medicine in New Orleans, LA. She interned in medicine and surgery at Kings County Hospital, Brooklyn, and did residencies in pathology at Providence Hospital, Detroit; Tulane University School of Medicine; and the Warren G.

Magnuson Clinical Center, NIH.

From 1957 to 1972, Dr. Kirschstein performed research in experimental pathology at the Division of Biologics Standards (now the Center for Biologics Evaluation and Research, FDA). During that time, she helped develop and refine tests to assure the safety of viral vaccines for such diseases as polio, measles, and rubella. Her work on polio led to selection of the Sabin vaccine for public use. For her role, she received the DHEW Superior Service Award in 1971.

In 1972, Dr. Kirschstein became Assistant Director of the Division of Biologics Standards. That same year, when the division was transferred to the FDA as a bureau, she was appointed Deputy Director. She subsequently served as Deputy Associate Commissioner for Science, FDA.

In 1974, Dr. Kirschstein was named Director of the National Institute of General Medical Services, NIH. She held that position for over nineteen years. From September 1990 to September 1991, she also served as Acting Associate Director of the NIH for research on women's health.

Dr. Kirschstein has twice taken part in World Health Organization deliberations in Geneva, Switzerland, in 1965 as a member of the WHO Expert Group on International Requirements for Biological Substances, and in 1967 as a consultant on problems related to the use of live poliovirus oral vaccine.

Dr. Kirschstein has received many honors and awards, including the PHS Superior Service Award, 1978; the Presidential Meritorious Executive Rank Award, 1980; election to the Institute of Medicine, 1982; the Public Health Service Equal Opportunity Achievement Award, 1983; a doctor of science, honoris causa, degree from Mt. Sinai School of Medicine, 1984; the PHS Special Recognition Award, 1985; the Presidential Distinguished Executive Rank Award, 1985; the Distinguished Executive Service Award of the Senior Executive Association, 1985; an honorary doctor of laws degree from Atlanta University, 1985; an honorary doctor of science degree from the Medical College of Ohio, 1986; the Harvey Wiley FDA Commissioner's Special Citation, 1987; selection by the Office of Personnel Management as 1 of 10 outstanding executives and organizations for its first group of "Profiles in Excellence," 1989; the Dr. Nathan Davis Award from the AMA, 1990; an honorary doctor of humane letters from Long Island University in 1991; election as a fellow of the American Academy of Arts and Sciences, 1992; and the Public Service Award from the Federation of American Societies for Experimental Biology in 1993.

In 2000, Dr. Kirschstein received the Albert B. Sabin Heroes of Science Award from the Americans for Medical Progress Education Foundation. The following year, she received honorary degrees from Spelman College in Atlanta, GA, and from Georgetown University Medical School in Washington, DC. She was also recognized by the Anti-Defamation League, which bestowed her with their Women of Achievement Award.

Michael Gottesman, M.D.

A well-known and respected basic cancer researcher who has focused on multidrug resistance in human cells, Dr. Gottesman was appointed NIH deputy director for intramural research (DDIR) in November 1993. He had been acting DDIR for the previous year and was acting director of the National Center for Human Genome Research from 1992 to 1993. He continues as chief of NCI's Laboratory of Cell Biology.

He received his B.A. degree from Harvard College in 1966 and earned his M.D. degree at Harvard Medical School in 1970.

In 1971 Dr. Gottesman came to NIH as a research associate in the National Institute of Arthritis, Metabolism and Digestive Diseases (now NIDDK), where he worked for 3 years. He spent a year as an assistant professor at Harvard Medical School and, together with his wife, joined the permanent staff of NCI in 1976. He became chief of the molecular cell genetics section, Laboratory of Molecular

Biology, NCI, in 1980 and chief of the Laboratory of Cell Biology, NCI, in 1990.

At NIH, his research interests have ranged from how DNA is replicated in bacteria to how cancer cells elude chemotherapy. In the past several years — collaborating with Dr. Ira Pastan, chief of NCI's Laboratory of Molecular Biology, and others, he has identified the human gene responsible for resistance of cancer cells to many of the most common anticancer drugs and has shown that this gene encodes a protein which acts to pump anticancer drugs out of drug-resistant human cancers.

This evidence supports the proposal, now widely accepted, that gp170 is an energy-dependent pump, ferrying toxins or drugs out of the cell. For several years, Dr. Gottesman has been examining clinical applications of his gp170 findings using gene therapy, monoclonal antibodies, and reversing agents to fight MDR. Recently, his lab has extended studies of multidrug resistance in cancer to the 47 other known ABC transporters and to mechanisms of resistance to the anti-cancer drug cisplatin.

His research has earned him many awards, including the Milken Family Foundation Award for Cancer Research, 1990; C.E. Alken Prize, 1991; the Rosenthal Foundation Award, 1992, and the American Society for Pharmacology and Experimental Therapeutics (ASPET) award in 1997. He was elected a fellow in the American Association for the Advancement of Science in 1988 and was elected to the Institute of Medicine of the National Academies of Science in 2003. He received the Public Health Service Commendation, Outstanding Service and Distinguished Service awards, the NIH Director's award in 2002, and the DHHS Secretary's Award for Distinguished Service in 2005.

Dr. Gottesman is also a member of the American Association for Cancer Research, the American Society for Biochemistry and Molecular Biology, and the American Society for Cell Biology. He has served on several editorial boards including the *Journal of Cell Biology*; the *Journal of Biological Chemistry*; *Molecular Pharmacology*; *Molecular Biology of the Cell*; *Cancer Research*; and *Human Gene Therapy*.

He has also been involved in initiating several training and mentoring initiatives at NIH for high school, undergraduate, graduate, medical, post-baccalaureate and post-doctoral students.

As DDIR, he has created the NIH Academy (supporting post-baccalaureate students in the study of health disparities); the Graduate Partnerships Program (which permits graduate students to conduct thesis research at NIH); and loan repayment programs for biomedical researchers supported by NIH. He has institutionalized an intramural tenure-track, new fellows' training programs, the NIDB (providing online information about all researchers and research at NIH), and other career development programs to help prepare biomedical research leaders of tomorrow.

Wendy Baldwin, Ph.D.

Dr. Baldwin was appointed NIH deputy director for extramural research in February 1994, after serving in an acting capacity since June 1993. She was responsible for guiding the NIH institutes and centers in the development of policies for their extramural research and research training programs. She also managed – for NIH and PHS – programs aimed at protection of human subjects in research and the proper care and use of laboratory animals in scientific studies.

She has made significant scientific contributions, primarily in adolescent fertility, contraceptive practice, childbearing patterns, AIDS risk behaviors, and infant mortality. She has published widely and has served on many NIH panels and committees, including the panel on NIH research on antisocial, aggressive, and violence-related behaviors, as well as the NIH advisory committee on women's health issues.

Dr. Baldwin joined NIH in 1973 as a health scientist administrator with NICHD. In 1979 she became chief of NICHD's Demographic and Behavioral Sciences Branch in the Center for Population Research. She was named deputy director of NICHD in 1991, a post she held until her appointment as NIH deputy director for extramural research.

She earned her Ph.D. in demography in 1973 and her M.A. in 1970 from the University of Kentucky. She received her B.A. from Stetson University in 1967.

Among her professional activities, she served as a temporary advisor to the WHO task force for social science research on reproductive health, on a National Academy of Sciences panel on adolescent pregnancy, and on a scientific advisory committee for demographic and health sciences. She is a past member of several editorial boards.

Dr. Baldwin has received many professional awards from PHS, NIH, and outside organizations.

Anthony L. Itteilag

Mr. Itteilag was NIH deputy director for management and chief financial officer, NIH, from January 1996 to October 2001.

Mr. Itteilag began his Federal career as a management intern in the Navy Department in 1964. After positions at Navy and at ACTION, in 1975 he became Chief of the Budget Branch in the U.S. Public Health Service (PHS). In 1978 he became the Director of the Division of Budget Policy and Management for the Department of Health and Human Services (DHHS).

From 1980 to 1984, he was Deputy Assistant Secretary for Budget, DHHS, and from 1984 to 1990 he was Director of Budget at the Department of the Interior.

In 1991 Mr. Itteilag became the Deputy Assistant Secretary for Health (Management and Budget), PHS, DHHS. He held that position through 1995.

Mr. Itteilag has a B.A. (summa cum laude) from the University of Rhode Island. He is the recipient of numerous awards including the Clifford R. Gross Award for Federal Public Service, American Society for Public Administration, (Maryland Chapter) in 2001; the Presidential Rank Award (Distinguished Senior Executive) in 1983 and 1992 and (Meritorious Senior Executive) in 1982 and 1988; the Department of the Interior Distinguished Service Award in 1991; the HHS Distinguished Service Award in 1981, 1997 (group) and 2001 (group); and the Public Health Service Exemplary Service Award in 1976. In 1980 he was corecipient of the Secretary's Exceptional Achievement Award, HHS.

He also is a member of the American Society for Public Administration, the American Association for Budget and Program Analysis, the American Political Science Association, the Federal Executive Institute Alumni Association, and the Senior Executives Association.

Mr. Itteilag has been a Senior Advisor to the NIH Director since October 2001.

Yvonne Thompson Maddox, Ph.D. (Acting)

Dr. Yvonne Thompson Maddox was named Acting Deputy Director, NIH in January 2000 and continued to serve in that role until May 20, 2002. In this position, she guided the organizations and programs within the Office of the Director, NIH and was a chief advisor to the Acting Director, NIH. In addition, Dr. Maddox is the Deputy Director of the National Institute of Child Health and Human Development (NICHD), a position she has held since 1995.

Dr. Maddox received her B.S. in biology from Virginia Union University, Richmond and a Ph.D. in Physiology from Georgetown University. Following completion of the Ph.D., she served as a National Research Service Award (NRSA) Post Doctoral Fellow and as an Assistant Professor of Physiology in the Department of Physiology and Biophysics at Georgetown. She studied as a Visiting Scientist at the French Atomic Energy Commission, Saclay, France, and is a graduate of the Senior Managers in Government Program of the Kennedy School of Government, Harvard

University.

Dr. Maddox came to NIH in November 1985 as a health scientist administrator in the National Institute of General Medical Sciences (NIGMS), where she managed the Congressionally mandated clinical and basic research grants program in trauma and burn injury. Following her initial appointment, she served NIGMS in various capacities: Acting Director, Minority Access to Research Careers (MARC) Program; Chief, Pharmacology and Physiological Sciences Section; and Deputy Director, Biophysics and Physiological Sciences Program.

In January 1995, Dr. Maddox joined NICHD as its Deputy Director. At the NICHD, Dr. Maddox manages the institute's diverse extramural program that supports research on population issues, reproductive biology, contraception, pregnancy, child development, nutrition, developmental biology, AIDS, mental retardation, and medical rehabilitation.

During her career at NIH, Dr. Maddox has received numerous honors and awards, including the Presidential Meritorious Executive Rank Award, the Public Health Service Special Recognition Award and the NIH Director's Award. She is a member of the American Physiological Society and serves on several public service and academic boards, including the Center for Development and Population Activities Advisory Board and the Robert Wood Johnson Health Policy Fellowship Advisory Board.

Dr. Maddox is author or coauthor of a number of scientific articles, book chapters and conference proceedings, including the often-cited paper on a method she developed to extract peritoneal macrophages from peritoneal dialysate, "A routine clinical source of peritoneal macrophages and their release of prostaglandins *in vitro*," which was published in 1984. She has delivered more than 100 lectures.

Charles E. Leasure, Jr.

Mr. Leasure was named NIH deputy director for management on October 7, 2001. He also served as NIH's chief financial officer and was acting executive officer for the Office of the Director, NIH, from 2000 to 2004.

Mr. Leasure began his career at NIH in 1965 as an employee management relations specialist in the Office of the Director. From 1966 to 1974 he held various administrative positions with the National Cancer Institute.

In 1974, Mr. Leasure became the associate director for administration at the National Institute of Allergy and Infectious Diseases. In 1984, he was named associate director for management at the National Institute of Environmental Health Sciences. He left that position in 1998 to become the associate director for management at the National Human Genome Research Institute.

Mr. Leasure has served as chair of the Administrative Training Committee that oversees the Presidential Management Intern Program, and as a member of the NIH-wide Leadership Development Committee. He has mentored NIH employees in several programs, including the Management Cadre Program, the Presidential Management Intern Program, and the Leadership Development Program.

Mr. Leasure has a B.A. from Georgetown University. He is also the recipient of the NIH Director's Award in 1996 and 2000 for his "outstanding efforts to improve the quality of life for NIH employees." He received the Presidential Meritorious Rank Award in 1994.

Raynard S. Kington

Dr. Raynard S. Kington was appointed Deputy Director of the National Institutes of Health (NIH) as of February 9, 2003. The Deputy Director, NIH, functions as the Principal Deputy Director to the

Director, NIH; and shares in the overall leadership, policy direction, and coordination of NIH biomedical research and research training programs of NIH's 27 Institutes and Centers. Prior to this appointment, he had been Associate Director of NIH for Behavioral and Social Sciences Research since September, 2000. In addition to this role, from January, 2002 to November, 2002, he served as Acting Director of the National Institute on Alcohol Abuse and Alcoholism. Prior to coming to NIH, Dr. Kington was Director of the Division of Health Examination Statistics at the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC). As Division Director, he also served as Director of the National Health and Nutrition Examination Survey (NHANES), one of the nation's largest studies to assess the health of the American people. Prior to coming to NCHS, he was a Senior Scientist in the Health Program at the RAND Corporation. While at RAND, Dr. Kington was a Co-Director of the Drew/RAND Center on Health and Aging, a National Institute on Aging Exploratory Minority Aging Center.

Dr. Kington attended the University of Michigan, where he received his B.S. with distinction and his M.D. He subsequently completed his residency in Internal Medicine at Michael Reese Medical Center in Chicago. He was then appointed a Robert Wood Johnson Clinical Scholar at the University of Pennsylvania. While at the University of Pennsylvania, he completed his M.B.A. with distinction and his Ph.D. with a concentration in Health Policy and Economics at the Wharton School and was awarded a Fontaine Fellowship. He is board-certified in Internal Medicine and Public Health and Preventive Medicine.

Dr. Kington's research has focused on the role of social factors, especially socioeconomic status, as determinants of health. His current research includes studies of the health and socioeconomic status of black immigrants, differences in populations in willingness to participate in genetic research, and racial and ethnic differences in infectious disease rates. His research has included studies of the relationship between wealth and health status; the health status of U.S. Hispanic populations; the determinants of health care services utilization; the economic impact of health care expenditures among the elderly; and racial and ethnic differences in the use of long-term care.

Norka Ruiz Bravo

Norka Ruiz Bravo began her tenure as NIH Deputy Director for Extramural Research on November 16, 2003 after her appointment was announced by the Director of NIH on October 30, 2003. She oversees the National Institutes of Health (NIH) external grants and awards program — a portfolio totaling approximately 83% of the NIH budget — providing trans-NIH coordination and directing the development of policies, standards, guidelines and staff training for extramural research.

A biologist by training, Dr. Ruiz Bravo earned her Ph.D degree in 1983 from Yale University. Her postdoctoral tour included completion of an NSRA Fellowship that began at the Johns Hopkins University and ended at the University of Texas M.D. Anderson Cancer Research Center in the fields of biochemistry and molecular biology. She then held faculty positions at the M.D. Anderson Cancer Research Center and at Baylor College of Medicine.

In 1990, Dr. Ruiz Bravo joined the NIH as a scientific review administrator in the National Institute of General Medical Sciences (NIGMS) Office of Review Activities. During the years that followed, she actively pursued and was appointed to numerous special assignments. Some of these included: Acting Deputy Director, NIGMS Division of Minority Opportunities in Research; Special Assistant, NIGMS Office of Extramural Activities; and, scientific review administrator at the National Center for Human Genome Research. She was concurrently a program director in the Division of Genetics and Developmental Biology, where she managed an active portfolio of grants in the field of transcriptional mechanisms.

In early 1997, Dr. Ruiz Bravo transferred her scientific, managerial, and administrative expertise to the National Cancer Institute (NCI), where she served as Deputy Director and then Acting Director for the Division of Cancer Biology.

She returned to the NIGMS in late 1999, as Deputy Associate Director for Extramural Activities, and

in 2000, was appointed Associate Director for Extramural Activities. In this role, Dr. Ruiz Bravo oversaw the \$1.7 billion (FY2003) NIGMS budget for research, and research training grant programs supporting basic biomedicine. She was a principal advisor to the NIGMS Director, providing counsel for strategic planning, development and management of Institute grant activities.

Involved in leadership activities trans-NIH, Dr. Ruiz Bravo currently chairs the Extramural Program Management Committee, co-chairs the Extramural Activities Working Group, and is a member of the Information Technology Working Group. The Working Groups are subcommittees of the NIH Director's Steering Committee, the NIH's governance body. Formerly, she participated in a variety of service committees, chaired the Office of Research Services Advisory Committee, was the chair and co-founder of the Extramural Information Systems Advisory Group at NCI and chaired the Staff Training in Extramural Programs Committee. In addition to her trans-NIH leadership activities, Dr. Ruiz Bravo co-chairs the National Science and Technology Council's (NSTC) Subcommittee on Research Business Models, a trans-agency group tasked with facilitating research by harmonizing policies and regulations across the government; and she is a former member of the NSTC's Working Group on Aligning Mechanisms with Scientific Opportunity. Dr. Ruiz Bravo is a member of the American Association for the Advancement of Science, the American Society for Cell Biology and the Society for Developmental Biology.

Colleen Barros

Ms. Barros received her M.A. in Public Administration from American University and has served in a variety of Federal administrative positions with special expertise in managing technical and scientific information systems and in R&D management. She began her career with NIH in 1979 as a Budget Analyst and served as Senior Administrative Officer in the NIH Office of the Director. In that position she was responsible for directing the efforts in establishing several new offices such as the Office of AIDS Research, the Office of Human Genome Research, the Office of Research on Minority Health and the Office of Alternative Medicine.

In 1995, Ms. Barros was selected as the Associate Director for Administration in the National Institute on Aging where she received several awards for her outstanding contributions toward improving the administrative operations of both the NIH and the NIA. In addition, she participated in several trans-NIH committees and projects including serving on the NIH Information Technology Central Committee responsible for advising the NIH Director on NIH information technology issues and as the NBRSS Project Leader responsible for the development and implementation of NIH's new business system.

In February of 2004, Ms. Barros joined the Office of the Director again as she took on the role of Acting Deputy Director for Management until May 30th when she was appointed Deputy Director for Management.

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Associate Directors

Vivian Pinn, Associate Director for Research on Women's Health
Diane Frasier, Acting Associate Director for Administration
Lana Skirboll, Associate Director for Science Policy
Marc Smolonsky, Associate Director for Legislative Policy and Analysis
Barnett Kramer, Associate Director for Disease Prevention
John Burklow, Associate Director for Communications
Andy Baldus, Acting Associate Director for Budget

Chronology of Associate Directors

Name	In Office from	To
Norman H. Topping	1948	1952
David E. Price	December 1, 1950	January 30, 1952
James A. Shannon	December 1, 1952	July 31, 1955
C.J. Van Slyke	December 1, 1952	December 2, 1958
Joseph E. Smadel	May 1, 1956	June 30, 1960
Kenneth M. Endicott	January 6, 1958	June 30, 1960
Jack Masur	July 1, 1960	March 8, 1969
Charles V. Kidd	September 13, 1960	December 9, 1964
Ernest M. Allen	August 10, 1960	January 8, 1963
Martin M. Cummings	July 11, 1963	January 1, 1964
John F. Sherman	January 1, 1964	October 31, 1968
Robert Q. Marston	February 1, 1966	March 31, 1968
Thomas J. Kennedy, Jr.	August 8, 1968	August 31, 1974
R.W. Lamont-Havers	November 3, 1968	October 1, 1972
Richard L. Seggel	January 4, 1969	November 28, 1971
Leonard D. Fenninger	November 10, 1969	May 4, 1973
Thomas C. Chalmers	February 9, 1970	October 20, 1973
Storm Whaley	July 1, 1970	February 3, 1992
Leon M. Schwartz	February 6, 1972	June 30, 1979
Thomas E. Malone	November 26, 1972	March 24, 1977
Leon Jacobs	July 30, 1972	July 3, 1978
Robert S. Gordon, Jr.	November 7, 1974	September 1, 1975
Joseph G. Perpich	February 15, 1976	December 12, 1981
Mortimer Lipsett	August 29, 1976	June 30, 1982
Seymour Perry	January 3, 1978	March 1980
William F. Raub	April 4, 1978	April 2, 1983
Charles U. Lowe (Acting)	January 3, 1980	July 9, 1982

Edwin D. Becker	March 1980	April 1988
Calvin Baldwin	August 1, 1980	January 31, 1986
Mark S. Beaubien (Acting)	July 1, 1982	January 18, 1984
Jay R. Shapiro (Acting)	July 1, 1982	July 1983
J. Richard Crout	July 12, 1982	April 16, 1984
Michael I. Goldberg	November 28, 1982	September 17, 1984
Philip S. Chen, Jr.	July 3, 1982	July 29, 1983
John L. Decker	August 1, 1983	June 1, 1990
Craig K. Wallace	January 19, 1984	February 8, 1991
George Galasso	February 5, 1984	January 2, 1996
Jay Moskowitz	January 1986	April 1993
John D. Mahoney	June 1986	April 1993
William T. Friedewald	November 1986	August 31, 1991
Itzhak Jacoby (Acting)	July 10, 1987	December 1999
Anthony S. Fauci	April 5, 1988	1994
Norman D. Mansfield	October 10, 1988	February 1992
John Ferguson (Acting)	September 1989	June 19, 1991
James D. Watson	October 1, 1989	April 10, 1992
Saul Rosen (Acting)	June 1990	June 1994
Ruth Kirschstein	September 1990	September 1991
William R. Harlan	June 30, 1991	April 30, 2001
Vivian Pinn	September 1991	Present
Stephen A. Ficca	February 1992	March 2004
R. Anne Thomas	April 14, 1996	April 21, 2002
William E. Paul	March 1994	November 21, 1997
Leamon Lee	July 10, 1994	January 2004
John Ruffin	August 26, 1990	January 9, 2001
Diane Wax	May 1995	October 1998
Norman Anderson	July 1995	March 2000
Lana Skirboll	August 1995	Present
Sue Quantius	September 1999	April 2002
Marc Smolonsky	July 1999	Present
Raynard Kington	October 2000	February 2003
Jack Whitescarver	October 20, 2000	Present
Barnett Kramer	May 6, 2001	Present
Donald Poppke	April 17, 2002	September 26, 2003
John Burklow	April 22, 2002	Present
Richard Turman	October 9, 2003	July 22, 2005
Andy Baldus (Acting)	July 23, 2005	Present

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Department of Health and Human Services*

Mike Leavitt, Secretary, HHS

Richard Carmona, Surgeon General of the Public Health Service

Chronology of HHS Secretaries

Name	In Office from	To
Oveta Culp Hobby	April 11, 1953	July 31, 1955
Marion B. Folsom	August 1, 1955	July 31, 1958
Arthur S. Flemming	August 1, 1958	January 1, 1961
Abraham A. Ribicoff	January 20, 1961	July 13, 1962
Anthony J. Celebrezze	July 31, 1962	August 17, 1965
John W. Gardner	August 18, 1965	February 29, 1968
Wilbur J. Cohen	May 9, 1968	January 19, 1969
Robert H. Finch	January 22, 1969	June 24, 1970
Elliot L. Richardson	June 24, 1970	January 29, 1973
Caspar W. Weinberger	February 12, 1973	August 10, 1975
David Mathews	August 8, 1975	January 20, 1977
Joseph A. Califano, Jr.	January 26, 1977	July 19, 1979
Patricia Roberts Harris	July 27, 1979	January 19, 1981
Richard S. Schweiker	January 22, 1981	February 3, 1983
Margaret M. Heckler	March 9, 1983	December 12, 1985
Otis R. Bowen	December 13, 1985	January 20, 1989
Louis Sullivan	March 1, 1989	January 1993
Donna Shalala	January 22, 1993	January 19, 2001
Tommy G. Thompson	February 2, 2001	January 25, 2005
Mike Leavitt	January 26, 2005	present

*Name changed from Department of Health, Education, and Welfare on May 14, 1980; separate Department of Education formed.

Chronology of Surgeons General of the Public Health Service

Name	In Office from	To
John Maynard Woodworth	April 1871	March 14, 1879 ¹
John B. Hamilton	April 3, 1879	May 31, 1891 ²
Walter Wyman	June 1, 1891	November 21, 1911 ³
Rupert Blue	January 13, 1912	March 1, 1920 ⁴

Hugh Smith Cumming	March 3, 1920	January 31, 1936 ⁵
Thomas Parran	April 6, 1936	April 5, 1948
Leonard A. Scheele	April 6, 1948	August 2, 1956
Leroy E. Burney	August 8, 1956	January 29, 1961
Luther L. Terry	March 24, 1961	October 1, 1965
William H. Stewart	October 2, 1965	August 1, 1969
Jessee L. Steinfeld	December 18, 1969	January 20, 1973
Julius B. Richmond	July 13, 1977	January 20, 1981
C. Everett Koop	November 16, 1981	October 1, 1988
Antonia Novello	March 9, 1989	June 30, 1993
Joycelyn Elders	September 7, 1993	1994
David Satcher	February 13, 1998	January 31, 2001
Richard Carmona	July 23, 2002	present

- 1 Served as supervising surgeon of the Marine Hospital Service until March 3, 1875, when his title was changed to supervising Surgeon General.
- 2 Surgeon General, Marine Hospital Service.
- 3 Surgeon General, Marine Hospital Service, and Surgeon General, Public Health and Marine Hospital Service (after July 1, 1902).
- 4 Surgeon General, Public Health and Marine Hospital Service, and Surgeon General, PHS (after August 14, 1912).
- 5 Surgeon General, PHS.

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NIH Office of the Director

The [Office of the Director](#) (OD) is responsible for setting policy for NIH and for planning, managing, and coordinating the programs and activities of all 27 of NIH's Institutes and Centers. The OD program offices include the [Office of AIDS Research](#) and the [Office of Research on Women's Health](#), among others.

NIH Institutes

- ▶ [National Cancer Institute \(NCI\)](#)
- ▶ [National Eye Institute \(NEI\)](#)
- ▶ [National Heart, Lung, and Blood Institute \(NHLBI\)](#)
- ▶ [National Human Genome Research Institute \(NHGRI\)](#)
- ▶ [National Institute on Aging \(NIA\)](#)
- ▶ [National Institute on Alcohol Abuse and Alcoholism \(NIAAA\)](#)
- ▶ [National Institute of Allergy and Infectious Diseases \(NIAID\)](#)
- ▶ [National Institute of Arthritis and Musculoskeletal and Skin Diseases \(NIAMS\)](#)
- ▶ [National Institute of Biomedical Imaging and Bioengineering \(NIBIB\)](#)
- ▶ [National Institute of Child Health and Human Development \(NICHD\)](#)
- ▶ [National Institute on Deafness and Other Communication Disorders \(NIDCD\)](#)
- ▶ [National Institute of Dental and Craniofacial Research \(NIDCR\)](#)
- ▶ [National Institute of Diabetes and Digestive and Kidney Diseases \(NIDDK\)](#)
- ▶ [National Institute on Drug Abuse \(NIDA\)](#)
- ▶ [National Institute of Environmental Health Sciences \(NIEHS\)](#)
- ▶ [National Institute of General Medical Sciences \(NIGMS\)](#)
- ▶ [National Institute of Mental Health \(NIMH\)](#)
- ▶ [National Institute of Neurological Disorders and Stroke \(NINDS\)](#)
- ▶ [National Institute of Nursing Research \(NINR\)](#)
- ▶ [National Library of Medicine \(NLM\)](#)

NIH Centers

- ▶ [Center for Information Technology \(CIT\)](#)

- ▶ [Center for Scientific Review \(CSR\)](#)
- ▶ [John E. Fogarty International Center \(FIC\)](#)
- ▶ [National Center for Complementary and Alternative Medicine \(NCCAM\)](#)
- ▶ [National Center on Minority Health and Health Disparities \(NCMHD\)](#)
- ▶ [National Center for Research Resources \(NCRR\)](#)
- ▶ [NIH Clinical Center \(CC\)](#)

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Office of the Director, NIH

The NIH is comprised of the Office of the Director and 27 Institutes and Centers. The Office of the Director is the central office at NIH. The OD is responsible for setting policy for NIH and for planning, managing, and coordinating the programs and activities of all the NIH components.

The NIH Director provides overall leadership to NIH activities in both scientific and administrative matters. Although each institute within the NIH has a separate mission, the NIH Director plays an active role in shaping the agency's research agenda and outlook. With a unique and critical perspective on the mission of the entire NIH, the Director is responsible for providing leadership to the institutes for identifying needs and opportunities, especially for efforts that involve several institutes. The NIH Director is assisted by the Principal Deputy Director, who shares in the overall direction of the agency's activities.

In carrying out these responsibilities, the NIH Director stays informed about program priorities and accomplishments through regular staff meetings, discussions, and briefing sessions with OD and institute staff. The Director also receives input from:

- the extramural scientific community, including both individual researchers and scientific organizations
- patient advocacy and voluntary health groups that deal directly with NIH or indirectly through Congress and the media
- the Congress, the Administration, and the Director's Council of Public Representatives, which brings public views to NIH.

Ongoing discussions with these groups and others provides the basis for an established framework within which priorities for the agency are identified, reviewed, and justified.

Program offices in the Office of the Director are responsible for stimulating specific areas of research throughout NIH and for planning and supporting research and related activities. Current program areas are: women's health, AIDS research, disease prevention, and behavioral and social sciences research. Program offices within the Office of the Director fund research through the institutes.

Staff Offices

The NIH Director is assisted by executive and administrative staff. The following describes the major staff offices in the Office of the Director:

Office of Extramural Research (OER)

On behalf of the NIH Director, the Office of Extramural Research provides guidance to institutes in research and training programs conducted through extramural (grant, contract, cooperative agreement) programs.

Office of Intramural Research (OIR)

On behalf of the NIH Director, the Office of Intramural Research coordinates research conducted directly by NIH personnel through intramural programs.

Office of Management (OM)

The Office of Management advises the NIH Director and staff on all phases of NIH-wide administration and management; provides leadership and direction to all aspects of management; and oversees the management of functions in the areas of budget and financial management, personnel management, management policy, management assessment, program integrity, contract, procurement, and logistics management, engineering services, safety, space and facility management, support services, and security operations.

Office of Administration (OA)

The Office of Administration advises the NIH Director and staff on administration and management; develops and implements policies; and provides oversight in the areas of information resources management, management assessment, grant administration and contract management, procurement, and logistics.

Office of AIDS Research (OAR)

The Office of AIDS Research formulates scientific policy for, and recommends allocation of research resources for AIDS research at NIH.

Office of Behavioral and Social Sciences Research (OBSSR)

The Office of Behavioral and Social Sciences Research advises the NIH Director and other key officials on matters relating to research on the role of human behaviors in the development of health, prevention of disease, and therapeutic intervention.

Office of Budget

The Office of Budget has primary responsibility for NIH-wide budget policy, planning, analysis, formulation and presentation; responsible for budget management once appropriations have been made including reprogramming and coordination of the use of the Director's Discretionary Fund and transfer authority; and provides budget advice to the Director, NIH and senior OD and IC officials.

Office of Communications and Public Liaison (OCPL)

The Office of Communications and Public Liaison advises the Director and communicates information about NIH policies, programs, and research results to the general public.

Office of Community Liaison (OCL)

The Office of Community Liaison advises the Director, plans, directs and oversees activities to promote collaboration between NIH and its community, and ensures effective communication on policy and programs involving the community.

Office of Disease Prevention (ODP)

The Office of Disease Prevention coordinates the activities of disease prevention, rare diseases, dietary supplements, and medical applications of research, and advises the NIH Director and senior staff on the following: research related to disease prevention, and promotion of disease prevention research; research related to dietary supplements and their role in disease prevention; research and activities related to rare diseases; and medical applications of research including drugs, procedures, devices and other technology developed from basic biomedical research at NIH. The Office also: Advises the Associate Director for Disease Prevention and provides guidance to the research institutes on research related to disease prevention; coordinates and facilitates the systematic identification of research activities pertinent to all aspects of disease prevention, including: identification of risk factors for disease; risk assessment, identification, and development of biologic, environmental, and behavioral interventions to prevent disease occurrence or progression of pre-symptomatic disease; and the conduct of field trials and demonstrations to assess interventions and encourage their adoption, if warranted; identifies, coordinates, and encourages fundamental research aimed at elucidating the chain of causation of acute and chronic diseases; coordinates and

facilitates clinically relevant NIH-sponsored research bearing on disease prevention, including interventions to prevent the progression of detectable but asymptomatic disease; promotes the coordinating linkage for research institutes on biobehavioral modification toward prevention of disease; coordinates with the Office of Medical Applications of Research to promote the effective transfer of identified safe and efficacious preventive interventions to the health care community and the public; works with the research institutes to initiate and develop RFAs, PAs, and RFPs to enhance disease prevention program development; and sponsors, singly or in combination with other organizations, workshops and conferences on disease prevention; provides a link between the disease prevention and health promotion activities of the research institutes of the NIH, the Surgeon General and Assistant Secretary for Health, and the Secretary, DHHS; monitors the effectiveness and progress of disease prevention and health promotion activities of the NIH; and reports expenditures and personnel involved in prevention activities at NIH.

Office of Education (OE)

The Office of Education provides a comprehensive guide to postdoctoral training opportunities available at the NIH.

Office of Equal Opportunity and Diversity Management (OEODM)

The Office of Equal Opportunity advises the Director and NIH staff on matters related to equal employment opportunity programs and policies.

Executive Office (ODEO)

The Executive Office serves in both a staff and operational capacity for all administrative support activities for the Office of the Director, excluding the Office of Research Services.

Office of Financial Management (OFM)

The Office of Financial Management advises the NIH Director and staff and provides leadership and direction for NIH financial management activities; develops policies and instructions for budget preparation and presentation; administers allocation of funds; and manages a system of fund and budgetary controls.

Office of Human Resources (OHR)

The Office of Human Resources advises the NIH Director and staff on human resource (HR) management; directs HR management services; provides NIH leadership and planning on HR program development, salary administration, corporate recruitment, and other functions; and conducts studies and makes recommendations to senior NIH management for new or redirected HR efforts, programs, and policies, as appropriate. .

Office of Research on Women's Health (ORWH)

The Office of Research on Women's Health (ORWH) serves as a focal point for women's health research at the NIH. The ORWH promotes, stimulates, and supports efforts to improve the health of women through biomedical and behavioral research. ORWH works in partnership with the NIH institutes and centers to ensure that women's health research is part of the scientific framework at NIH and throughout the scientific community.

Office of Research Facilities Development and Operations (ORF)

The mission of ORF is to support the advancement of NIH scientific and program priorities by building, managing, and maintaining state-of-the-science facilities critical to new and expanding research initiatives and the NIH mission. Research Facilities is the single point of accountability for all NIH facility activities. ORF is responsible for:

- Assisting the NIH Director with the formulation and execution of the buildings and facilities appropriation;
- Developing and maintaining policies and standards governing the use of real property;
- Planning and directing facility related services such as master planning and construction, renovation, maintenance and management of real property;
- Providing centralized acquisition services for architecture, engineering, and construction

- contracting and for real property purchasing and leasing activities;
- Protecting the NIH environment.

Additional information about Research Facilities is available at <http://orf.od.nih.gov/>.

Office of Research Services (ORS)

The Office of Research Services (ORS) provides a comprehensive portfolio of services to support the biomedical research mission of the NIH. Some examples of the diverse services ORS provides include: laboratory safety, police and fire departments, veterinary resources, the NIH Library, events management, travel and transportation, services for foreign scientists, and programs to enrich and enhance the NIH worksite.

Office of Portfolio Analysis and Strategic Initiatives (OPASI)

Supports regular trans-NIH scientific planning and initiatives and the successful and adaptive priority-setting process for identifying areas of scientific and health improvement opportunities.

Office of Science Policy (OSP)

The Office of Science Policy advises the NIH Director on science policy issues affecting the medical research community; participates in the development of new policy and program initiatives; monitors and coordinates agency planning and evaluation activities; plans and implements a comprehensive science education program; and develops and implements NIH policies and procedures for the safe conduct of recombinant DNA activities.

Office of Legislative Policy and Analysis (OLPA)

The Office of Legislative Policy and Analysis serves as the principal legislative policy, analysis and development office for the Director, NIH, and other senior NIH staff; develops legislative policy and proposals; and provides analysis and liaison with the Congress, the U.S. Department of Health and Human Services, and other Federal agencies on issues affecting NIH programs and activities.

NIH Ethics Office

The NIH Ethics Office provides oversight and strategic direction of NIH activities relating to ethics policy, oversight, and operational activities; develops and administers the NIH policies and procedures for implementing the Government-wide conflict of interest statutes and regulations, the HHS supplemental conflict of interest regulations, and HHS policies; implements a program for trans-NIH ethics oversight that includes information technology (IT) support systems, periodic reviews, audits, delegations of authority, training, and records management; determines real or potential conflicts of interest and assesses ethical considerations in scientific reporting, clinical trials, and scientific conferences and workshops; and serves as the liaison and coordinates the NIH response to requests from Congress, the Inspector General, HHS, and the Office of Government Ethics, and performs appropriate liaison activities.

Office of the Ombudsman/Center for Cooperative Resolution

The NIH Office of the Ombudsman, Center for Cooperative Resolution provides the NIH community with confidential and informal assistance in resolving work-related conflicts, disputes and grievances; promotes fair and equitable treatment within NIH; offers effective, efficient and innovative dispute resolution services; helps people use non-adversarial approaches in resolving disputes; and works toward improving the overall quality of worklife at NIH.

Office of Program Coordination

The Office of Program Coordination coordinates the Director's program and administrative decision-making process; facilitates communication among the Director, the NIH Deputy and Associate Directors, other senior OD staff and IC Directors; advises the Director, NIH on the status and implications of activities NIH-wide; brings the attention of the Director and recommends actions to resolve trans-NIH issues; directs the Executive Secretariat and the Office of Federal Advisory Committee Policy; and directs the operations of the immediate staff of the Director, NIH.

Office of Technology Transfer (OTT)

The Office of Technology Transfer has been designated as the lead Public Health Service (PHS) agency for technology transfer activities. The office is responsible for the central development and implementation of technology transfer policies and procedures for the three major research components of the PHS – the NIH, the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA).

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NIAID Responds to Hurricane Katrina

Information for researchers,
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OFFICE OF AIDS RESEARCH

The Office of AIDS Research is located within the
Office of the Director of NIH and is responsible
for the scientific, budgetary, legislative, and policy elements
of the NIH AIDS research program.

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OFFICE OF RESEARCH ON WOMEN'S HEALTH

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Department of Health and Human Services

Upcoming Events:

Women's Health Special Interest Group Meeting

Date: February 24, 2006

Time: 11:30 AM - 12:30 PM

Title: Disparity in X-Chromosome Gene Dosage and the Risk for Coronary Disease

Speaker: Carolyn A. Bondy, M.D.

Affiliation: National Institute of Child Health and Development

Location: Wilson Hall, Bldg. 1, Third Floor



[Flyer](#)

Women's Health Initiative Wrap Up Conference:

Title: The WHI Legacy to Future Generations of Women

Date: Feb. 28 - Mar. 1, 2006

Location: Bldg. 45, Bethesda, MD

Room: William H. Natcher Conference Center

[Conference website](#)

[Register today](#)

News Release

NIH/ORWH Announces New BIRCWH Awards to Promote Interdisciplinary Research Careers in Women's Health

[Press Release](#)

Features



[2006 NIH Research Priorities on Women's Health](#)



New Publication: [2003-2004 Office of Research on Women's Health and NIH Support for Research on Women's Health Issues](#)

New Publication: [New report- Beyond Women's Health: Incorporating Sex and Gender Differences Into the Public Health Curriculum](#)

WISHnet: Women in Science and Health Care Network

— Website designed to encourage and mentor girls and women who are interested in careers in science, research, and healthcare.

[New NIH Office of Extramural](#)



National
Institutes
of
Health

[Research Website on Sex and
Gender in the Biomedical Science
Workforce](#)

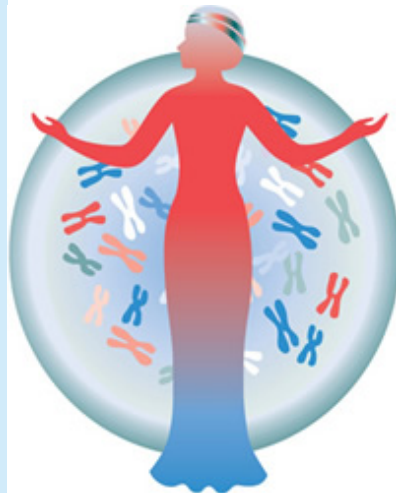
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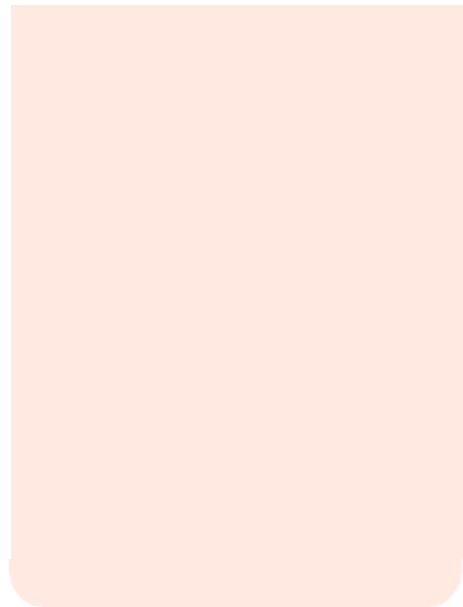
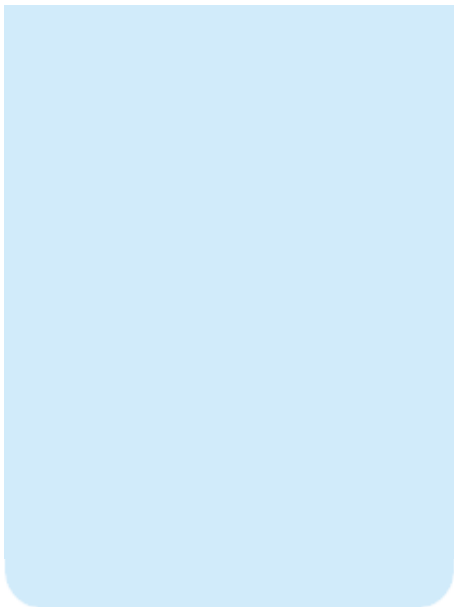
FirstGov

**Women's Health Research for the
21st Century: [2005 Seminar Series](#)**



Overview

- Established in 1990 within the Office of the Director at NIH
- Coordinates and serves as a focal point for women's health research funded by the NIH
- Promotes, stimulates, and supports efforts to improve the health of women through biomedical and behavioral research on the roles of sex (biological characteristics of being female or male) and gender (social influences based on sex) in health and disease
- Works in partnership with the NIH institutes and centers to ensure that women's health research is part of the scientific framework at NIH and throughout the scientific community



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National Cancer Institute

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Mission

The mission of the National Cancer Institute is to eliminate the suffering and death due to cancer. Under the leadership of Director Andrew C. von Eschenbach, M.D., NCI is committed to achieve this goal by the year 2015 through a process of *discovery, development, and delivery*.

Within this framework, NCI researchers work to more fully integrate discovery activities through interdisciplinary collaborations; accelerate development of interventions and new technology through translational research; and ensure the delivery of these interventions for application in the clinic and public health programs as state-of-the-art care for all those in need.

As the leader of the National Cancer Program, NCI provides vision and leadership to the global cancer community. NCI conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation, and the continuing care of cancer patients. Critical to the success of its programs are collaborations and partnerships that further NCI's success in serving cancer patients and those who care for them.

NCI supports a broad range of research to expand *scientific discovery* at the molecular and cellular level, within a cell's microenvironment, and in relation to human and environmental factors that influence cancer development and progression. Each year, almost 5,000 principal investigators lead research projects that result in better ways to combat cancer. Intramural research serves as a hub for new development through cutting edge basic, clinical, and epidemiological research. Extramural program experts provide guidance and oversight for research conducted at universities, teaching hospitals, and other organizations. Proposals are selected for funding by peer review, a rigorous process by which scientific experts evaluate new proposals and recommend the most scientifically meritorious for funding. In addition to direct research funding, NCI offers the Nation's cancer scientists a variety of useful research tools and services: tissue samples, statistics on cancer incidence and mortality, bioinformatic tools for analyzing data, databases of genetic information, and resources through NCI-supported Cancer Centers, Centers of Research Excellence, and the Mouse Models of Human Cancer Consortium.

NCI also uses collaborative platforms and an interdisciplinary environment to promote *translational research and intervention development*. Discovery of a new tool that first helps to understand the underlying mechanism of cancer may eventually be used to help diagnose it, and then may be further still developed to help treat it. For example, recent advances in bioinformatics and the related explosion of technology for genomics and proteomics research are dramatically accelerating the rate for processing large amounts of information for cancer screening and diagnosis. The largest collaborative research activity is the Clinical Trials Program for testing interventions for preventing cancer, diagnostic tools, and cancer treatments and access as early as possible to all who can benefit. NCI supports over 1,300 clinical trials a year, assisting more than 200,000 patients.

NCI research impacts the *delivery of improved cancer interventions to cancer patients and those who care for them*. Timely communication of NCI scientific findings help people make better health choices and advise physicians about treatment options that are more targeted and less invasive, resulting in fewer adverse side effects. NCI researchers are also seeking the causes of disparities among underserved groups and gaps in quality cancer care, helping to translate research results into better health for groups at high risk for cancer, including cancer survivors and the aging population. In addition, NCI is fostering partnerships with other agencies and organizations to accelerate the pace for moving targeted drugs through the pipeline of discovery, development, and delivery.

Information about the National Cancer Institute's research and activities is available through its new public Web site, <http://cancer.gov>.

Important Events in NCI History

August 5, 1937 – President Franklin D. Roosevelt signed the National Cancer Institute Act.

November 9, 1937 – The National Advisory Cancer Council held its first meeting.

November 27, 1937 – The Surgeon General awarded first grants-in-aid on the recommendation of the National Advisory Cancer Council.

January 3, 1938 – The National Advisory Cancer Council recommended approval of first awards for fellowships in cancer research.

August 1940 – The *Journal of the National Cancer Institute* published its first issue.

July 1, 1946 – The cancer control program was established with appropriations to the states for support of cancer control activities. Staff was organized into six sections: biology, biochemistry, biophysics, chemotherapy, epidemiology, and pathology.

July 1, 1947 – NCI reorganized to provide an expanded program of intramural cancer research, cancer research grants, and cancer control activities.

November 13, 1947 – The Research Grants and Fellowship Branch was established. It became the administrative arm of the Advisory Council.

October 1948 – A grants program to medical, dental, and osteopathic schools was initiated for improvement of training in the field of cancer research, diagnosis, and treatment.

July 2, 1953 – NCI inaugurated a full-scale clinical research program in the new Clinical Center.

April 1955 – The Cancer Chemotherapy National Service Center was established in the institute to coordinate the first national, voluntary, cooperative cancer chemotherapy program.

1957 – The first malignancy (choriocarcinoma) was cured with chemotherapy at NCI.

November 1959 – The *Journal of the National Cancer Institute* inaugurated a series of occasional publications as *Monographs* to be used for in-depth scientific communications in specific subject areas.

September 13, 1960 – The NCI director appointed an associate director for grants and training, associate director for field studies, and associate director for collaborative research.

January 12, 1961 – The Laboratory of Viral Oncology was established to investigate the relationship of viruses to human cancer.

April 2, 1962 – An exhibit, "Man Against Cancer," opened in Washington, D.C., to commemorate the institute's 25th anniversary and inaugurate Cancer Progress Year.

May 7, 1962 – The Acute Leukemia Task Force held its first meeting. It focused the combined efforts and resources of scientists on studies of therapy of the acute leukemia patient, and was the forerunner of other task forces on specific forms of cancer.

October 25, 1962 – The Human Cancer Virus Task Force held its first meeting. The task force, of scientists from NCI and other institutions, stimulated the development of special programs in viral oncology.

1963 – Studies were initiated at NCI in Hodgkin's disease with combination chemotherapy.

December 1964 – The report of the President's Commission on Heart Disease, Cancer, and Stroke was published.

January 11, 1966 – NCI reorganized to coordinate related activities. Scientific directors oversaw three newly established scientific divisions: etiology, chemotherapy, and a group of discipline-oriented laboratories and branches referred to as general laboratories and clinics. Two associate directors were named for program and for extramural activities.

February 13, 1967 – A cancer research center, USPHS Hospital, was established in Baltimore by the institute to conduct an integrated program of laboratory and clinical research.

April 27, 1970 – At the request of Senator Ralph W. Yarborough, chairman of the Committee on Labor and Public Welfare, the Senate approved the establishment of the National Panel of Consultants on the Conquest of Cancer.

November 25, 1970 – The national panel of consultants submitted to the Senate committee a report entitled "National Program for the Conquest of Cancer."

October 18, 1971 – President Nixon converted the Army's former biological warfare facilities at Fort Detrick, Md., to house research activities on the causes, treatment and prevention of cancer.

December 23, 1971 – President Nixon signed the National Cancer Act of 1971.

July 27, 1972 – A Bureau-level organization was established for the National Cancer Institute, giving the institute and its components organizational status commensurate with the responsibilities bestowed on it by the National Cancer Act of 1971. Under the reorganization, NCI was composed of the Office of the Director and four divisions: Cancer Biology and Diagnosis; Cancer Cause and Prevention; Cancer Treatment; and Cancer Grants (renamed successively the Division of Cancer Research, Resources and Centers, and later the Division of Extramural Activities).

June 20, 1973 – NCI director Dr. Frank J. Rauscher, Jr., announced that eight institutions were recognized as Comprehensive Cancer Centers to bring results of research as rapidly as possible to a maximum number of people. Additional centers were announced on November 2, 1973; June 13, 1974; October 18, 1974; April 8, 1976; December 30, 1976; July 27, 1978; and March 2, 1979, increasing the number of Comprehensive Cancer Centers to 20. (In July 2000 there are 37.)

September 5, 1973 – The President transmitted to Congress the first annual report of the director of the National Cancer Program, a 5-year strategic plan for the program, and the report of the National Cancer Advisory Board. Preparation and transmittal of the documents were mandated by the

National Cancer Act of 1971.

September 10, 1974 – The Division of Cancer Control and Rehabilitation was established to plan, direct, and coordinate an integrated program of cancer control and rehabilitation activities with the goal of identifying, testing, evaluating, demonstrating, communicating, and promoting the widespread use of available and new methods for reducing cancer incidence, morbidity, and mortality.

September 12, 1974 – NCI made its first cancer control awards to state health departments for a 3-year program to screen low-income women for cancer of the uterine cervix. At its peak in 1978, the program had grown to a total of 32 states and territories.

December 17, 1974 – NCI and the National Library of Medicine established CANCERLINE, a jointly developed computerized service to provide scientists across the country with information on cancer research projects and published findings.

December 19, 1974 – The Clinical Cancer Education Program was announced to develop more innovative teaching methods in cancer prevention, diagnosis, treatment, and rehabilitation in schools of medicine, dentistry, osteopathy, and public health; affiliated teaching hospitals; and specialized cancer institutions.

1975 – The Cooperative Minority Biomedical Program, as approved by the National Cancer Advisory Board, represented a cofunding effort by NCI to implement and foster cancer research through the DRR Minority Biomedical Research Support Program and the NIGMS Minority Access to Research Careers Program.

July 1, 1975 – The Cancer Information Service (CIS) was established on July 1, 1975, following the mandate of the National Cancer Act of 1971, which gave NCI new responsibilities for educating the public, patients, and health professionals.

August 5, 1977 – NCI celebrated its 40th anniversary with a ceremony on the NIH campus. Senator Warren G. Magnuson of Washington who, as a member of the House of Representatives, introduced a bill to establish the NCI in 1937, sent a message stating: "Those one and a half million Americans who are alive today – cured of cancer – are ample justification for all that we've appropriated over the last 40 years."

1979 – The first human RNA virus (HTLV-I) was discovered by NCI's Dr. Robert C. Gallo.

July 18, 1979 – NCI and the National Naval Medical Center, Bethesda, Md., signed an agreement to cooperate in a cancer treatment research program.

July 10, 1980 – HHS Secretary Patricia Roberts Harris approved institute-wide reorganization. A newly created Division of Resources, Centers, and Community Activities incorporated functions of the former Division of Cancer Control and Rehabilitation and programs for education, training, construction, cancer centers, and organ site research of the former Division of Cancer Research, Resources, and Centers (DCRRC). Other activities of the DCRRC were incorporated into the new Division of Extramural Activities.

April 27, 1981 – A new Biological Response Modifiers Program was established in the Division of Cancer Treatment to investigate, develop and bring to clinical trials potential therapeutic agents that may alter biological responses that are important in the biology of cancer growth and metastasis.

September 1982 – PDQ, a computerized database on cancer treatment information, became available nationwide via the National Library of Medicine's MEDLARS system.

December 16, 1982 – NCI purchased what is now the R. A. Bloch International Cancer Information Center through generous donations to the NCI Gift Fund. This building houses the *Journal of the National Cancer Institute*; the Scientific Information Branch, which publishes *Cancer Treatment Reports* and *Cancer Treatment Symposia*; the International Cancer Research Data Bank; and PDQ.

July 16, 1983 – NCI launched the Community Clinical Oncology Program (CCOP) to establish a cancer control effort that combines the expertise of community oncologists with NCI clinical research programs. The CCOP initiative is designed to bring the advantages of clinical research to cancer patients in their own communities.

September 1983 – The Office of International Affairs was reorganized to add a Scientific Information Branch and a Computer Communications Branch. The Scientific Information Branch is composed of a literature research section, cancer treatment reports section, *Journal of the National Cancer Institute* section, and the international cancer research data bank section.

Community Clinical Oncology Program, an NCI resource that links community-based physicians with cooperative groups and cancer centers for participation in institute-approved clinical trials, was created.

December 5, 1983 – The name of the Division of Cancer Cause and Prevention was changed to the Division of Cancer Etiology (DCE).

The Division of Resources, Centers and Community Activities was renamed the Division of Cancer Prevention and Control (DCPC) to emphasize the division's roles in cancer prevention and control research.

1984 – A policy statement regarding the relationship of the NCI, the pharmaceutical industry, and NCI-supported cooperative groups was developed. The statement articulates the need for collaboration between the NCI and the pharmaceutical industry in pursuing the joint development of anticancer drugs of mutual interest. It also sets forth guidelines for the handling of issues such as the joint sponsorship of trials, the sharing of information between sponsors, maintaining the confidentiality of certain classes of data, the funding of cooperative groups by drug companies, the review of protocols and the publication of results.

The Comprehensive Minority Biomedical Program, DEA, was established to widen the focus of the minority effort along lines of the programmatic thrusts of the institute, thereby giving it trans-NCI responsibilities.

The Cancer Control Science program was established in DCPC to develop programs in health promotion research and to stimulate widespread application of existing cancer control knowledge. Branches include health promotion sciences, cancer control applications and cancer training.

March 6, 1984 – DHHS Secretary Margaret M. Heckler launched a new cancer prevention awareness program by NCI to inform the public about cancer risks and steps individuals can take to reduce risk.

April 1984 – An NCI scientist, Dr. Robert C. Gallo, reported the isolation of a new group of viruses found in the helper T-cells of patients with AIDS or pre-AIDS symptoms, as well as from healthy individuals at high risk for developing AIDS. These viruses were ultimately named human immunodeficiency virus or HIV. This discovery made the control of blood-product-transmitted AIDS feasible by enabling the development of a simple test for the detection of AIDS-infected blood by blood banks and diagnostic laboratories.

August 1985 – The Cancer Prevention Fellowship Program, one of the first formal postdoctoral research training programs in cancer prevention, began.

November 10, 1986 – The International Cancer Information Center was established in the Office of International Affairs, NCI Office of the Director.

May 1987 – As part of NIH's centennial celebration year, NCI commemorated its 50th anniversary.

October 15, 1987 – The DCPC established the Laboratory for Nutrition and Cancer Research with the basic nutrition science section and the clinical/metabolic human studies section.

October 24, 1987 – The Office of Technology Development was established in the NCI Office of the Director as the institute's focal point for the implementation of pertinent legislation, rules and regulations, and the administration of activities relating to collaborative agreements, inventions, patents, royalties, and associated matters.

October 26, 1987 – The DCT abolished the following branches, sections, and laboratory: the chromosome structure and function section in the Laboratory of Molecular Pharmacology; the Drug Evaluation Branch and its sections; the drug synthesis section and the acquisition section in the Drug Synthesis and Chemistry Branch; the fermentation section and the plant and animal products section in the Natural Products Branch; the chemical resources section, the analytical and product development section and the clinical products section in the Pharmaceutical Resources Branch; the Extramural Research and Resources Branch; and the Animal Genetics and Production Branch; the sections of the Information Technology Branch; the Laboratory of Experimental Therapeutics and Metabolism and its sections; the sections of the Laboratory of Pharmacology and Experimental Therapeutics.

The DCT changed the name of the Laboratory of Pharmacology and Experimental Therapeutics to the Laboratory of Biochemical Pharmacology. The division also established the Laboratory of Medicinal Chemistry, Pharmacology Branch, Biological Testing Branch, and Grants and Contracts Operations Branch.

1988 – In DCT's Clinical Oncology Program, the Clinical Pharmacology Branch merged with the Medicine Branch.

The International Cancer Information Center established a separate office in the NCI Office of the Director.

January 1988 – NCI journals *Cancer Treatment Reports* and *Journal of the National Cancer Institute* were consolidated into a biweekly *Journal of the National Cancer Institute*.

September 30, 1988 – The first Consortium Cancer Center was established, comprised of three historically black medical schools. Component universities supported by this core grant – Charles R. Drew University of Medicine and Science in Los Angeles, Meharry Medical College in Nashville, and Morehouse School of Medicine in Atlanta – focus their efforts on cancer prevention, control, epidemiology, and clinical trials.

April 1989 – The NCI-initiated mechanism of supplementing research grants to encourage recruitment of minority scientists and science students into extramural research laboratories is published as an NIH-wide extramural program announcement. This initiative will be expanded to cover science students and scientists who are women or persons with disabilities.

May 22, 1989 – NCI scientist Dr. Steven A. Rosenberg conducted the first human gene transfer trial using human tumor-infiltrating lymphocytes to which a foreign gene has been added.

September 14, 1990 – Scientists from NCI and NHLBI conducted the first trial in which a copy of a faulty gene was inserted into white blood cells to reverse the immune deficiency it causes. This was the first human gene therapy trial and adenosine deaminase deficiency was treated.

December 19, 1990 – The institute began its year-long celebration of the 20th anniversary of the National Cancer Act by inaugurating a series of articles in the *Journal of the National Cancer Institute*. The series described the growth in knowledge that has occurred in cancer research since 1971.

January 29, 1991 – The first human gene therapy to treat cancer was started. Patients with melanoma were treated with tumor-infiltrating lymphocytes to which a gene for tumor necrosis factor has been added.

September 24, 1991 – Congress held a special hearing to commemorate the 20th anniversary of the National Cancer Act. Dr. Samuel A. Broder, NCI director, thanked Congress for its "consistent vision, leadership, and commitment to the goal of alleviating the death and suffering caused by cancer in this country."

October 1991 – NCI began its Five-a-Day program, in partnership with the nonprofit group Produce for Better Health, to encourage Americans to eat at least five fruits and vegetables a day.

December 18, 1992 – Taxol (paclitaxel), an anticancer drug extracted from the bark of the Pacific yew, received approval by the FDA for the treatment of ovarian cancer that has failed other therapy. NCI spearheaded the development of the drug through collaboration with the USDA's Forest Service, the Department of the Interior's Bureau of Land Management, and Bristol-Myers Squibb Company, made possible by the Federal Technology Transfer Act of 1986.

November 1993 – The Prostate, Lung, Colorectal, and Ovarian trial, designed to determine whether certain screening tests will reduce the number of deaths from these cancers, began recruiting 148,000 men and women, ages 55-74.

February 1995 – The results of the Community Intervention Trial for Smoking Cessation were completed and published.

1995/1996 – NCI leadership initiated a major reorganization, based on recommendations of the Ad Hoc Working Group of the National Cancer Advisory Board and NCI streamlining work groups and quality improvement teams. Two extramural divisions were created – the Division of Cancer Treatment, Diagnosis and Centers and the Division of Cancer Biology. Two intramural divisions were also created – the Division of Basic Sciences and the Division of Clinical Sciences – and one combined intramural/extramural division – the Division of Cancer Epidemiology and Genetics. The Divisions of Cancer Prevention and Control and Extramural Activities remain a part of the NCI structure, but in the extramural program.

November 1996 – Cancer mortality rates decline nearly 3 percent between 1991 and 1995, the first sustained decline since national record keeping was instituted in the 1930's.

1996 - The NCI Office of Liaison Activities is established to ensure that advocates have an input concerning NCI research and related activities. The office supports NCI's research and programs by fostering strong communications and partnerships with the cancer advocacy community, professional societies, and Federal agencies.

August 1, 1997 – NCI, in partnership with government, academic, and industrial laboratories, launches the Cancer Genome Anatomy Project with two overall goals: to enhance the discovery of the acquired and inherited molecular changes in cancer and to evaluate the clinical potential of these discoveries. The project includes a website allowing scientists to rapidly access data generated through the project and apply it to their studies.

October 1997 – NCI reorganization continues, with the creation of the Division of Cancer Prevention and the Division of Cancer Control and Population Sciences from the former Division of

Cancer Prevention and Control and the extramural component of the Division of Cancer Epidemiology and Genetics.

1997 — The NCI Director's Consumer Liaison Group is established to advise and provide recommendations to the NCI Director from the perspective and viewpoint of cancer advocates on a wide variety of issues, programs, and research priorities and to maintain strong collaborations between NCI and the advocacy community.

March 1998 – Cancer incidence rates show first sustained decline since NCI began keeping records in 1973 - the rates dropped 0.7 percent per year from 1990 to 1995. Cancer mortality rates continue to decline.

April 6, 1998 – Results of the Breast Cancer Prevention Trial, testing the effectiveness of tamoxifen to prevent the disease, are announced 14 months earlier than expected: women taking tamoxifen had 45 percent fewer breast cancer diagnoses than women on the placebo, proving that breast cancer can be prevented. Rare but serious side effects are shown to occur in some postmenopausal women on tamoxifen - endometrial cancer and blood clots. A study to compare tamoxifen to another, potentially less toxic drug is planned for fall 1998.

September 25, 1998 – The Food and Drug Administration approved the monoclonal antibody Herceptin® (Trastuzumab) for the treatment of metastatic breast cancer in patients with tumors that produce excess amounts of a protein called HER-2. (Approximately 30 percent of breast cancer tumors produce excess amounts of HER-2.)

May 25, 1999 – The Study of Tamoxifen and Raloxifene, or STAR, one of the largest breast cancer prevention studies ever, began recruiting volunteers at more than 400 centers across the United States, Puerto Rico, and Canada. The trial will include 22,000 postmenopausal women at increased risk of breast cancer to determine whether the osteoporosis prevention drug raloxifene (Evista) is as effective in reducing the chance of developing breast cancer as tamoxifen (Nolvadex) has proven to be.

October 6, 1999 – NCI awarded nearly \$8 million in grants toward the creation of the Early Detection Research Network, a network to discover and develop new biological tests for the early detection of cancer and of biomarkers for increased cancer risk. The awards created 18 Biomarker Developmental Laboratories to identify, characterize, and refine techniques for finding molecular, genetic, and biologic early warning signals of cancer.

December 8, 1999 – The National Cancer Institute published the new *Atlas of Cancer Mortality, 1950-94*, showing the geographic patterns of cancer death rates in over 3,000 counties across the country over more than four decades. This atlas updated the first atlas, published in 1975. The 254 color-coded maps in the atlas made it easy for researchers and state health departments to identify places where high or low rates occur. For the first time, maps were presented for both white and black populations. An interactive version of the data was made available on the Internet for the first time, as well.

April 6, 2000 – A \$60 million program is announced to address the unequal burden of cancer within certain special populations in the United States over the next 5 years. The Special Populations Networks for Cancer Awareness Research and Training are intended to build relationships between large research institutions and community-based programs. Eighteen grants at 17 institutions will create or implement cancer control, prevention, research, and training programs in minority and underserved populations. The cooperative relationships established by the Networks will be used to foster cancer awareness activities, support minority enrollment in clinical trials, and encourage and promote the development of minority junior biomedical researchers.

June 7, 2000 – President Clinton issued an executive memorandum directing the Medicare program to reimburse providers for the cost of routine patient care in clinical trials. The memorandum also

provides for additional actions to promote the participation of Medicare beneficiaries in clinical studies.

December 3, 2000 – NCI established the Center to Reduce Cancer Health Disparities. The Center absorbed the former Office of Special Populations Research. The NCI Strategic Plan to Reduce Health Disparities is part of a major national commitment to identify and address the underlying causes of disease and disability in racial and ethnic communities. Because these communities carry an unequal burden of cancer-related health disparities, NCI is working to enhance its research, education, and training programs that focus on populations in need.

January 12, 2001 – NCI announced the creation of the Center for Cancer Research, merging two intramural divisions at NCI – the Division of Basic Sciences and the Division of Clinical Sciences, to provide greater opportunities to translate fundamental research into pioneering clinical research and molecular medicine.

May 10, 2001 – The Food and Drug Administration announced its approval of the drug Gleevec, also known as STI571, as an oral treatment for chronic myelogenous leukemia (CML). This marked the approval of the first molecularly targeted drug that directly turns off the signal of a protein known to cause a cancer. Clinical trials are continuing to expand as clinical investigators test Gleevec in a variety of cancers that share common molecular abnormalities.

July 24, 2001 – The largest-ever prostate cancer prevention study was launched by the NCI and a network of researchers known as the Southwest Oncology Group (SWOG). The Selenium and Vitamin E Cancer Prevention Trial, or SELECT, will determine if these two dietary supplements can protect against prostate cancer, the most common form of cancer, after skin cancer, in men. The study will include a total of 32,400 men.

September 4, 2001 – NCI and the American College of Radiology Imaging Network (ACRIN) launched the first large, multicenter study to compare digital mammography to standard mammography for the detection of breast cancer.

September 10, 2001 – NCI launched the Consumer Advocates in Research and Related Activities (CARRA) program – a landmark initiative convening a large network of dedicated advocates who bring the viewpoint of those affected by cancer to NCI. NCI staff, including researchers and scientists, are able to rely on the CARRA network of more than 200 advocates to give insight and feedback from the consumer's perspective to their developing programs.

February 7, 2002 – Scientists from NCI and FDA reported that patterns of proteins found in patients' serum may reflect the presence of ovarian cancer, even at early stages. Currently, more than 80 percent of ovarian cancer patients are diagnosed at a late clinical stage and have a 20 percent or less chance of survival at five years. This new diagnostic concept is potentially applicable to the diagnosis of other diseases.

May 19, 2002 – Researchers from NCI reported that the molecularly targeted drug bevacizumab slowed tumor growth in patients with metastatic renal cell carcinoma, the most common form of kidney cancer in adults.

June 19, 2002 – NCI scientists used microarray technology to determine the patterns of genes that are active in tumor cells from which they were able to predict whether patients with the most common form of non-Hodgkin's lymphoma in adults are likely to be cured by chemo-therapy. Trials designed to correlate clinical results with molecular data will allow researchers to identify drugs that are effective in subgroups of cancer patients, an approach that has already proven effective in finding new agents to treat breast cancer and leukemia.

July 16, 2002 – Postmenopausal women who used estrogen replacement therapy for 10 or more years were at significantly higher risk of developing ovarian cancer than women who never used

hormone replacement therapy in an NCI-funded trial. The relative risk for 10 to 19 years of use was 80 percent higher risk than non-users, and increased to a 220 percent higher risk than non-users for women who took estrogen for 20 or more years.

September 18, 2002 – NCI launched the National Lung Screening Trial to compare two ways of testing for early lung cancer in current and former heavy smokers: spiral computed tomography and single-view chest x-ray. Both spiral CT scans and chest x-rays have been used in clinical practice to detect lung cancer in asymptomatic individuals, but scientific evidence is inconclusive as to whether screening for lung cancer with either method will reduce lung cancer mortality. NLST will examine the relative risks and benefits of both tests in 50,000 current and former smokers at 30 study sites throughout the United States.

September 19, 2002 – A new approach to cancer treatment that replaces a patient's immune system with cancer-fighting cells can lead to tumor shrinkage. NCI researchers demonstrated that immune cells, activated in the laboratory against patients' tumors and then administered to those patients, could attack cancer cells in the body. The experimental technique, known as adoptive transfer, has shown promising results in patients with metastatic melanoma who have not responded to standard treatment.

October 16, 2002 – Patterns of proteins found in patients' blood may help distinguish between prostate cancer and benign conditions, according to scientists from NCI and FDA. The technique, which relies on a simple test using a drop of blood, may be useful in deciding whether to perform a biopsy in men with elevated levels of prostate specific antigen (PSA).

October 31, 2002 – NCI researchers have discovered that a molecule best known for its antimicrobial properties also has the ability to activate key cells in the immune response. This newly discovered function suggests the molecule, a peptide called β -defensin 2, may be useful in the development of more effective cancer vaccines.

December 12, 2002 – A new clinical trial has shown that reducing the interval between successive doses of a commonly used chemotherapy regimen improves survival in women whose breast cancer has spread to the lymph nodes. While previous research has evaluated the use of various forms of "dose dense" chemotherapy, this is the first major controlled study to show a clear survival benefit for women with node-positive breast cancer.

2003 – A novel approach to treatment of solid cancers involves therapeutic agents that inhibit the generation of new blood vessels in growing tumors (angiogenesis). The evidence linking tumor growth and metastases with angiogenesis is compelling: in colorectal and breast cancers, the density of microvessels in histologic specimens has been correlated with disease recurrence, metastases, and survival. Of the identified angiogenic factors, vascular endothelial growth factor has been shown to be the most potent and specific.

February 2003 – NCI scientists, using DNA microarrays, found that the length of survival following diagnosis of mantle cell lymphoma can be accurately predicted based on gene expression measurements in the diagnostic tumor biopsy. This molecular predictor can identify one quartile of these patients who have a very indolent disease, with a median survival of greater than 6 years, and another quartile that have an aggressive disease, with a median survival of less than one year. Using this predictor, patients with the indolent form of mantle cell lymphoma can be managed conservatively, whereas new clinical trials can be designed specifically for those patients with the more aggressive tumors.

March 5, 2003 – Taking daily aspirin for as little as three years was shown to reduce the development of colorectal polyps by 19 percent to 35 percent in people at high risk for colorectal cancer in two randomized, controlled NCI clinical trials published in the *New England Journal of Medicine*.

April 24, 2003 – NCI, CDC, AHRQ, and SAMHSA, in collaboration with the American Cancer Society, launched the Cancer Control PLANET (Plan, Link, Act, Network with Evidence-based Tools), a web portal providing access to regularly updated cancer surveillance data and program resources including cancer control interventions. PLANET is designed to also help state- and community-based planners, program staff, and researchers develop, implement, and evaluate evidence-based cancer control programs. The portal is accompanied by in-person technical support meetings with state and regional public and private sector partnership staff who are working together to use PLANET resources for comprehensive cancer control. (Visit <http://cancercontrolplanet.cancer.gov/> for more information.)

May 30, 2003 – Under an agreement between the Food and Drug Administration and the National Cancer Institute, the two agencies, overseen by an Interagency Oncology Task Force, will share knowledge and resources to facilitate the development of new cancer drugs and speed their delivery to patients.

June 24, 2003 – Results of the Prostate Cancer Prevention Trial, testing the effectiveness of finasteride to prevent the disease are announced about a year earlier than expected: men taking finasteride had 25 percent fewer prostate cancer diagnoses than men on the placebo, proving that prostate cancer can be prevented. There was a note of caution, however; the men who did develop prostate cancer while taking finasteride were more likely to have high-grade tumors.

July 1, 2003 – New data from the Prostate, Lung, Colorectal, and Ovarian (PLCO) Cancer Screening Trial give fresh insight into the appropriate screening intervals for colorectal cancer after a negative exam. This is the largest study to date of repeat sigmoidoscopy screening after an exam. The current accepted interval for sigmoidoscopy, a technique in which the rectum and lower colon are examined with a lighted instrument called a sigmoidoscope, is 5 years after a negative exam. This recommendation is based primarily on indirect evidence. Exactly how often to repeat sigmoidoscopy is an evolving field of research. Whether data from the new study, which measures the incidence of growths or polyps three years after an initial exam, will play a role in changing the current five-year interval is not clear.

September 2, 2003 – Death rates from the four most common cancers – lung, breast, prostate, and colorectal – continued to decline in the late 1990s according to new data from the "Annual Report to the Nation on the Status of Cancer, 1975-2000.

October 9, 2003 – A Canadian-led international clinical trial has found that post-menopausal survivors of early-stage breast cancer who took the drug letrozole after completing an initial five years of tamoxifen therapy had a significantly reduced risk of cancer recurrence compared to women taking a placebo. The clinical trial has been halted early because of the positive results and researchers are notifying the 5,187 women worldwide who have participated in the study.

November 6, 2003 – NCI scientists demonstrated that the growth factors interleukin-2 (IL-2) and IL-15 have contrasting roles in the life and death of lymphocytes, an observation that has implications for the immunotherapy of cancer and autoimmune diseases.

June 3, 2004 – NCI's Annual Report to the Nation finds cancer incidence and death rates on the decline as survival rates show significant improvement. Overall, cancer death rates for all racial and ethnic populations combined declined by 1.1 percent per year from 1993 to 2001 and also declined for many of the top 15 cancers in both men and women. Lung cancer death rates among women leveled off for the first time between 1995 and 2001 after increasing continuously for many decades.

July 16, 2004 – An NCI Phase I clinical trial is underway to test the safety and efficacy of BMS-354825 in chronic myeloid leukemia patients with imatinib resistance. The effectiveness of imatinib (Gleevec), a small-molecule drug that inhibits the aberrant activity of the BCR-ABL protein tyrosine kinase, has been limited due to the problem of drug resistance. BMS-354825, a closely related drug, overcomes much of this resistance.

September 13, 2004 – NCI announces the Alliance for Nanotechnology in Cancer, a five-year initiative to integrate nanotechnology development into basic and applied cancer research to facilitate the rapid application of this science to the clinic. It will support the development of nanomaterials and nanoscale devices for molecular imaging and early detection, reporters of efficacy, and multifunctional therapeutics to combat the cancer process.

November 18, 2004 – Scientists at NCI have created a model that predicts the survival of 191 follicular lymphoma patients based on the molecular characteristics of their tumors at diagnosis. The model is based on two sets of genes – called survival-associated signatures. Understanding the molecular causes of such differences in survival could provide a more accurate method to determine patient risk, which could be used to guide treatment and may suggest new therapeutic approaches.

December 10, 2004 – An NCI study determined that a new molecular test can predict the risk of breast cancer recurrence and may identify women who will benefit most from chemotherapy. The test is based on levels of expression (increased or decreased) of a panel of cancer-related genes that is used to predict whether estrogen-dependent breast cancer will come back.

NCI Legislative Chronology

February 4, 1927 – Senator M. M. Neely, West Virginia, introduced S. 5589, "To authorize a reward for the discovery of a successful cure for cancer, and to create a commission to inquire into and ascertain the success of such cure." The reward was to be \$5 million.

March 7, 1928 – Senator M. M. Neely introduced S. 3554, "To authorize the National Academy of Sciences to investigate the means and methods for affording Federal aid in discovering a cure for cancer and for other purposes."

April 23, 1929 – Senator W. J. Harris, Georgia, introduced S. 466, "To authorize the Public Health Service and the National Academy of Sciences jointly to investigate the means and methods for affording Federal aid in discovering a cure for cancer and for other purposes."

May 29, 1929 – Senator W. J. Harris introduced S. 4531, authorizing a survey in connection with the control of cancer and providing "That the Surgeon General of the Public Health Service is authorized and directed to make a general survey in connection with the control of cancer and submit a report thereon to the Congress as soon as practicable, together with his recommendations for necessary Federal legislation."

April 2, 1937 – Senator Homer T. Bone of Washington introduced S. 2067, "Authorizing the Surgeon General of the Public Health Service to control and prevent the spread of the disease of cancer." It authorized an annual appropriation of \$1 million. Congressman Warren G. Magnuson of Washington introduced an identical bill (H.R. 6100) in the House.

April 29, 1937 – Congressman Maury Maverick of Texas introduced H.R. 6767, "To promote research in the cause, prevention, and methods of diagnosis and treatment of cancer, to provide better facilities for the diagnosis and treatment of cancer, to establish a National Cancer Center in the Public Health Service, and for other purposes." It authorized an appropriation of \$2,400,000 for the first year and \$1 million annually thereafter. The legal office of PHS had helped draft the bill on the basis of suggestions made by Dr. Dudley Jackson of San Antonio, Tex.

July 8, 1937 – A joint hearing of the Senate and House committees was conducted before a subcommittee on cancer research and a revised bill was written.

July 23, 1937 – The National Cancer Institute Act was passed by Congress.

August 5, 1937 – The National Cancer Institute Act, P.L. 244, 75th Congress, was signed by President Franklin D. Roosevelt, "To provide for, foster, and aid in coordinating research relating to cancer; to establish the National Cancer Institute; and for other purposes." An appropriation of \$700,000 for each fiscal year was authorized.

March 28, 1938 – House Joint Resolution 468, 75th Congress, was passed, "To dedicate the month of April in each year to a voluntary national program for the control of cancer."

July 1, 1944 – The Public Health Service Act, P.L. 410, 78th Congress, provided that "The National Cancer Institute shall be a division in the National Institute of Health." The act also revised and consolidated many revisions into a single law. The limit of \$700,000 annual appropriation was removed.

August 15, 1950 – Public Law 692, 81st Congress, increased the term of office of National Advisory Cancer Council members from 3 to 4 years and the size of the Council from 6 to 12 members, exclusive of the ex-officio members.

December 23, 1971 – President Nixon signed P.L. 92-218-the National Cancer Act of 1971 – providing increased authorities and responsibilities for the NCI director; initiating a National Cancer Program; establishing a 3-member President's Cancer Panel and a 23-member National Cancer Advisory Board, the latter replacing the National Advisory Cancer Council; authorizing the establishment of 15 new research, training, and demonstration cancer centers; establishing cancer control programs as necessary for cooperation with state and other health agencies in the diagnosis, prevention, and treatment of cancer; and providing for the collection, analysis, and dissemination of all data useful in the diagnosis, prevention, and treatment of cancer, including the establishment of an international cancer data research bank.

July 23, 1974 – The National Cancer Act Amendments of 1974 (P.L. 93-352) were signed by the President to improve the National Cancer Program and to authorize appropriations for the next three fiscal years. P.L.93-352 also included provisions for disseminating information on nutrition as related to the therapy or causation of cancer, for trials of cytology test programs for the diagnosis of uterine cancer, and for peer review of grant applications and contract projects. It also established a President's Biomedical Research Panel.

August 1, 1977 – The NCI mandate was extended for 1 year when the President signed the Health Planning and Health Services Research and Statistics Extension Act (P.L. 95-83).

November 9, 1978 – The President signed the Community Mental Health Centers Act (P.L. 95-622) amending the National Cancer Act to emphasize education and demonstration programs in cancer treatment and prevention, and stipulating that NCI devote more resources to prevention, focusing particularly on environmental, dietary and occupational cancer causes.

December 17, 1980 – The Health Programs Extension Act of 1980 (P.L. 96-538) was signed into law, extending NCI authorization for 3 years.

November 20, 1985 – The Health Research Extension Act of 1985 (P.L. 99-158) was signed into law. It affirmed the special authorities of NCI and emphasized the importance of information dissemination to the public.

November 4, 1988 – The Health Research Extension Act of 1988 (P.L. 100-607) was signed into law. The 2-year extension reaffirmed the special authorities of NCI and added information dissemination mandates, as well as a requirement to assess the incorporation of cancer treatments into clinical practice and the extent to which cancer patients receive such treatments. A representative from the Department of Energy was added to the National Cancer Advisory Board as an ex officio member.

June 10, 1993 – The NIH Revitalization Act of 1993, P.L. 103-43, was signed. The act encouraged NCI to expand and intensify its efforts in breast cancer and other women's cancers and authorized increased appropriations. Similar language is included for prostate cancer. The institute is also directed to collaborate with NIEHS, to undertake a case control study to assess biological markers of environmental and other potential risk factors contributing to the incidence of breast cancer in specific counties in the Northeast. In FY1994 NCI is directed to allocate 7 percent of its appropriation to cancer control, in FY 1995, 9 percent, and in FY1996, 10 percent.

August 13, 1998 – The Stamp Out Breast Cancer Act (PL 105-41) was signed into law. The bill established a special alternative rate of postage up to 25 percent higher than a regular first-class stamp. Seventy percent of the profits from the sale of the stamp, also referred to as semipostal, would go to NIH to fund breast cancer research; the remaining 30 percent would go toward DOD breast cancer research.

July 28, 2000 – President Clinton signed into law the Semipostal Authorization Act (P.L. 106-253), which gave the U.S. Postal Service the authority to issue semipostals. These stamps are sold at a premium in order to help provide funding for a particular area of research. The law also extended the Breast Cancer Stamp Act until July 29, 2002.

July 10, 2000 – The Radiation Exposure Compensation Amendments of 1999 (P.L. 106-245) was signed into law. The bill allowed more workers who handled radioactive material for weapons programs to be eligible to receive federal compensation for radiation-induced illness. The law expanded previously written compensation acts, making more grades of workers eligible for compensation, and to include compensation for brain, lung, bladder, colon, ovary, and salivary gland cancers.

November 12, 2001 – The President signed PL 107-67 making appropriations for the Treasury Department, the United States Postal Service, the Executive Office of the President, and certain Independent Agencies, for the fiscal year ending September 30, 2002, and for other purposes. Within this bill was a provision to reauthorize the Breast Cancer Research Postage Stamp through July 29, 2008.

January 4, 2002 – President Bush signed PL 107-109 - S. 1789, the Best Pharmaceuticals for Children Act. This legislation was designed to improve the safety and efficacy of pharmaceuticals for children, by reauthorizing legislation that encourages pediatric drug research by giving drug companies an incentive of 6 months of additional market exclusivity to test their products for use in children.

May 14, 2002 – The President signed the Hematologic Cancer Research Investment and Education Act of 2002 (PL 107-172) that directed the NIH Director, through the NCI Director, to conduct and support research on blood cancers. In addition, the CDC was directed to establish and carry out an information and education program.

September 10, 2002 – The Public Health Security and Bioterrorism Preparedness and Response Act (PL 107-188) was signed and contains a provision that instructs Federal agencies to stockpile and distribute potassium iodide (KI) to protect the public from thyroid cancer in the event of a radiation emergency.

Biographical Sketch of NCI Director Andrew C. von Eschenbach, M.D.

Dr. Andrew von Eschenbach became the 12th Director of the National Cancer Institute in its 66 year history on January 22, 2002. A nationally recognized urologic surgeon, Dr. von Eschenbach has dedicated his professional life and administrative expertise to eliminating the suffering and death due to cancer. His distinguished career as a key leader in the fight against cancer spans three decades and is fueled by a passionate commitment to rapidly translating the fruits of scientific discovery to all who are in need.

This commitment helped form the basis of NCI's Challenge Goal: To eliminate the death and suffering from cancer by the year 2015. With a strong emphasis on new enabling technologies, exploitation of breakthroughs in basic research, and the formation of innovative partnerships, Dr. von Eschenbach is fusing this ambitious vision of accelerated progress across the cancer research community and among NCI's public and private stakeholders.

Prior to accepting the appointment to lead the NCI, Dr. von Eschenbach directed both the Genitourinary Cancer Center and the Prostate Cancer Research Program at the University of Texas M.D. Anderson Cancer Center, one of the nation's top scientific research institutions. As the founder and driving force behind the Center's Prostate Cancer Research Program, his dynamic leadership is credited with fostering model integrated research programs in the biology, epidemiology, prevention and treatment of prostate cancer. From 1997 to 1999, he also served as Vice President for Academic Affairs and then as Executive Vice President and Chief Academic Officer, leading a faculty of almost 1,000 cancer researchers and clinicians.

Dr. von Eschenbach arrived at M.D. Anderson as a urologic oncology fellow in 1976 and was invited to join the faculty a year later. In 1983--just six years after joining the staff--he was named chairman of the Department of Urology. Other positions he held include Consulting Professor of Cell Biology and Professor of Urology.

Dr. von Eschenbach, himself a two-time cancer survivor, has had an impact on the fight against cancer that extends beyond research, clinical and academic communities. He was a founding member of the National Dialogue on Cancer and prior to his accepting the position at the NCI, he was President-elect of the American Cancer Society. Dr. von Eschenbach has contributed more than 200 articles, books, and chapters to the scientific literature.

Dr. von Eschenbach has been widely recognized for his leadership in the fight against cancer by many influential organizations. The American Urological Association selected him to deliver the prestigious Ramon Guiteras Lecture at their annual meeting. He was recently awarded an honorary degree from his medical school alma mater, Georgetown University School of Medicine. Dr. von Eschenbach also received the Julie Rogers "Spirit of Love" award for exemplary dedication, commitment and spirit in the fight against cancer, the Achievement Award in Prostate Cancer from Partners in Courage for outstanding support and leadership, the Medical Award of Excellence from Cancer Counseling, and the Certificate of Meritorious Service for Outstanding Contributions to Prostate Disease Research from the Uniformed Services University of the Health Sciences.

Dr. von Eschenbach received his medical degree from Georgetown University Medical School in 1967. He completed residencies in general surgery and urology at Pennsylvania Hospital in Philadelphia, then was an instructor in urology at the University of Pennsylvania School of Medicine. He served as a Lieutenant Commander in the U.S. Navy Medical Corps.

NCI Directors

Name	In Office From	To
Carl Voegtlin	January 13, 1938	July 31, 1943
Roscoe Roy Spencer	August 1, 1943	July 1, 1947
Leonard Andrew Scheele	July 1, 1947	April 6, 1948
John Roderick Heller	May 15, 1948	July 1, 1960
Kenneth Millo Endicott	July 1, 1960	November 10, 1969
Carl Gwin Baker	July 13, 1970	May 5, 1972
Frank Joesph Rauscher, Jr.	May 5, 1972	November 1, 1976
Arthur Canfield Upton	July 29, 1977	December 31, 1980
Vincent T. DeVita, Jr.	July 9, 1980	September 1, 1988

Samuel Broder	December 22, 1988	April 1, 1995
Richard D. Klausner	August 1, 1995	September 30, 2001
Andrew C. von Eschenbach	January 22, 2002	Present

Research Programs

[Extramural](#) | [Intramural](#)

Extramural Research

With guidance and oversight from program experts in NCI's Divisions of Cancer Biology, Cancer Treatment and Diagnosis, Cancer Prevention, Cancer Control and Population Sciences, and Extramural Activities, cancer research is conducted with NCI funding in nearly every state in the United States and more than 20 foreign countries. Extramural Divisions also support cancer research training, education, and career development; provide leadership for setting national priorities in cancer research; allocate resources; and integrate their projects with other Divisions within NCI and Institutes within NIH and with Federal and state agencies, professional agencies, cancer centers, and other organizations.

Division of Cancer Biology

The Division of Cancer Biology (DCB) manages a multidisciplinary program of basic and applied research on cancer cell biology, including research on carcinogenesis and cancer immunology. Six Branches within DCB support a variety of broad-based investigator-initiated research grants from academic institutions, research institutes, and small businesses. Two high profile NCI programs are also coordinated through the Division's Office of the Director.

The *Cancer Cell Biology Branch* encourages and supports basic research projects covering a broad spectrum of topics directed at understanding the biological basis of cancer. The portfolio includes the search for proteins and networks responsible for the cancer phenotype, investigation of aberrantly modified regulatory processes that promote cell proliferation or inhibit cell death, and the identification of connecting pathways that ensure tumor cell survival. The research utilizes non-mammalian organisms as well as mammalian models to undertake the functional analysis of abnormal gene expression in parallel with studies on human tumor cells and tissues to confirm the physiological relevance of the research findings. Other areas of special focus include the subcellular location and trafficking of proteins in the cell, cellular processes of proteolysis, and cancer cell physiology. Investigations in all tumor cell types are included.

The *Cancer Etiology Branch* develops and manages a national extramural research program dealing with biological, chemical and physical agents that are possible etiological factors or co-factors in cancer and with the control of these agents and their associated diseases. Specific agents of interest include infectious agents such as viruses and bacteria and chemical carcinogens such as polycyclic aromatic hydrocarbons and hormones. Investigations include studies of the agents themselves and their properties, mechanisms of oncogenesis and carcinogenesis, interactions of oncogenic microbiological agents with their hosts, and basic studies to identify possible targets for preventive or therapeutic measures.

The *Cancer Immunology and Hematology Branch* supports research in basic and tumor immunology and the biology of malignancies of the immune system (leukemias and lymphomas). Areas of major interest include the immune response to tumors; receptor biology/signal transduction cascades ; cytokines; antibodies and antibody genes; T-cell biology; the biology of antigen-presenting cells and nonspecific effectors of the immune system (e.g., natural killer cells); granulocytes and macrophages; hematopoietic differentiation; oncogenes; the biology of hematopoietic tumors (including AIDS lymphomas); immunologic aspects of bone-marrow transplantation; and the stem cell biology of hematologic malignancies.

The *DNA and Chromosome Aberrations Branch* supports a basic cancer research program that

emphasizes cancer genetics and genomic studies at the DNA and chromosome level, including discovery of genes at sites of chromosome breaks, deletions, and translocations, DNA repair, transcription, structure and mechanisms of chromosome alterations, epigenetic changes, radiation- and chemical-induced changes in DNA replication and other alterations, and supporting analytical technologies. Research on chemically induced changes to cell macromolecules is supported in areas such as the genetics of tumor susceptibility and resistance, mutagenesis, and DNA damage/repair. The DNA damage/repair area covers studies in mismatch, base-excision, nucleotide excision, double-strand breaks, transcription-coupled and replication-coupled DNA repair. Research on relationships between ionizing and non-ionizing radiation induced DNA damage signaling, cell cycle control, chromatin remodeling and individual or coordinated groupings of DNA repair networks are also supported. Other areas of special focus include the genetics of cancer susceptibility and resistance, and the use of mammalian and non-mammalian organisms to model human cancer.

The *Structural Biology and Molecular Applications Branch* focuses on structural and molecular approaches to understanding processes involved in carcinogenesis and tumorigenesis. The Branch also supports integrated and systems biology approaches in cancer biology, employing high throughput technologies, information science, and computational modeling. Research interests include structural biology; genomics; proteomics; molecular and cellular imaging; nanotechnology; enzymology; bio-related and combinatorial chemistry; bioinformatics; and modeling and theoretical approaches to cellular and molecular cancer biology. The Branch also supports the development and application of technologies to advance cancer biology.

The *Tumor Biology and Metastasis Branch* supports research that seeks to understand the interactions of cancer cells with the tumor or host microenvironment to delineate the molecular mechanisms and signaling pathways of tumor growth, angiogenesis, lymphangiogenesis, cell migration and invasion, and tumor progression and metastasis. This includes examination of cell-cell and cell-matrix interactions and matrix-degrading enzymes, and the roles played by cellular growth factors and cytokines, cell adhesion molecules, cytoskeleton, the nuclear matrix and lamins, the pathobiology of solid tumors and tumor bearing animals, and the development of technology to facilitate these studies. An area of emphasis is the microenvironment created by inflammation and the inflammatory signaling molecules in tumor initiation and progression, and elucidating the role of tumor stem cells in tumor initiation and metastasis. Emphasis is also placed on the following areas: the role of the extracellular matrix and tissue microenvironment in development and tissue morphogenesis; the role of glycoproteins and proteoglycans in tumor growth, invasion, and metastasis; the role of caveolae/lipid rafts and plasma membranes; and the role of steroid hormones, their receptors and coactivators during tumor growth, progression and the acquisition of the hormone independent phenotype. Models used in these studies may include animal models, tumor tissues/cells, their components, or their products. Special attention is also given to delineating mechanisms of organ-specific metastasis, and the development of organotypic models that closely mimic in vivo models is encouraged.

The *Mouse Models of Human Cancers Consortium (MMHCC)* is a multi-disciplinary program of human/mouse integrative cancer research. The MMHCC is composed of twenty-five groups of investigators, numbering more than 300 members at 70 institutions in the US and abroad. The Consortium has substantial crosscutting expertise in all areas of cancer research. This enables the Consortium to address major questions about the natural history and clinical course of human cancers. Together, the MMHCC members use novel strategies to derive appropriate cancer-prone mice and compare them to the corresponding human diseases. They also promote the application of cancer models to translational and population research.

The MMHCC is an NCI cooperative group whose members work closely with the NCI to provide information resources for the entire cancer research community through the eMICE website (<http://emice.nci.nih.gov>). The website provides access to a cancer models database (<http://cancermodels.nci.nih.gov>), a cancer images database (<http://cancerimages.nci.nih.gov>), and the NCI Mouse Repository (<http://mouse.ncifcrf.gov/>), which accepts donations of mouse cancer models from the research community and deploys them worldwide.

The *Integrative Cancer Biology Program (ICBP)* promotes the analysis of cancer as a complex biological system, with an ultimate goal of developing reliably predictive in silico models for development of cancer interventions and understanding. The complexity of cancer together with increases in information concerning the cancer cell and its environment raises both challenges and opportunities in modern cancer biology. A comprehensive understanding of these genome-scale datasets depends on our ability to apply computational or mathematical modeling to them. The development of models is necessary as a framework for data analysis and validation. In turn, new data will help to refine model development. Multi-component, interactive processes at the sub-cellular, cellular, tissue, and organ levels should be amenable to modeling and simulation in ways previously limited by the lack of adequate data. Because this field is largely undeveloped, this is an opportunity to facilitate its development.

To address this opportunity, we currently support 9 centers employing over 100 investigators in a variety of approaches and cancer systems. All of the centers require a concerted effort at integrating the various disciplines into a collaborative systems biology program consisting of a cohesive group of dedicated researchers working on a common problem in cancer biology. This requires the involvement of scientists with new areas of expertise, particularly from the computational disciplines of mathematics, engineering, physics, and computer science. The need for quantitative data will drive the development of new instrumentation and methods. The organization and representation of these data streams and their relation to preexisting knowledge will require bioinformatics advances, and the development of computer-based cancer biology hypotheses and intra- and inter-cellular simulations will require mathematical expertise, as will the development of new theoretical frameworks. Because of the dependence on computational approaches, the ICBP is also closely linked to the NCI CaBIG initiative. ICBP is also committed to the development of a strong educational and outreach program for the NCI community.

The Beamline Initiative - The National Cancer Institute through The Division of Cancer Biology has joined with the Institute of General Medicine to construct a new, state of the art, experimental facility for structural biology. Structural biology plays a critical role in both basic research into cancer mechanisms and translational research into structure based drug design. Beginning in 2005, this X-Ray crystallography facility, the GM/CA CAT, a part of the Advanced Photon Source at Argonne National Lab, will provide the cancer community access to three state of the art experimental stations to facilitate the determination of the atomic structures of important cancer related molecules. This information may be used to develop and refine high-resolution pictures of the mechanisms behind the development of cancers, develop and refine targets for rational drug design, and develop and refine chemotherapeutics for use in the clinic.

Additional information about NCI's Division of Cancer Biology can be found at <http://dcb.nci.nih.gov> or <http://cancer.gov>.

Division of Cancer Control and Population Sciences

The Division of Cancer Control and Population Sciences (DCCPS) strives to understand the causes and distribution of cancer in populations; support the development and implementation of effective interventions; and monitor and explain cancer trends. DCCPS both generates new knowledge and seeks to ensure that the products of cancer control research are effectively applied in all segments of the population.

The Office of Cancer Survivorship supports research that explores the long and short term physical and psychological effects of cancer and its treatment. The Office provides a focus within the NIH for the support of research and education aimed at professionals who deal with cancer patients and survivors. In consultation with the medical and consumer communities, the Office articulates and coordinates a research strategy that will result in improvement in the quality of life, and a reduction in morbidity and mortality in cancer survivors.

The Applied Research Program evaluates patterns and trends in cancer associated health behaviors and practices, genetic susceptibilities, outcomes, and services. The Program monitors

and evaluates cancer control activities in general and specific populations in the United States and determines the influence of these factors on patterns and trends in cancer incidence, morbidity, mortality, and survival. The Program is comprised of three branches: Health Services and Economics, Outcomes Research, and Risk Factor Monitoring and Methods.

The *Behavioral Research Program* supports investigations ranging from basic behavioral research to research on the development and dissemination of interventions in areas such as tobacco use, dietary behavior, sun protection, decision making, and counseling about testing for cancer susceptibility and participation in cancer screening. The Program is comprised of the Applied Cancer Screening Research Branch, Basic Biobehavioral Research Branch, Health Communication and Informatics Research Branch, Health Promotion Research Branch, and Tobacco Control Research Branch.

The *Epidemiology and Genetics Research Program* supports population-based research to increase our understanding of the etiology and prevention of cancer. Staff manages and fosters a range of etiologic research on genetic, environmental, infectious, hormonal, lifestyle, and pharmacologic factors in cancer etiology. The Program includes the Analytic Epidemiology Research Branch and the Clinical and Genetic Epidemiology Research Branch.

The *Surveillance Research Program* supports cancer surveillance and health services research to answer key questions about cancer incidence and mortality in diverse regions and populations of the U.S. The Surveillance, Epidemiology, and End Results Program (SEER), a major component of the Program, collects cancer data on a routine basis from designated population-based cancer registries in various areas of the country. The Program includes the Cancer Statistics Branch and the Statistical Research and Applications Branch.

Additional information about NCI's Division of Cancer Control and Population Sciences can be found at <http://cancercontrol.cancer.gov>.

Division of Cancer Prevention

The Division of Cancer Prevention (DCP) is the primary unit of the National Cancer Institute devoted to cancer prevention research. DCP works through 11 Research Groups that focus on either defined scientific subject areas or specific organ systems.

The *Chemopreventive Agent Development Research Group* focuses on the identification, preclinical development, and qualification of potential cancer preventive agents for phase I clinical studies. Research includes all classes of agents and a wide range of methodologies and technologies. This group also manages the Rapid Access to Preventive Intervention Development program (RAPID), which helps bridge the gap between discovery and clinical testing; supports clinical trial development, agent acquisition, Investigational New Drug (IND) – directed toxicology and related research; and provides technical support and research resources to extra- and intramural investigators and industry for chemopreventive agent development.

The *Community Oncology and Prevention Trials Research Group* works to improve clinical oncology in community settings via the Community Clinical Oncology Program. The CCOP promotes interaction between community oncologists and clinical cooperative groups; stimulates psychosocial and physical rehabilitation research; develops and conducts research on the management of cancer pain and on supportive care for patients and families; studies the impact of cancer control programs on the community; and conducts preliminary Phase II cancer control studies of education, attitudes, and behavior of health professionals to serve as the basis for subsequent cancer control studies. NCI's large-scale prevention trials are coordinated through the CCOP program, including the Study of Tamoxifen and Raloxifene (STAR) for breast cancer prevention and the Selenium and Vitamin E Cancer Prevention Trial (SELECT) for prostate cancer prevention.

The *Nutritional Science Research Group* generates and tests hypotheses relating diet to the

causation and prevention of cancer; and works to establish a comprehensive understanding of the precise role of bioactive food components in determining cancer risk and tumor behavior. The group seeks to determine how specific genes and/or molecular targets are influenced by either essential or non-essential nutrients, allowing the identification of people who will or will not benefit from a prevention intervention.

The *Basic Prevention Science Research Group* integrates fundamental research from intramural and extramural divisions to study the role of molecular markers in cancer prevention. Specific components of this approach include the molecular genetics of cancer risk and the molecular pathogenesis of precancer and cancer. Specimens under study by this group are generated from population studies as well as clinical trials, and the ultimate goal is to apply accumulated data to clinical trials in cancer prevention.

The *Cancer Biomarkers Research Group* is the principal resource in the NCI for biomarker information pertaining to cancer detection and risk assessment. This group of basic and clinical scientists support research for the development and validation of promising early cancer biomarkers for risk prediction and early detection of cancer, including development of databases and informatics systems to track the utility of new biomarkers and new or refined technologies for studying the molecular circuitry of preneoplastic cells. The Early Detection Research Network, a program of translational research to identify early cancer and cancer risk, is managed by this group.

The *Early Detection Research Group* develops scientific information and concepts to aid in the dissemination of knowledge of early detection techniques, practices, and strategies to reduce mortality and morbidity from cancer. This group manages and supports clinical trials for early detection and analyzes research results on screening; fosters technology development and statistical modeling of new technologies; and encourages the publication of scientific findings and adoption of early detection practices. NCI's large-scale early detection trials are coordinated through this program, including the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) and the National Lung Screening Trial (NLST).

The *Biometry Research Group* plans and conducts independent and cooperative research studies on cancer epidemiology, prevention, screening, and diagnosis using methods of mathematical and analytic statistics. This Group provides consultation and advice on biostatistical methodology, study design, and biometry to investigators inside and outside of NCI.

The four organ-specific research groups in DCP are the *Breast and Gynecologic Cancer Research Group*, the *Gastrointestinal and Other Cancers Research Group*, the *Lung and Upper Aerodigestive Cancer Research Group*, and the *Prostate and Urologic Cancer Research Group*. Each group focuses on cancer sites within their defined organ group, overseeing and supporting research in chemoprevention, nutrition, and other prevention strategies that include nutritional, pharmacologic, biologic, and genetic approaches; vaccine development or immunologic intervention; cancer screening and early detection. Each group supports clinical trials that lead to new technologies for identifying and modifying premalignant lesions as well as trials that develop agents based on measures of efficacy, such as cancer incidence reduction. Surrogate endpoint biomarkers studies also measure the modulation of the biomarkers as a potential indicator of efficacy.

In addition to the research groups, the *Office of Preventive Oncology* leads an accredited program to train individuals from diverse health science disciplines in the field of cancer prevention and cancer control. NCI-sponsored venues comprise a summer curriculum, mentored research, a weekly colloquia series, and condensed field assignments at other institutions.

Additional information about NCI's Division of Cancer Prevention can be found at <http://www3.cancer.gov/prevention> or <http://cancer.gov>.

Division of Cancer Treatment and Diagnosis

The Division of Cancer Treatment and Diagnosis (DCTD), through its cancer research programs, identifies the most promising areas of science and technology for development of better diagnostic and therapeutic interventions for the wide range of cancers affecting children and adults.

The Division of Cancer Treatment and Diagnosis Office of the Director (OD) plans, directs, and coordinates the Division's research activities in the treatment and diagnosis of cancer supported by grants, contracts, and cooperative agreements with universities, private industry, other Federal agencies.

The *Cancer Imaging Program* promotes and supports outstanding basic, translational, and clinical research in the imaging sciences and technology, and applies the discoveries to solving national healthcare needs in cancer.

The *Cancer Diagnosis Program* stimulates and supports research aimed at the development of better tools to aid in the clinical management of cancer patients.

The *Cancer Therapy Evaluation Program* plans, assesses, and coordinates all aspects of clinical trials including extramural clinical research programs, internal resources, treatment methods and effectiveness, and compilation and exchange of data as it pertains to the development and evaluation of anticancer agents.

The *Developmental Therapeutics Program* stimulates and supports research programs directed towards preclinical development of therapeutic modalities for cancer.

The *Radiation Research Program* catalyzes and supports research programs directed towards clinical radiation research.

The *Biometric Research Branch* provides the statistical methods for the development and clinical testing of diagnostics, imaging technologies, and therapeutics.

Additional information about NCI's Division of Cancer Treatment and Diagnosis can be found at <http://cancer.gov/dctd> or <http://cancer.gov>.

Division of Extramural Activities

The Division of Extramural Activities (DEA):

1. administers and directs the National Cancer Institute's grant and contract review activities;
2. provides for receipt, referral, and initial technical and scientific merit review of grants and contracts for the Institute;
3. represents the Institute on overall NIH extramural and collaborative program policy committees and coordinates such policy for the review and administration of grants and contracts;
4. coordinates the Institute's review of research grants and training programs with the National Cancer Advisory Board and the President's Cancer Panel;
5. administers and coordinates the development and implementation of committee management policies within the Institute and provides the Institute's staff support for the National Cancer Advisory Board, the President's Cancer Panel, the Board of Scientific Advisors, and the Board of Scientific Counselors;
6. administers and coordinates the operation of the Boards of Scientific Advisors to assure uniformity and timeliness of the concept review of extramural projects to be developed under grant, contract or in response to RFAs;
7. coordinates program planning and evaluation in the extramural area; and
8. provides scientific reports and analyses on research conducted by the Institute's grant and contract programs.

Additional information about NCI's Division of Extramural Activities can be found at <http://deainfo.nci.nih.gov> or <http://cancer.gov>.

Intramural Research

Center for Cancer Research

NCI's Center for Cancer Research (CCR) was created in March 2001 by merging two vital components of the NCI's Intramural Research Program – the Division of Basic Sciences and the Division of Clinical Sciences. This merger, initiated by former NCI Director Richard Klausner, M.D. was an important step in the goal to promote closer links between basic researchers and clinical investigators, thereby enhancing their opportunities for both scientific discovery and translational research (bench-to-bedside and bedside-to-bench). CCR is committed to supporting and training young scientists and clinicians as they launch their careers in basic and clinical research. CCR offers numerous predoctoral, postdoctoral, and clinical training positions with world-class scientists and physicians who are outstanding mentors and experts in their respective fields.

CCR is composed of over 300 Principal Investigators in 54 Laboratories, Branches, and Programs. As one of the world's largest cancer research centers, CCR takes advantage of the breadth of its researchers to foster interdisciplinary programs and facilitate translational research. Basic research is a strength of CCR, with areas of investigation including immunology, carcinogenesis, human genetics, mouse genetics, viral oncology, HIV, chromatin biology, structural biology, DNA replication and recombination, signal transduction, apoptosis, cell cycle regulation, cytokines and chemokines, cellular, molecular and developmental biology, medicinal chemistry and natural products chemistry, molecular pharmacology, xenobiotic metabolism, radiation biology, computational biology, and bioinformatics. Areas of excellence in clinical and translational research include cancer vaccines, clinical proteomics, molecular targets of cancer, molecular imaging, biologic mediators, cell-based therapies, immunotoxin therapy, radiation therapy, cancer genetics, molecular epidemiology, cancer prevention, multidrug resistance, clinical pharmacology, angiogenesis, and molecular pathology.

New Scientific Opportunities in Interdisciplinary and Translational Research. The CCR mission is to reduce the burden of cancer through exploration, discovery, and translation. The goals of the NCI restructuring with the creation of the Center for Cancer Research are to foster interdisciplinary research, facilitate translational research, expedite technology development, enhance training, particularly in interdisciplinary and translational research, and build partnerships between NCI and other NIH Institutes, Federal agencies, academia, biotechnology companies and the pharmaceutical industry.

CCR, along with the Division of Cancer Epidemiology and Genetics, has defined new institutional approaches to translate scientific knowledge towards achieving more effective cancer prevention, intervention, and treatment. The goal is to create an integrated, multidisciplinary research environment that brings together scientists from diverse fields to work on translating basic research findings into clinical applications. Collaboration, technology support and development, and access to resources are critical to achieving this goal. NCI has responded to this challenge by establishing Faculties composed of scientists from diverse laboratories and branches working cooperatively with a common interest in a particular discipline, disease, or approach to scientific discovery. Faculties foster collaboration, open access to new technologies and clinical resources, and challenge NCI researchers to become more involved in clinical research.

The goals of the faculties are to promote translational and interdisciplinary research, develop new technologies and resources, enhance mentoring, recruitment and training of fellows, improve communication through retreats and seminars, sponsor visiting scientists, provide strategic planning and oversight, and advise NCI leadership on important and innovative programs critical to the success of the NCI Intramural Program.

The Medical Oncology Clinical Research Unit (MOCRUC) was recently established to enhance the

medical oncology clinical infrastructure and to enhance clinical investigation within the CCR. The MOCRU is a group of physicians who conduct clinical studies on a specific disease or therapeutic area as a team effort. The MOCRU is composed of Clinical Research Sections in breast cancer, genitourinary/gynecologic malignancies, vaccines, lymphoma, transplantation, immunotherapy, AIDS malignancies, lung/gastrointestinal cancer, and clinical genetics. Institutional support for the program is also provided through a Phase I Clinical Research Section, scientific core services, and offices for clinical operations, protocol support, research nurses, nurse practitioners, physician's assistants, fellowship training, translational research, and Navy-Oncology. The mission of the MOCRU is to provide access to clinical research across the Center, excellence in clinical care, clinical training opportunities, and career growth for clinical staff.

Technology Development and Support. Technology development and support is another important goal of the CCR intramural program. Current technology initiatives include clinical proteomics, molecular targets drug discovery, microarray technology, animal models development, and imaging technologies. The proteomics initiative involves the search for new serum markers for cancer, development of antibody chips, protein arrays and reverse phase chips, a mass spectrometry center, protein expression laboratory and bioinformatics support. The molecular targets discovery program provides a full range of drug discovery scientific support; advising scientists on molecular target discovery, development of screening assays, conducting screens of pure compound libraries, validation of hits, and assistance in preclinical and clinical development of promising lead compounds. The microarray initiative uses modern lab automation and robotic methods for the production of gene microarrays to allow simultaneous study of the differential expression of large numbers of genes in normal, diseased, or treated cells. The animal models initiative includes transgenic and knockout core services, molecular and comparative pathology support, mouse proteomics, rodent imaging, phenotyping core support, and an animal brain tumor therapeutic and diagnostic core. The imaging initiative incorporates clinical imaging, advanced imaging applications, experimental and innovative technologies, and animal imaging into an interrelated imaging resources program.

Mentoring and Training. The CCR places a particular emphasis on training the next generation of investigators in basic, interdisciplinary, and translational cancer research. Programs offered in the CCR include Accreditation Counsel on Graduate Medical Education (ACGME) accredited residency programs in anatomic pathology, radiation oncology, and dermatology. Additionally, ACGME clinical fellowship training programs in medical oncology, pediatric hematology/oncology, hematology/pathology, and cytology/pathology are available. Fellowship programs in surgical oncology, urological oncology, neuro-oncology, HIV and AIDS malignancy, gynecologic oncology, cancer epidemiology, cancer genetics and cancer prevention are also offered. Translational research opportunities include fellowships in Multidisciplinary Breast Cancer Research, Postdoctoral Fellowships in Radiation Sciences, Clinical Cancer Research Fellowship for Ph.D.s., and a Training Program in Veterinary Pathology. Interdisciplinary fellowship programs include a Biostatistics/Mathematics Training Fellowship (Informatics Training Program) and a Program for Interdisciplinary Training in Chemistry.

The Center is actively involved in the recently established NIH-Graduate Program Partnership initiative, which attracts outstanding graduate students to CCR laboratories. Areas of partnership currently under development include bioinformatics, chemistry, and comparative pathology. The Cancer Research Training Award and the Visiting Fellows program for foreign trainees are available in all the Laboratories, Branches, and Programs.

The CCR Office of Training and Education (OTE) was created in November of 2001 to support the training and mentoring experience for postdoctoral fellows. The OTE mission is to have a programmatic impact on the overall training experience of the basic scientists and clinical fellows in cancer research. This mission is achieved by facilitating and promoting training opportunities for fellows utilizing NCI, NIH, and academic courses; planning and implementing new courses and training programs to prepare fellows as successful independent biomedical researchers; providing opportunities for secondary mentors and expanded collaborative interactions; providing funding mechanisms to reward outstanding research efforts by postdoctoral fellows; implementing funding mechanisms such as the Career Development Awards (K22) to facilitate the fellows'

competitiveness as candidates for academic faculty positions; assisting trainees as they transition into academic positions and offering exposure to alternative career paths; and assisting investigators in the recruiting of new postdoctoral candidates. The major responsibilities of the OTE include the CCR Fellows and Young Investigators Retreat, the Tenure Track Investigators Retreat, exceptional pay increases for Postdoctoral Fellows, the CCR Fellows Editorial Board, and the Summer Intern Program. The OTE serves as a resource for the fellows' community and as a liaison to the Office of the Director. The Office of Training and Education will represent the Center both within the NIH and at outside meetings and institutions to recruit quality scientific and professional staff for the research programs.

Partnerships with Academia and Industry. CCR is committed to forming partnerships that encourage technology development with industry, academia and the private sector. CCR scientists and clinicians have a history of successful research collaborations with colleagues nationally and internationally. The CCR is also active in the area of technology transfer and strives to ensure that scientific breakthroughs reach the public through formal agreements between the government and industry. During the last year there were over 140 active Collaborative Research and Development Agreements (CRADAs) between CCR investigators and outside institutions. These CRADA collaborations were with more than 85 different organizations.

In addition, CCR has further excelled through partnership by participating in many informal collaborations and formal collaborations by way of material transfer agreements, licensing agreements, and memorandums of understanding.

Unique Aspects of the Intramural Research Program. The juxtaposition of basic and clinical researchers in this large, diverse yet highly interactive Center provides exceptional translational research and training opportunities. With the resources available at the NIH Clinical Center, which houses over 50% of the NIH-funded general clinical research center beds in the U.S., CCR scientists have a unique environment to move new drugs and diagnostics quickly from the bench to the bedside. Medical care is provided without charge to patients enrolled on NCI protocols.

CCR is a center of excellence for vaccine development and cell-based cancer immunotherapies utilizing specialized expertise, techniques and facilities that exist within the Intramural Program. An example of the uniqueness of the Intramural Program is seen in the basic and clinical proteomics initiative – a collaboration between the NCI and the FDA built on Laser Capture Microdissection technology. Laser Capture Microdissection, developed in the CCR Laboratory of Pathology, involves identification and extraction of microscopic homogenous cellular subpopulations from surrounding tissue.

This technology is now being used to isolate tumor versus normal cellular subpopulations to identify potential molecular targets for cancer therapies. The long-range commitment needed to develop the technology to accurately identify specific targets for various cancers requires support that is unique to the Intramural Research Program. Another component of the proteomics initiative is the identification of novel markers for early cancer detection.

These types of long-term, high-risk projects can accelerate the pace of medical research with public health importance and have an immeasurable impact on improving the nation's health care.

The Future. With the creation of CCR, communication, collaborations, and translational research opportunities among the intramural scientists have been increased. To go from bench to bedside and back requires an environment that is not available to most individual investigators or at most research institutions. CCR is unique in having strong basic and clinical components within the same institutional organization and an institutional infrastructure that facilitates the translation of discoveries from the laboratory to the clinic and, in turn, submits clinical observations back to the laboratory for further analysis.

The CCR and the Intramural Research Program are an invaluable resource for generating initiatives that will help guide and shape the direction of the NCI. CCR will continue to serve as a model for

interdisciplinary and translational biomedical research programs, and lead the development of new technologies, provide advanced training for the next generation of cancer scientists, and pioneer new avenues for cancer prevention, diagnosis and treatment.

Additional information about NCI's Center for Cancer Research can be found at <http://ccr.cancer.gov>.

Division of Cancer Epidemiology and Genetics

Through its broadly-based programs in epidemiology, genetics, statistics, and related areas, the Division of Cancer Epidemiology and Genetics (DCEG) carries out population-based and interdisciplinary research both nationally and internationally to discover the genetic and environmental determinants of cancer. DCEG is uniquely positioned to conduct epidemiologic research projects that are high-risk in nature and require (a) long-term commitments of scientific staff and funding support through contracts, (b) a coordinated national programmatic approach, or (c) a rapid response to emerging public health or scientific issues. The Division develops multi-disciplinary infrastructures and resources for use throughout the scientific community, including database management software for biospecimen inventories and family-based studies, a variety of software packages for exposure assessment and for estimation of dietary intake, and interactive cancer atlases to generate leads into the environmental determinants of cancer. DCEG also has a firm commitment to training the next generation of scientists, and has developed specialized tracks in genetic epidemiology, radiation epidemiology, molecular epidemiology, and biostatistics. The research conducted by the Division often provides a scientific basis for public health recommendations and policies.

The Epidemiology and Biostatistics Program consists of six branches that conduct independent and collaborative epidemiologic and biostatistical investigations to identify the distribution, characteristics, and causes of cancer in human populations. The Program investigates demographic variation in the occurrence of cancer by age, race, gender, geography, and over time (descriptive studies). Special emphasis is placed on the studies into carcinogenic effects of occupational and environmental exposures, ionizing and non-ionizing radiation, dietary and nutritional factors, medicinal agents such as hormones, infectious agents, and host factors including genetic susceptibility to cancer-causing exposures. The Program also develops biostatistical methods for family-based and population-based studies.

The Human Genetics Program provides an expanded focus for interdisciplinary research into the genetic determinants of human cancer. Its two branches explore and identify heritable factors that predispose to cancer, including studies of gene-environment interactions. Program investigators study cancer-prone families to identify and clone predisposing genes; investigate the prevalence of identified genes in the general population; conduct pharmacogenetic studies to evaluate genetic polymorphisms as determinants of cancer risk and treatment outcomes; develop new methodologies in genetic epidemiology; and translate advances in molecular genetics into evidence-based management strategies, such as genetic testing and counseling, cancer screening and prevention strategies, and assessment of social and behavioral aspects of heritable cancer.

The DCEG fellowship program allows participants to design, conduct, and analyze research related to the etiology of cancer in human populations. Fellows participate in protocol development and data collection; feasibility studies; case-control and prospective cohort studies; family-based studies; genetic and biochemical assays; and manuscript preparation and publication. Opportunities exist to initiate new investigations, compete for funding, and present at scientific meetings. Professional skills development and preparation for a future career in epidemiology are an integral part of the program. Postdoctoral training lasts for up to 5 years under the mentorship of NCI senior scientists, with opportunities to work with multiple researchers on a variety of projects. The fellowships may be tailored to one or more specialty tracks including molecular, genetic, occupational, environmental, radiation, viral, and nutritional epidemiology, as well as biostatistics and cancer health disparities.

Additional information about NCI's Division of Cancer Epidemiology and Genetics can be found at <http://dceg.cancer.gov>.



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National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892



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National Eye Institute

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Mission

The National Eye Institute (NEI) conducts and supports research, training, health information dissemination, and other programs with respect to blinding eye diseases, visual disorders, mechanisms of visual function, preservation of sight, and the special health problems of individuals who are visually impaired or blind.

Vision research is supported by the NEI through research grants and training awards made to scientists at more than 250 medical centers, hospitals, universities, and other institutions across the country and around the world. The NEI also conducts laboratory and patient-oriented research at its own facilities located on the NIH campus in Bethesda, Maryland.

Another part of the NEI mission is to conduct public and professional education programs that help prevent blindness and reduce visual impairment. To meet these objectives, the NEI has established the National Eye Health Education Program, a partnership of more than 60 professional, civic, and voluntary organizations and government agencies concerned with eye health. The program represents an extension of the NEI's support of vision research, where results are disseminated to health professionals, patients, and the public.

Important Events in NEI History

August 16, 1968 – Public Law 90-489 authorized formation of the National Eye Institute.

December 26, 1968 – The National Eye Institute was established.

April 3-4, 1969 – The National Advisory Eye Council held its first meeting.

January 11, 1970 – Dr. Carl Kupfer was appointed NEI director.

December 15, 1970 – Reorganization of NEI resulted in the formation of an Office of Biometry and Epidemiology; an Office of the Director of Intramural Research; and a Laboratory of Vision Research and a Clinical Branch as the foci of intramural research.

April 1975 – Publication of the National Advisory Eye Council's report, *Vision Research Program Planning*, was the first comprehensive assessment of major needs and opportunities in vision research in the United States.

April 1978 – Publication of the National Advisory Eye Council's 5-year plan, *Vision Research: 1978-1982*, included review and analysis of vision research and research training in the United States and discussion of future priorities.

September 1978 – A Laboratory of Sensorimotor Research was established within the intramural research program.

November 1978 – Public Law 95-623, Health Services Research, Health Statistics, and Health Care Technology Act, authorized NEI to carry out a grants program for construction or renovation of public and nonprofit private vision research facilities.

June 1981 – A Laboratory of Molecular and Developmental Biology was established within the intramural research program.

May 1983 – The National Advisory Eye Council's second 5-year plan (1983-87) recommended future NEI programs.

July 19, 1984 – The Office of Biometry and Epidemiology was transferred out of the Office of the Director and established as the Biometry and Epidemiology Program (now Division of Epidemiology and Clinical Research).

August 1985 – An Intramural Research Program reorganization abolished the Laboratory of Vision Research and created the Laboratories of Mechanisms of Ocular Diseases; Retinal Cell and Molecular Biology; and Immunology.

1987 – The National Advisory Eye Council's, *Vision Research – A National Plan: 1983-1987, 1987 Evaluation and Update*, discussed accomplishments since the 1983-87 plan was published, evaluated the status of NEI-supported research activities, and revised priorities for the next 2 years.

December 1987 – The Collaborative Clinical Vision Research Branch was established to provide overall scientific management and administration for NEI grants, contracts, and cooperative agreements supporting clinical trials and epidemiologic studies.

February 1989 – The Office of International Program Activities was created to enhance coordination of NEI's international activities, particularly those relating to cooperation with nongovernmental organizations, international agencies, and the international components of other Federal agencies.

February 10, 1990 – The Ophthalmic Genetics and Clinical Services Branch (now Ophthalmic Genetics and Visual Function Branch) was established in the intramural program.

December 1991 – NEI established the National Eye Health Education Program (NEHEP), which it coordinates in partnership with national organizations in the public and private sector that conduct eye health education programs. The focus of the NEHEP is on public health education programs that encourage early detection and timely treatment of glaucoma and diabetic eye disease and the appropriate treatment for low vision.

Spring 1993 – Spring 1995 – A "Celebration of Vision Research" commemorated the NEI's 25th anniversary.

June 1993 – The NEI and its advisory body, the National Advisory Eye Council (NAEC), produced and distributed its fifth long-range plan, *Vision Research – A National Plan: 1994-1998*, that contained policy recommendations and scientific program priorities.

June 1998 – The NEI and National Eye Advisory Council (NAEC) produced and distributed *Vision Research – A National Plan: 1999-2003*, that contained policy recommendations and scientific program priorities. In developing this 5-year plan, the NEI and NAEC assembled panels of over 100 experts representing each of NEI's formal programs and special interest areas. In drafting this plan, special consideration was given to the purpose, intent, and requirements of the Government Performance and Review Act.

October 19, 1999 – The NEI launched the Low Vision Education Program, part of the National Eye Health Education Program.

2000 – NEI designated lead agency for new focus area on vision in HHS's Healthy People 2010.

July 15, 2000 – Dr. Carl Kupfer steps down after 30 years as Director of the NEI; Dr. Jack A. McLaughlin named Acting Director, NEI.

June 17, 2001 – Dr. Paul A. Sieving assumes duties as Director, NEI.

October 2003 – The NEI published and released its *National Plan for Eye and Vision Research*. The first strategic plan produced through the new, two-phase planning process. This ongoing planning process involves the assessment of important areas progress in eye and vision research and the development of new goals and objectives that address outstanding needs and opportunities for additional progress. Workshops, conferences, or symposia in critical or emerging areas of science are conducted during the second phase of the planning process to explore how they might be applied to diseases of the eye and disorders of vision.

Biographical Sketch of NEI Director Paul A. Sieving, M.D., Ph.D.

Dr. Sieving became director of the National Eye Institute in June 2001. He came from the University of Michigan where he was the Paul R. Lichter Professor of Ophthalmic Genetics and director of the Center for Retinal and Macular Degeneration in the Department of Ophthalmology and Visual Sciences. During his training, he studied nuclear physics at Yale Graduate School in 1970-73 and attended Yale Law School from 1973-74. He obtained his M.D. from the University of Illinois Medical School in 1978, and a Ph.D. in bioengineering from the University of Illinois Graduate School in 1981. Dr. Sieving did his ophthalmology residency at the University of Illinois Eye and Ear Infirmary in Chicago, and he then completed fellowship training at the University of California, San Francisco, and at Harvard Medical School.

Dr. Sieving's area of personal research is in human hereditary retinal and macular degenerations. He maintains a clinical practice for patients with these genetic forms of retinal disease which are otherwise known by the terms retinitis pigmentosa and Stargardt macular degeneration. His laboratory is studying pharmacological approaches to retard degeneration in transgenic and naturally occurring animal models that are corollaries of human eye disease. He served as the vice chair for clinical research for The Foundation Fighting Blindness, Baltimore, MD, from 1996-2001. Dr. Sieving has received a number of awards, including Distinguished Alumnus Award, Valparaiso University, 1991; membership in the American Ophthalmological Society, 1993; The Best Doctors in America: Midwest Region, 1996-97; RPB Senior Scientific Investigator Award, 1998, Alcon Award, Alcon Research Institute, 2000; The Best Doctors in America, 1998-99 and 2001-2002; and Doctor of Science (Honorary), Valparaiso University; 2003.

Major Programs

The NEI's extramural research activities are organized into six areas: retinal diseases; corneal diseases; lens and cataract; glaucoma and optic neuropathies; strabismus, amblyopia, and visual processing; and low vision and blindness rehabilitation.

Retinal Diseases

NEI-supported investigations include studies of the development, molecular and cell biology, and metabolism of the photoreceptor cells and their dependence on the underlying retinal pigment epithelium; the mechanism of the retina's response to light and the initial processing of information that is transmitted to the visual centers of the brain; and the pathogenesis, etiology, and molecular biology and genetics of retinal diseases such as diabetic retinopathy; uveitis; ocular melanoma; retinitis pigmentosa, age-related macular degeneration, and retinal detachment.

Corneal Diseases

NEI-supported projects include studies of the regulation of genes that express proteins unique to corneal tissue; details of the assembly of corneal extracellular matrices; mechanisms that maintain corneal hydration and transparency; physiologic basis for immune privilege in the cornea; cell biology of corneal wound healing; corneal biomechanics; and the pathogenesis of corneal transplant rejection.

Lens and Cataract

NEI-supported research includes studies of normal lens development and aging; the molecular and cellular characterization of lens transparency; control of lens cell division; structure and regulation of the expression of lens-specific genes; the impact of environmental insults on the lens; and the pathogenesis of human cataract.

Glaucoma and Optic Neuropathies

NEI supports a range of research designed to better understand the pathophysiology underlying glaucoma, the discovery of drugs and surgical techniques for its treatment, the basis of racial and ethnic disparities in the incidence and severity of the disease, and the development of procedures for earlier diagnosis. Studies include the molecular genetics of glaucoma syndromes; physiologic mechanisms regulating fluid flow in the disease; the cell and molecular biology of optic nerve damage; ganglion cell death; and neuroprotection.

Strabismus, Amblyopia, and Visual Processing

The NEI supports studies concerned with the function of the neural pathways from the eye to the brain, the central processing of visual information, visual perception, the optical properties of the eye, the function of the pupil, and control of the ocular muscles. Support is provided for research on eye movement disorders, and the development of myopia. Particular emphasis is placed on studies of strabismus and amblyopia, as these are frequent causes of lifelong visual impairment.

Low Vision and Blindness Rehabilitation

The NEI supports research in low vision and rehabilitation of people with visual impairments. Examples include projects aimed at improving the methods of specifying, measuring, and categorizing loss of visual function; devising strategies to help visually impaired people maximize the use of their residual vision; systematically evaluating new and existing visual aids; and studying the optical, electronic, and other rehabilitative needs of people with visual impairments.

This page was last reviewed on December 27, 2005 .

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National Institutes of Health (NIH)
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National Heart, Lung, and Blood Institute

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Until October 10, 1969, the National Heart Institute; until June 25, 1976, the National Heart and Lung Institute.

Mission

The National Heart, Lung, and Blood Institute (NHLBI):

- Provides leadership for a national program in diseases of the heart, blood vessels, lungs, and blood; sleep disorders; and blood resources.
- Plans, conducts, fosters, and supports an integrated and coordinated program of basic research, clinical investigations and trials, observational studies, and demonstration and education projects related to the causes, prevention, diagnosis, and treatment of heart, blood vessel, lung, and blood diseases, and sleep disorders conducted in its own laboratories and by scientific institutions and individuals supported by research grants and contracts.
- Plans and directs research in development, trial, and evaluation of interventions and devices related to the prevention of diseases and disorders in the above areas and the treatment and rehabilitation of patients suffering from such conditions.
- Conducts research on clinical use of blood and all aspects of the management of blood resources.
- Supports research training and career development of new and established researchers in fundamental sciences and clinical disciplines to enable them to conduct basic and clinical research related to heart, blood vessel, lung, and blood diseases; sleep disorders; and blood resources through individual and institutional research training awards and career development awards.
- Coordinates relevant activities with other research institutes and all Federal health programs in the above areas, including the causes of stroke.
- Conducts educational activities, including development and dissemination of materials for health professionals and the public in the above areas, with emphasis on prevention.
- Maintains continuing relationships with institutions and professional associations, and with international, national, state, and local officials as well as voluntary agencies and organizations working in the above areas.
- Oversees management of the Women's Health Initiative.

Important Events in NHLBI History

June 16, 1948 — President Harry S Truman signed the National Heart Act, creating and establishing the National Heart Institute (NHI) in the Public Health Service (PHS) and the National Advisory Heart Council.

August 1, 1948 — Surgeon General Leonard A. Scheele, by General Circular No. 36, Organization Order No. 14, established the NHI as one of the National Institutes of Health to assume responsibility for heart research, training, and administration as set forth in the National Heart Act. Intramural research projects in cardiovascular diseases (CVD) and gerontology, conducted elsewhere in NIH, were transferred to the NHI. The director of the NHI was designated to lead and coordinate the total PHS heart program.

September 8, 1948 — The National Advisory Heart Council held its first meeting. Dr. Paul Dudley White served as the Council's Executive Director.

January 1949 — Cooperative research units were established at the University of California, University of Minnesota, Tulane University, and Massachusetts General Hospital. Pending completion of the NHI's own research organization and availability of further research facilities, the units were jointly financed by the NIH and the institutions.

July 1, 1949 — The NHI intramural research program was established.

The Heart Disease Epidemiology Study at Framingham, Massachusetts, was transferred from the Bureau of State Services, PHS, to the NHI.

July 6, 1953 — The Clinical Center admitted its first patient for heart disease research.

July 1, 1957 — The first members of the NHI Board of Scientific Counselors began their terms. The Board was established in 1956 "to provide advice on matters of general policy, particularly from a long-range viewpoint, as they relate to the intramural research program."

February 19, 1959 — The American Heart Association and the NHI presented a report to the Nation on "A Decade of Progress Against Cardiovascular Disease."

October 16, 1968 — A Nobel Prize in Physiology or Medicine was awarded to Dr. Marshall W. Nirenberg, chief of the NHI Laboratory of Biochemical Genetics, for discovering the key to deciphering the genetic code. Dr. Nirenberg was the first NIH Nobel laureate and the first Federal employee to receive a Nobel Prize.

October 26, 1968 — The NHI received the National Hemophilia Foundation's Research and Scientific Achievement Award for its "medical leadership ... tremendous stimulation and support of research activities directly related to the study and treatment of hemophilia."

November 10, 1969 — The NHI was renamed the National Heart and Lung Institute (NHLI), reflecting expansion of functions.

February 18, 1971 — In his Health Message to the Congress, President Richard M. Nixon identified sickle cell anemia as a high-priority disease target and called for increased Federal expenditures. Subsequently, the Health, Education, and Welfare (HEW) Assistant Secretary for Health and Scientific Affairs, assigned the NIH and NHLI as the lead agencies responsible for coordinating a National Sickle Cell Disease (SCD) Program.

June 12, 1972 — HEW Secretary Elliot Richardson approved a nationwide program of hypertension information and education. The secretary appointed the Hypertension Information and Education Advisory Committee, chaired by the Director, NIH, and the Interagency Working Group, chaired by

the Director, NHLI, to implement the national effort.

July 1972 — The NHLI initiated the National High Blood Pressure Education Program (NHBPEP).

July 14, 1972 — Secretary Richardson approved a reorganization of NHLI, elevating the Institute to Bureau status within the NIH.

June 25, 1976 — The NHLI was renamed the National Heart, Lung, and Blood Institute (NHLBI), reflecting an expansion in blood-related activities within the Institute.

November 1979 — The results of the Hypertension Detection and Follow-up Program (HDFP), a clinical trial initiated by the NHLBI in 1971, provided evidence that systematic, aggressive treatment of hypertension saves lives.

October 1981 — The NHLBI Beta-Blocker Heart Attack Trial demonstrated benefits to those in the trial who received propranolol compared with the control group.

October 1983 — The NHLBI Coronary Artery Surgery Study results demonstrated that mildly symptomatic patients with coronary artery disease can safely defer coronary artery bypass surgery until symptoms worsen.

January 1984 — The NHLBI Lipid Research Clinics Coronary Primary Prevention Trial established conclusively that reducing total blood cholesterol reduces the risk of coronary heart disease in men at increased risk because of elevated cholesterol levels. Each 1 percent decrease in cholesterol was shown to reduce heart attack risk by 2 percent.

April 1985 — Phase I of the NHLBI Thrombolysis in Myocardial Infarction Trial found that the new thrombolytic agent recombinant tissue plasminogen activator (rt-PA) is approximately twice as effective as streptokinase in opening thrombosed coronary arteries.

November 1985 — The NHLBI initiated the National Cholesterol Education Program (NCEP).

June 1986 — Results of the NHLBI Prophylactic Penicillin Trial demonstrated the efficacy of prophylactic penicillin in reducing morbidity and mortality associated with pneumococcal infections in children with SCD.

March 1989 — The NHLBI initiated the National Asthma Education Program. The program was later renamed the National Asthma Education and Prevention Program (NAEPP).

September 1990 — Scientists from the NHLBI and the National Cancer Institute began the first gene therapy trial in a human patient, a 4-year-old girl with an inherited immune dysfunction.

January 1991 — The NHLBI developed an Obesity Education Initiative to educate the public and health professionals about obesity as an independent risk factor for CVD and its relationship to other risk factors such as high blood pressure and high blood cholesterol.

June 1991 — The NHLBI initiated the National Heart Attack Alert Program.

July 1991 — The NHLBI Systolic Hypertension in the Elderly Program demonstrated that low-dose pharmacologic therapy of isolated systolic hypertension in those over age 60 significantly reduces stroke and myocardial infarction.

August 1991 — The NHLBI Studies of Left Ventricular Dysfunction demonstrated that use of enalapril — an angiotensin converting enzyme inhibitor — causes significant reduction in mortality and hospitalization for congestive heart failure in patients with symptomatic heart failure.

January 1995 — Results of the NHLBI Multicenter Study of Hydroxyurea demonstrated that hydroxyurea reduced the number of painful episodes by 50 percent in severely affected adults with SCD. This is the first effective treatment for adult SCD patients.

September 1995 — Results of the NHLBI Bypass Angioplasty Revascularization Investigation demonstrated that patients on drug treatment for diabetes who had blockages in two or more coronary arteries and were treated with coronary artery bypass surgery had, at five years, a markedly lower death rate than similar patients treated with angioplasty.

May 1996 — Framingham Heart Study investigators concluded that earlier and more aggressive treatment of hypertension is vital to preventing congestive heart failure.

The Treatment of Mild Hypertension Study demonstrated that lifestyle approaches, such as weight loss, a healthy eating plan, and physical activity, are crucial for reducing blood lipids in those treated for Stage I hypertension.

September 1996 — Findings from the NHLBI Asthma Clinical Research Network indicated that inhalation of a beta-agonist at regularly scheduled times is safe for people with asthma but provides no greater benefit than use of the medication only when asthma symptoms occur.

November 1996 — Two studies, the Dietary Approaches to Stop Hypertension (DASH) trial and the Trial of Nonpharmacologic Intervention in the Elderly, that show that lifestyle changes, such as modifying one's diet and losing weight, substantially reduce blood pressure in adults and eliminate the need for antihypertensive medication in some older patients.

January 1997 — Results from the Pathobiological Determinants of Atherosclerosis in Youth program showed that atherosclerosis develops before age 20 and that high density lipoprotein cholesterol, low density lipoprotein cholesterol, and cigarette smoking affect progression of atherosclerosis equally in women and men regardless of race.

May 1997 — Results from the Antiarrhythmic versus Implantable Defibrillator clinical trial demonstrated that implantable cardiac defibrillators are superior to antiarrhythmic drug therapy for improving overall survival for patients with life-threatening heart arrhythmias.

October 1, 1997 — The NHLBI is given responsibility for the Women's Health Initiative (WHI), a study begun in 1991 to address chronic diseases in women.

March 1999 — A large clinical trial of mechanical ventilator use for intensive care patients with acute respiratory distress syndrome demonstrated that approximately 25 percent fewer deaths occurred among patients receiving small, rather than large, breaths of air from a mechanical ventilator.

August 1999 — The Early Revascularization for Cardiogenic Shock study showed improved survival, at 6 months, in patients treated with balloon angioplasty or coronary bypass surgery compared with patients who received intensive medical care to stabilize their condition.

September 2000 — NHLBI-supported investigators identified a gene for primary pulmonary hypertension.

January 2001 — Results of the Dietary Approaches to Stop Hypertension (DASH) Sodium Trial showed that dietary sodium reduction substantially lowers blood pressure in persons with high blood pressure; the greatest effect was seen when sodium reduction was combined with a diet rich in fruits and vegetables and low in saturated fat previously shown to lower blood pressure (i.e., the DASH diet).

April 2001 — The NHLBI released international guidelines for diagnosis, management, and prevention of chronic obstructive pulmonary disease.

July 2001 — A self-contained artificial heart was implanted in a patient for the first time.

September 2001 — The NHLBI, along with the American Heart Association and other partners, launched a national Act in Time to Heart Attack Signs campaign to increase awareness of the symptoms of heart attack and the need for a fast response.

July 2002 — The NHLBI stopped early the trial of estrogen plus progestin component of the WHI due to increased breast cancer risk and lack of overall benefits. The multicenter trial also found increases in coronary heart disease, stroke, and pulmonary embolism in participants on estrogen plus progestin compared to women taking placebo pills. In 2004, the WHI component evaluating estrogen-alone hormone therapy also was stopped early because the long-term risks of the medications outweighed the long-term benefits.

December 2002 — Results of the NHLBI Atrial Fibrillation Follow-up Investigation of Rhythm Management Trial indicated that a strategy involving rate control rather than rhythm control may be the preferred treatment for patients with atrial fibrillation. The rate control strategy involves the use of less expensive drugs and fewer hospitalizations.

December 2002 — Results from the NHLBI Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT), the largest hypertension clinical trial ever conducted, showed that traditional diuretics are at least as good as newer medicines (calcium channel blockers and ACE inhibitors) to treat high blood pressure and to prevent some forms of heart disease. These findings were in addition to ALLHAT results from 2000, when researchers reported that an alpha-adrenergic blocker was less effective than the diuretic in reducing risk of some forms of CVD.

January 2003 — A study demonstrated that magnetic resonance imaging can detect heart attacks faster and more accurately than traditional methods in patients who arrive at an emergency room with chest pain.

February 2003 — The NHLBI Prevention of Recurrent Venous Thromboembolism (PREVENT) trial was stopped because treatment with low-dose warfarin to prevent recurrence of the blood clotting disorders deep vein thrombosis and pulmonary embolism was found to benefit the patients.

May 2003 — The NHLBI National Emphysema Treatment Trial found that lung volume reduction surgery benefits emphysema patients who have certain clinical characteristics. The findings will help determine the Medicare coverage policy for the surgery.

July 2003 — The NHLBI and Gen-Probe Corporation developed a test to screen donated blood for the West Nile virus.

March 2004 — Preliminary results of the NHLBI Sudden Cardiac Death in Heart Failure study demonstrated that an implantable cardiac defibrillator can reduce the risk of death for from arrhythmiaheart failure patients.

August 2004 — The NHBPEP Working Group on High Blood Pressure in Children and Adolescents released *The Fourth Report on the Diagnosis, Evaluation, and Treatment of High Blood Pressure in Children and Adolescents* .

August 2004 — An NHLBI-funded study showed that nucleic acid-amplification testing for HIV-1 and hepatitis C virus further safeguards the nation's blood supply.

October 2004 — Researchers participating in the NHLBI Asthma Clinical Research Network

demonstrated that genetic differences affect how adult patients with mild asthma respond, over time, to daily doses of inhaled albuterol (a drug used for relief of acute asthma symptoms).

November 2004 — Results of the NHLBI Prevention of Events with Angiotensin Converting Enzyme Inhibition study demonstrated that many coronary heart disease patients who were receiving state-of-the-art therapy do not gain extra cardiovascular protection from ACE inhibitors.

December 2004 — The NHLBI Stroke Prevention Trial II showed that children with SCD who receive transfusions to prevent stroke revert to high risk for stroke when transfusions are stopped. STOP II was initiated after an earlier trial demonstrated that periodic red blood cell transfusions reduce the stroke rate by 90 percent among high-risk children with SCD.

January 2005 — The NHLBI issued new guidelines for managing asthma during pregnancy.

February 2005 — NHLBI-supported scientists identified two genetic mutations common in individuals of African descent that are associated with a 40 percent reduction in LDL cholesterol.

April 2005 — Results of the NHLBI Azithromycin and Coronary Events Study showed that a one-year course of weekly azithromycin (an antibiotic) does not alter the risk of cardiac events among patients with stable coronary artery disease.

NHLBI Legislative Chronology

June 16, 1948 — The National Heart Act (P.L. 80-655) authorized NHI. The act's purpose was "To improve the health of the people of the United States through the conduct of researches, investigations, experiments, and demonstrations relating to the cause, prevention, and method of diagnosis and treatment of diseases of the heart and circulation; assist and foster such researches and other activities by public and private agencies, and promote the coordination of all such researches and activities and the useful application of their results; provide training in matters relating to heart diseases, including refresher courses for physicians; and develop, and assist States and other agencies in use of the most effective methods of prevention, diagnosis, and treatment of heart diseases."

December 30, 1963 — House Joint Resolution 848 (P.L. 88-254) authorized and requested the President to issue an annual proclamation designating February as American Heart Month, inviting governors of states and territories to issue similar proclamations.

May 16, 1972 — The National Sickle Cell Anemia Control Act (P.L. 92-294) established a national program for diagnosis, control, and treatment of and research in sickle cell anemia. The act did not mention NHLI but had special pertinence because NHLI was designated to coordinate the National Sickle Cell Disease Program.

September 19, 1972 — The National Heart, Blood Vessel, Lung, and Blood Act of 1972 (P.L. 92-423) enlarged institute authority to advance the national attack on heart, blood vessel, lung, and blood diseases. The act provided for expanded, intensified, and coordinated institute activities in accordance with a comprehensive, specified National Heart, Blood Vessel, Lung, and Blood Disease Program to be planned by the director and the Advisory Council.

It also called for establishment of prevention and control programs; development of 15 new centers for basic and clinical research, training, demonstration, and prevention programs for heart, blood vessel, and blood diseases; and development of 15 such centers for chronic lung diseases.

June 25, 1976 — Title I of the Health Research and Health Services Amendments of 1976 (P.L. 94-278) redesignated NHLI as NHLBI to advance the national attack on heart, blood vessel, lung, and blood diseases, and to conduct research in use of blood and blood products and in management of blood resources. The NHLBI director and the National Heart, Lung, and Blood Advisory Council

continue to plan the national program under the basic P.L. 92-423 provisions with some refinements.

August 1, 1977 — The Biomedical Research Extension Act of 1977 (P.L. 95-83) reauthorized NHLBI, with continued emphasis on both the national program and related prevention and dissemination activities.

December 17, 1980 — The Health Programs Extension Act of 1980 (P.L. 96-538) reauthorized NHLBI, with continued emphasis on both the national program and related prevention programs.

January 4, 1983 — The Orphan Drug Act (P.L. 97-414) amended the Public Health Service Act to mandate development and support of not less than 10 comprehensive centers for sickle cell disease.

November 20, 1985 — The Health Research Extension Act (P.L. 99-158) reauthorized the NHLBI, provided for the establishment of information dissemination and education programs, and provided for an Associate Director for Prevention.

September 20, and November 4, 1988 — The National Bone Marrow Donor Registry (P.L. 100-436, P.L. 100-607) was established. With enactment of these authorization and appropriation measures, NHLBI was given the task of developing an implementation plan for the voluntary bone marrow registry. Responsibility for the Registry later was transferred to the Health Resources and Services Administration.

June 10, 1993 — The NIH Revitalization Act of 1993 (P.L. 103-43) established a National Center on Sleep Disorders Research within NHLBI.

October 31, 1998 — Section 104 of the Women's Health Research and Prevention Amendments (P.L. 105-340) instructed the NHLBI director to expand and intensify research and related activities of the institute with respect to heart attack, stroke, and other CVDs in women and to collaborate with other NIH institutes.

October 17, 2002 — The Children's Health Act (P.L. 106-310) mandated that the Director, NHLBI, through the Coordinating Committee of the National Asthma Education and Prevention Program, develop a federal plan for responding to asthma and recommended ways to strengthen coordination of federal asthma-related activities.

Biographical Sketch of NHLBI Director Elizabeth G. Nabel, M.D.

Elizabeth G. Nabel, Director of the National Heart, Lung, and Blood Institute (NHLBI) of the National Institutes of Health, joined the NHLBI in September 1999 as the Institute Scientific Director of Clinical Research. Dr. Nabel is a board-certified cardiologist who has taken care of many patients with cardiovascular disease, including women with heart disease. Previously she had been Chief, Division of Cardiology, Director, Cardiovascular Research Center, and Professor of Internal Medicine and Physiology at the University of Michigan.

A native of Minneapolis, Minnesota, Dr. Nabel received her medical education at Cornell University Medical College before moving to Brigham and Women Hospital and Harvard University where she completed an internship and residency in internal medicine and a clinical and research fellowship in cardiovascular medicine.

She joined the faculty at the University of Michigan in 1987 as an Assistant Professor of Medicine and rose through the ranks, becoming Director of the Cardiovascular Research Center in 1992, Professor of Internal Medicine and Physiology in 1994, and Director of the Division of Cardiology in 1997. While at the University of Michigan, she became known for her research in the field of vascular biology and molecular cardiology and for her gene transfer studies of the cardiovascular system.

Dr. Nabel has had a longstanding interest in genetic and cellular therapies for cardiovascular disease, having developed techniques for the introduction and expression of recombinant genes into blood vessels in vivo. Her group has conducted a number of basic studies, investigating the expression and function of growth factor, cytokine, and cell cycle genes in the vasculature. Those studies led to several clinical gene therapy trials of cardiovascular diseases in the United States and Europe.

Dr. Nabel has intertwined basic research and translation to clinical medicine and practice throughout her career and has championed the concept of “bench to bedside.” Her current research interests are focused on the regulation of vascular growth and the molecular genetics of vascular diseases. Dr. Nabel has investigated the regulation of smooth muscle cell growth by cell cycle regulatory proteins, a process important for the development of atherosclerosis and restenosis.

Her Vascular Biology Lab at the NIH has characterized the role of the cyclin-dependent kinase inhibitors on vascular proliferation, inflammation, and progenitor cells using a variety of genetic tools. The inhibitors are important negative regulators of vascular smooth muscle cell growth and vascular inflammation, and work from her lab has opened up new avenues for therapeutic targets in the vasculature. She is also conducting clinical studies examining genomics and proteomics in vascular diseases, such as one study of in-stent restenosis. The Vascular Biology Lab has published more than 200 papers and Dr. Nabel has mentored 42 students and fellows associated with her lab.

Dr. Nabel has received numerous awards, including the Distinguished Achievement Award from the Basic Cardiovascular Sciences Council of the American Heart Association and the Amgen-Scientific Achievement Award from the American Society for Biochemistry and Molecular Biology. She is an elected member of the American Society of Clinical Investigation, the Association of American Physicians, and the Institute of Medicine of the National Academy of Sciences. In 2001, Dr. Nabel received an honorary doctoral degree from the University of Leuven, Leuven, Belgium.

Dr. Nabel is an editorial board member of *The New England Journal of Medicine*. She has been a reviewing editor for *Science* and an editorial board member of the *Journal of Clinical Investigation*. She also served as a consulting editor for *Circulation*, *Circulation Research*, and *Arteriosclerosis, Thrombosis, and Vascular Biology*.

Dr. Nabel has served on American Heart Association committees, including the Board of Directors; the Scientific Publishing Committee (Chair); the Atherosclerosis, Thrombosis and Vascular Biology Council (Chair); the executive committee of the Basic Cardiovascular Sciences Council; and the Science Advisory and Coordinating Committee.

Other national and international leadership roles include President of the North American Vascular Biology Organization, Councilor of the American Society of Clinical Investigation, member of the Board of Directors for the Keystone Symposium, member of the Scientific Advisory Board of The Stanley J. Sarnoff Endowment for Cardiovascular Science, and member of the membership committee of the Institutes of Medicine. She has also served on international advisory committees including the Center for Transgene Technology and Gene Therapy and the Center for Molecular and Vascular Biology at the University of Leuven, and the International Vascular Biology Organization.

NHLBI Directors

Name	In Office From	To
Cassius James Van Slyke	August 1, 1948	November 30, 1952
James Watt	December 1, 1952	September 10, 1961
Ralph E. Knutti	September 11, 1961	July 31, 1965
William H. Stewart	August 1, 1965	September 24, 1965
Robert P. Grant	March 8, 1966	August 15, 1966

Donald S. Frederickson	November 6, 1966	March 1968
Theodore Cooper	March 15, 1968	April 19, 1974
Robert I. Levy	September 16, 1975	June 1981
Claude Lenfant	July 1, 1982	September 2, 2003
Elizabeth G. Nabel	February 1, 2005	Present

NHLBI Programs

NHLBI research programs are implemented through five extramural program units [the Division of Heart and Vascular Diseases (DHVD), the Division of Epidemiology and Clinical Applications (DECA), the Division of Lung Diseases (DLD), the Division of Blood Diseases and Resources (DBDR), and the National Center on Sleep Disorders Research (NCSDR)], one extramural service division [the Division of Extramural Affairs (DEA)], and one intramural unit [the Division of Intramural Research (DIR)]. The NHLBI also has primary responsibility for the Women's Health Initiative (WHI). Research grants, program project grants, specialized center grants, cooperative agreements, research contracts, research career development awards, and institutional and individual national research service awards are used to support research and research training. Specific programs foster career development. A more detailed description of NHLBI activities is contained in the NHLBI Factbook (<http://www.nhlbi.nih.gov/about/factpdf.htm>).

Extramural Research

Division of Heart and Vascular Diseases

The DHVD plans and directs a coordinated research program on the causes of heart and vascular diseases and on their prevention, diagnosis, and treatment. Multidisciplinary programs advance basic knowledge of disease and improve clinical management and prevention strategies. Clinical trials are an important part of the research program; they provide an opportunity to test and apply promising preventive or therapeutic measures.

The Division is organized into three programs:

- The Heart Research Program
- The Vascular Biology Research Program
- The Clinical and Molecular Medicine Program

The *Heart Research Program* supports clinical and fundamental studies in cardiac diseases from embryonic life through adulthood. Specific areas include heart arrhythmias and electrical abnormalities, cardiomyopathies, normal and abnormal cardiac development, pediatric heart disease, heart failure and cardiogenic shock, ischemic heart disease, inflammation and infectious disorders of the heart, exercise physiology, heart transplantation, and myocardial preservation.

The *Vascular Biology Research Program* supports investigations in atherosclerosis, hypertension, vascular biology, and gene therapy for prevention and treatment of vascular diseases. Other areas are the etiology, pathogenesis, and treatment of CVD in diabetes mellitus, molecular medicine and atherosclerosis, molecular genetics of hypertension, and cardiovascular complications of HIV/AIDS.

The *Clinical and Molecular Medicine Program* supports clinical, basic, and engineering research on CVD and health. Areas of interest include genetic, genomic, and proteomic research; bioengineering; informatics and simulation; and clinical trials in disease mechanisms, management, and treatment. Although the primary focus is on studies involving patients with CVD, rather than the general population, other areas, such as the role of lipid interventions, nutrition, and exercise also are pursued. Bioengineering projects include innovative ventricular assist systems, implantable total artificial hearts, genetically enhanced cardiovascular implants, magnetic resonance angiography, mathematical models and simulation, imaging, biomaterials, tissue engineering, and other

therapeutic devices. Genomic applications include development of animal models of disease, support of human and model organism genomic resources, and advances in bioinformatics to understand heart, lung, and blood diseases.

Division of Epidemiology and Clinical Applications

The DECA plans, directs, and evaluates research on the causes, prevention, diagnosis, and treatment of cardiovascular, lung, and blood disease. It supports epidemiologic studies, clinical trials, demonstration and education research, disease prevention and health promotion research, and basic and applied research in behavioral medicine. It provides training and professional development in cardiovascular, lung, and blood diseases and sleep disorders research for individuals at all stages of their careers.

The Division is organized into two programs, the Clinical Applications and Prevention Program and the Epidemiology and Biometry Program, and the Office of Biostatistics Research.

The *Clinical Applications and Prevention Program* oversees research in prevention of heart and vascular, pulmonary, and blood diseases through activities such as clinical trials, community interventions, health education research, nutrition research, and behavioral medicine. It supports large studies in hypertension, heart failure, hyperlipidemia, and platelet aggregation. Prevention and education programs test interventions to reduce CVD risk factors when delivered in a community or outpatient setting. Ongoing programs include studies of prevention and treatment of hyperlipidemia, obesity, and other risk factors in children and adolescents; interventions to improve delivery of care using evidence-based guidelines; and community-wide prevention programs.

The *Epidemiology and Biometry Program* oversees studies of heart and vascular, lung, and blood diseases using clinical epidemiology, genetic epidemiology, and analytical resources. Studies focus on development and progression of risk factors in children and young adults; development and progression of atherosclerosis in middle-aged or older adults; and development and progression of overt CVD and pulmonary disease in older adults. Also emphasized are genetic and environmental influences on CVD and its risk factors; trends in incidence, prevalence, and mortality from CVD, stroke, peripheral vascular disease, congestive heart failure, and cardiomyopathy; and relationships between insulin, insulin resistance, and overt diabetes and CVD and its risk factors.

The *Office of Biostatistics Research* provides statistical expertise to all NHLBI Divisions and performs diverse functions in planning, design, implementation, and analysis of NHLBI-sponsored studies. Designing efficient trials and monitoring data collection are important functions of the Office. It develops statistical solutions to problems for which techniques are not yet available. Research includes new methods for permitting extension or early suspension of ongoing clinical trials and for analyzing complex survival data, trials with multiple endpoints, and trials involving multiple treatments.

Division of Lung Diseases

The DLD plans and directs a coordinated research program on the causes and progression of lung diseases and on their prevention, diagnosis, and treatment. Activities focus on understanding the structure and function of the respiratory system, increasing fundamental knowledge of mechanisms associated with pulmonary disorders, and applying new findings to evolving treatment strategies for patients.

The Division is organized into two programs:

- The Airway Biology and Disease Program
- The Lung Biology and Disease Program

The *Airway Biology and Disease Program* focuses on basic and clinical research, education, and

training related to topics including asthma, bronchiolitis (bronchopneumonia), chronic obstructive pulmonary diseases, cystic fibrosis, gene therapies for patients who have airway diseases, and respiratory neurobiology. Research programs include delineation of the genetic and metabolic defects underlying pulmonary complications associated with cystic fibrosis and alpha-1-proteinase inhibitor deficiency, pathogenesis of smoking — and environmentally related airway diseases, genetics and treatment of asthma, and neurochemicals that control breathing.

The *Lung Biology and Disease Program* supports research, education, and training programs in lung cell and vascular biology; lung growth and development; pediatric lung disease; acute lung injury and critical care medicine; interstitial lung diseases, including pulmonary fibrosis; and AIDS and tuberculosis (TB). Projects include a clinical network for treatment of acute respiratory distress syndrome; activities to address pathobiology of TB and *Pneumocystis carinii* and basic cell biology of pulmonary manifestations of AIDS; and a program to develop lung specific drug delivery systems for enhanced TB treatment.

Division of Blood Diseases and Resources

The DBDR plans and directs a coordinated research program on the causes and prevention of blood diseases and disorders. Areas of interest encompass a broad spectrum of research from stem cell biology to medical management of blood diseases, with a focus on non-malignant and pre-malignant processes. The Division also has a major responsibility to improve the adequacy and safety of the Nation's blood supply. It has taken a leading role in developing cell-based therapies, combining the expertise of transfusion medicine and stem cell technology with the exploration of repair and regeneration of human tissues and biological systems.

The Division is organized into three programs:

- The Blood Diseases Program
- The Thrombosis and Hemostasis Program
- The Blood Resources Program

The *Blood Diseases Program* supports research and training in nonmalignant disorders affecting red blood cells, including anemias, erythropoiesis, iron overload, malaria, SCD, and thalassemia. It oversees the Comprehensive Sickle Cell Centers, which collectively form a SCD clinical research network and individually conduct basic and clinical research while providing state-of-the-art patient care, educational activities for patients and health professionals, community outreach, and genetic counseling services.

The *Thrombosis and Hemostasis Program* supports research and training in hemostasis, thrombosis, and endothelial cell biology. It focuses on understanding the pathogenesis of both arterial and venous thrombosis to improve diagnosis, prevention, and treatment of thrombosis in heart attack, stroke, and peripheral vascular diseases. Areas of interest include gene transfer, clinical proteomics, inflammation and thrombosis, coagulation activation, autoimmune disease, and thrombotic complications of obesity, diabetes, and cancer. A major goal is to find platelet inhibitors, anticoagulants, and fibrinolytic agents for improving treatments of thrombotic and thromboembolic disorders. Finding an effective treatment for hemophilia is another priority. Bleeding disorders associated with defects in coagulation proteins or abnormal platelet function, such as the immune thrombocytopenias, also are being studied.

The *Blood Resources Program* supports research and training in transfusion medicine, stem cell biology and disease, and cell-based therapies. Areas of interest include transmission of disease through transfusion, development of methods to detect and inactivate viruses in donated blood, improvement of blood donor screening procedures, and identification of emerging diseases that may be transmitted by blood transfusions. It also supports basic and clinical investigations related to transfusion immunobiology, focusing on graft-versus-host disease and graft-versus-leukemia effect.

National Center on Sleep Disorders Research

The NCSDR plans, directs, and supports a program of basic, clinical, and applied research; health education; and prevention-related research in sleep and sleep disorders. It oversees developments in its program areas; assesses the national need for research on causes, diagnosis, treatment, and prevention of sleep disorders and sleepiness; and coordinates sleep research activities across the Federal Government and with professional, voluntary, and private organizations. Research topics include cellular, molecular, and genetic basis of sleep and its disorders; epidemiology of sleep and sleepiness in health and disease; effects of sleep loss on the waking function of the brain, other systems, and behavior; and pathophysiology and optimal management of common sleep disorders. Development of programs to train investigators to become sleep researchers is also a priority.

Division of Extramural Affairs

The DEA provides a number of services to the Institute. For example, it represents the Institute on overall NIH committees on extramural program policies and oversees compliance with such policies within the NHLBI. It also provides grant and contract management and processing services to the Institute's program divisions, and conducts initial scientific merit review of applications for research project grants, program project and center grants, research training and development grants, cooperative agreements, and research contracts. In addition, the DEA coordinates the Institute's Committee Management Activities and the meetings of the National Heart, Lung, and Blood Advisory Council.

Women's Health Initiative

When the WHI was established in 1991, it consisted of three major components: randomized controlled clinical trials of promising but unproven approaches to prevention, an observation study to identify predictors of disease, and a study of community approaches to developing healthful behaviors. The community component, which was completed in 2000, focused on strategies to persuade women, especially those of different races, ethnic groups, and socioeconomic strata, to adopt healthful behaviors. The clinical trials and the observational study, consisting of more than 167,000 women, 50 to 79 years of age, sought to answer questions on benefits and risks of hormone replacement therapy and changes in dietary patterns and calcium/vitamin D supplements in disease prevention.

The clinical trials of estrogen-plus-progestin and estrogen-alone hormone therapies were stopped early because researchers found that the long-term risks of the medications outweighed the long-term benefits. The observational study and the clinical trials of Dietary Modification and of Calcium and Vitamin D Supplements ended in March 2005 as originally planned. Now, participants are completing annual health forms as part of the WHI Extension Study, which will continue until 2010. Biologic resources from the studies will be available to the broader scientific community in 2006.

Examples of FY 2005 Research Initiatives

In FY 2005, the NHLBI initiated programs to:

- Improve methods of diagnosing, preventing, and treating cardiomyopathies, left ventricular dysfunction, metabolic abnormalities, congestive heart failure, and rhythm disturbances.
- Develop and test behavioral interventions to reduce CVD risk in American Indians and Alaska Natives interventions.
- Elucidate mechanisms and consequences of asthma exacerbation and define pathways that are altered during resolution of exacerbations.
- Understand the causes of, and molecular pathways involved in, acute exacerbations of chronic obstructive pulmonary disease.
- Evaluate existing or new medications, combinations of medications, and treatment strategies for patients who have idiopathic pulmonary fibrosis.

- Develop treatments for SCD patients who have pulmonary complications and encourage research on the role of upper airway obstruction and sleep disturbances in acute chest syndrome and other pulmonary complication of SCD.
- Develop a quality-of-life questionnaire for use in clinical trials and outcomes research among adults with SCD.
- Understand immune reactions and safety issues related to therapies for hemophilia and other hereditary bleeding disorders.
- Discover cellular and genetic markers associated with the origin and progression of myeloproliferative disorders.
- Determine the etiology and pathophysiology of myelodysplastic syndrome.
- Improve the safety, efficacy, and availability of blood, blood and bone marrow components, and plasma derivatives.
- Establish a clinical proteomics program to validate candidate protein markers that will enable early detection of heart, lung, blood, and sleep disorders.
- Apply nanotechnology and nanoscience to the diagnosis and treatment of heart, lung, blood, and sleep disorders.
- Support preclinical and clinical studies on cell-based therapy for treatment of heart, lung, and blood diseases.

Office of Prevention, Education, and Control

The OPEC, located in the NHLBI Office of the Director, conveys results of heart, lung, and blood research to health care professionals, their patients, and the public. It disseminates and translates up-to-date research findings that will help practitioners be more effective and provides scientific knowledge to patients and the public that will enable them to make "healthy decisions."

The *National High Blood Pressure Education Program* (NHBPEP) was established in 1972 to translate and disseminate research findings and scientific consensus about high blood pressure to improve medical care outcomes and the public's health. In collaboration with a coordinating committee consisting of national medical, public health, and voluntary organizations and other Federal agencies, the NHBPEP strives to increase public awareness about high blood pressure, promote activities to encourage detection of the disease especially among underserved groups, and encourage hypertensive patients to seek medical care and follow their doctor's advice. In 2005, the NHBPEP launched a campaign, Prevent and Control High Blood Pressure: Mission Possible, to help organizations throughout the country more aggressively promote high blood pressure prevention and control. The campaign incorporates recommendations from the Seventh Report of the Joint National Committee on the Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VII), which the NHLBI released in May 2003.

The *National Cholesterol Education Program* (NCEP) was initiated in 1985 to educate health professionals and the public about high blood cholesterol as a risk factor for coronary heart disease (CHD) and about benefits of lowering cholesterol levels to reduce illness and death from CHD. In 2005, the NCEP and the National Center for Health Statistics developed a paper, Trends in Serum Lipids and Lipoproteins of Adults: National Health and Nutrition Examination Surveys, 1960–2002, that showed continued decline in total and LDL cholesterol levels among older age groups, and a reduction to 17 percent of U.S. adults who have high total cholesterol levels, thereby meeting one of the Healthy People 2010 objectives for the Nation. In collaboration with the NHLBI Obesity Education Initiative, the NCEP developed Your Guide to Lowering Your Cholesterol with TLC, which provides advice on implementing therapeutic lifestyle changes (TLC) — diet, physical activity, and weight management — to control elevated blood LDL cholesterol levels, as well as the metabolic syndrome. The guide reflects the latest recommendations from the NCEP's Adult Treatment Panel III (ATP III) for the detection, evaluation, and treatment of high blood cholesterol in adults.

The *National Asthma Education and Prevention Program* (NAEPP) was initiated in 1989 to raise awareness of asthma as a serious, chronic disease; to promote more effective management of asthma through professional, patient, and public education; and to provide up-to-date information on asthma care. It employs a number of outreach strategies and works with schools, health care

professionals, and patients to improve asthma care, prevent disruptions of daily routine, limit hospitalizations, and reduce deaths caused by uncontrolled asthma. In 2005, the NAEPP issued new treatment guidelines for managing asthma during pregnancy that emphasize the importance of controlling asthma not only for the well-being of the mother, but also for the healthy development of the fetus.

The *National Heart Attack Alert Program* (NHAAP) was initiated in 1991 to reduce morbidity and mortality from acute myocardial infarction and sudden cardiac arrest through education of health care professionals, patients, and the public about the importance of rapid identification and treatment of individuals with heart attack symptoms. In 1997, the program broadened its scope to include early identification and treatment of individuals with acute coronary syndromes encompassing unstable angina as well as acute heart attack. In 2005, the NHAAP continued to promote Act in Time to Heart Attack Signs, a campaign to urge physicians, in collaboration with allied health care providers, to educate their patients about heart attack risk, warning signs, and survival.

The NHLBI *Obesity Education Initiative* (OEI) was initiated in 1991 to inform health care professionals and the public on the health risks associated with overweight and obesity. Obesity is not only an independent risk factor for CVD, but also a contributor to high blood pressure and high blood cholesterol and is related to sleep apnea. OEI encourages individuals to adopt heart-healthy eating patterns and physical activity habits to reduce the prevalence of overweight and obesity and their related CHD risk factors along with sleep apnea, and thereby reduce morbidity and mortality from CHD. In 2005, the NHLBI, in collaboration with the National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of Child Health and Human Development, and the National Cancer Institute, launched We Can! (Ways To Enhance Children's Activity and Nutrition), a national education program to prevent overweight and obesity among youth, 8 to 13 years of age. Major elements of the program include community outreach, partnerships, and national media and consumer outreach.

The Office also coordinates the Institute's nutrition program. The NHLBI Nutrition Coordinator is the Institute's representative to other components of the NIH, the DHHS, and the Federal Government on nutrition research and policy. Major activities include contributing to the revised Dietary Guidelines for Americans, which was released by the DHHS and USDA in 2005; joining the DHHS/USDA discussions on revising the Food Guide Pyramid; and working with the U.S. Food and Drug Administration on consumer education efforts about food labels.

As a key part of its response to the Healthy People 2010 Objectives for the nation, the NHLBI established CVD educational outreach programs in high-risk communities. The programs — Enhanced Dissemination and Utilization Centers (EDUCs) — are partnerships between the NHLBI and local communities to eliminate cardiovascular health disparities and improve the health of underserved populations. Encouraging results from an EDUC with public housing residents in Baltimore, Maryland, has prompted discussions with potential partners to implement clinical and public health activities developed by the Baltimore EDUC in public housing communities throughout the nation.

The Institute's *Salud para su Corazón* (Health for Your Heart) Initiative, a community-based heart-health program for Latinos, has expanded across the United States to include communities along the U.S./Mexico border in Texas, California, and New Mexico. Trained local lay health workers (*promotores*), applying the values and culture of the communities and mobilizing partners, are teaching people how to reduce their risk of developing CVD. As advocates for change, they have increased the number of Latinos in their communities who are engaging in heart-healthy behaviors.

The NHLBI and the Indian Health Service have worked together since 2000 to bring heart health to American Indian and Alaska Native communities. Initial steps were focused on identifying the unique needs and issues that affect tribal communities. The NHLBI developed a training manual, *Honoring Your Gift of Heart Health*, for community instructors to enable them to provide a culturally appropriate 10-session course on heart health. In 2003, a national training workshop was held for key tribal leaders and health practitioners across the United States. In 2005, three additional training

workshops were completed.

The NHLBI Asian American and Pacific Islander Cardiovascular Health Outreach program has focused on underserved groups with high levels of CVD risk factors such as high blood pressure, obesity, and physical inactivity. To date, cardiovascular health educational materials have been developed for people of Filipino and Vietnamese heritage. Development of a school-based, intergenerational cardiovascular health education curriculum for Native Hawaiian elementary school children is underway.

The NHLBI Women's Heart Health Education Initiative was begun in 2001 to coordinate research and educational programs related to CVD in women. In 2002, it started The Heart Truth campaign to raise awareness of heart disease among women 40 to 60 years of age. Now, an extensive cadre of community and corporate partners are supporting the Institute's goal of reaching women with critical messages about heart health and promoting the red dress as the national symbol for women and heart disease awareness. A focus for the campaign in 2005 and 2006 is to expand outreach to women of color.

Chronic obstructive pulmonary disease (COPD) is another area of education emphasis for the NHLBI. In 2005, in response to recommendations made at an NHLBI-sponsored workshop on COPD, the Institute awarded a 3-year contract for planning, developing, implementing, and evaluating a COPD awareness and education campaign.

Education activities associated with von Willebrand disease were initiated in 2004. Recommendations from an expert panel convened by the NHLBI to review current literature on the diagnosis and treatment of von Willebrand disease are expected to be released in 2006.

Division Intramural Research

The DIR conducts laboratory and clinical research in heart, vascular, lung, blood, and kidney diseases and develops technology related to CVD and pulmonary diseases.

In FY 2005, the DIR was reorganized into four centers and four branches.

- Biochemistry and Biophysics Center
- Cell Biology and Physiology Center
- Genetics and Development Biology Center
- Immunology Center
- Cardiovascular Branch
- Hematology Branch
- Pulmonary Critical Care Medicine Branch
- Vascular Medicine Branch

The *Biochemistry and Biophysics Center* studies the molecular basis of structure–function relationships of proteins and biologically relevant molecules. It performs state-of-the-art studies of protein structure and functional interactions, develops mathematical tools for generating models of protein structure — function relationships, elucidates mechanisms of enzyme function, and investigates relationships between protein structure — function and cell signaling pathways.

The *Cell Biology and Physiology Center* evaluates mechanisms that control different molecular machines within the cytosol, including those involved in muscle contraction, and cytosolic and membrane transport processes. The Center studies cellular signaling events associated with hormone action, cytosolic trafficking, and energy metabolism; investigates the role of cellular processes on function and adaptation in whole animal model systems; and develops unique measuring devices for studying biochemical and physiological processes in intact cells, whole animals, and clinical situations.

The *Genetics and Development Biology Center* studies mechanisms that regulate cardiovascular development and the etiology of congenital heart anomalies and CVD. It evaluates the function of specific genes and transcription factors in the development heart and other tissues, develops techniques and approaches for gene delivery and gene therapy, and investigates processes that regulate and interpret the genetic code in development and disease.

The *Immunology Center* studies intracellular and signaling processes involved in the activation of lymphocytes and mast cells, investigates mechanisms by which drugs and other agents result in allergic — autoimmune reactions, and applies the results to the development of diagnostic and therapeutic approaches.

The *Cardiovascular Branch* develops new diagnostic and therapeutic modalities for treatment of CVD. It focuses on mechanistic studies and clinical protocols.

The *Hematology Branch* investigates normal and abnormal hematopoiesis in patients and in cellular, molecular, and immunologic laboratory research. It focuses on bone marrow failure, viral infections of hematopoietic cells, gene therapy of hematologic and malignant diseases, bone marrow transplantation, and mechanisms of immunologically mediated syndromes like graft-versus-host disease and autoimmune diseases.

The *Pulmonary Critical Care Medicine Branch* studies the lung and the cardiovascular system to define, at a molecular level, normal function and disease. It focuses on understanding biochemical and immunologic events involved in intra- and intercellular communication and organ function.

The *Vascular Medicine Branch* conducts research on the lung and vasculature directed at defining, on a molecular, biochemical, and functional level, normal physiological function and novel mechanisms of disease. It focuses on translational study and therapeutic modulation of physiological functions to mitigate vasculopathy in lung and heart disease.

This page was last reviewed on January 4, 2006 .

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National Institutes of Health (NIH)
9000 Rockville Pike
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The NIH Almanac – Organization

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National Human Genome Research Institute

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Mission

The National Human Genome Research Institute (NHGRI), established originally as the National Center for Human Genome Research in 1989, led the National Institutes of Health's (NIH's) contribution to the International Human Genome Project. This project, which had as its primary goal the sequencing of the 3 billion base pairs that make up human genome, was successfully completed in April 2003.

NHGRI's mission has evolved over the years to encompass a broad range of studies aimed at understanding the structure and function of the human genome and its role in health and disease. To that end, the institute supports the development of resources and technology that will accelerate genome research and its application to human health. A critical part of NHGRI's mission continues to be the study of the ethical, legal and social implications (ELSI) of genome research. NHGRI also supports the training of investigators, as well as the dissemination of genome information to the public and to health professionals.

NHGRI is organized into three main divisions: the Office of the Director, which provides guidance to scientific programs and oversees the general operation of the institute; the Division of Extramural Research, which supports and administers the role of NIH in genomic research; and the Division of Intramural Research, which is home to the institute's in-house, genetics research laboratories.

Research guidance and final approval of NHGRI grants come from the 15-member National Advisory Council for Human Genome Research, which meets three times a year, usually in Bethesda, Maryland. Members include representatives from health and science disciplines, public health, social sciences and the general public. Portions of the council meetings are open to the public.

The History of NHGRI and the Human Genome Project

While the Human Genome Project had its ideological origins in the mid-1980s, the effort to determine the order of all the letters in the human genetic instruction book owes much of its success to a series of pioneering genetics discoveries dating back to the early 20th Century. For example, Alfred Sturtevant created the first gene map for the fruitfly *Drosophila* in 1911. In 1953, Francis Crick and James D. Watson provided the crucial first step for molecular genome analysis with their description of the double helical structure of the DNA molecule. The two researchers, along with Maurice Wilkins, won the 1962 Nobel Prize for physiology or medicine.

In the mid-1970s, Frederick Sanger developed techniques to sequence DNA, for which he received a Nobel Prize in chemistry in 1980. With the automation of DNA sequencing in the 1980s, the idea of analyzing the entire human genome was first proposed by a few academic biologists.

The U.S. Department of Energy (DOE), seeking data on protecting the genome from the mutagenic

(gene-mutating) effects of radiation, established an early version of the genome project in 1987. The following year, Congress funded both NIH and DOE to embark on further exploration of the concept, and the two agencies formalized an agreement by signing a Memorandum of Understanding to "coordinate research and technical activities related to the human genome." James D. Watson was appointed to lead the NIH component, which was dubbed the Office of Human Genome Research. The following year the Office of Human Genome Research evolved into the National Center for Human Genome Research (NCHGR).

Before the Human Genome Project could officially launch in October 1990, Congress asked NIH to develop a strategic plan for the monumental project. NCHGR collaborated with DOE and, in April 1990, published a joint research plan, "Understanding Our Genetic Inheritance: The Human Genome Project, The First Five Years, FY 1991-1995." This plan set out specific goals for the first five years of what was then projected to be a 15-year research effort. If the ultimate goal of sequencing the human genome was to be completed by 2005, it was imperative to construct detailed human genetic maps, to improve physical maps of the human genome and of the genomes of certain model organisms, and to develop better technologies for DNA sequencing and information handling.

The initial plan also set aside 3 percent of the project's budget for the study of the ethical, legal and social implications (ELSI) of genome research so that policy options could be developed to address concerns such as genetic discrimination. Since 1990, the insights gained through ELSI research have informed the development of federal guidelines, regulations and legislation to safeguard against misuse of genetic information, as evidenced by the recent passage of the "Genetic Information Nondiscrimination Act of 2003" by the U.S. Senate. Through the ELSI research program, NHGRI also supports a variety of ethics- and policy-related research studies, workshops and conferences to further explore and address such issues. Between 1990 and 2001, ELSI-funded activities included 235 research and education projects; more than 550 peer-reviewed journal articles, books, newsletters, Web sites and broadcast media programs; and dozens of workshops, conferences and related activities focused on translating ELSI research into clinical and public health practices.

During its first five years, a large part of the work of the Human Genome Project was devoted to developing improved technologies and techniques for accelerating the elucidation of the genome. Advances that helped to speed scientific research and analysis during this time period included: restriction fragment-length polymorphisms, polymerase chain reaction, bacterial and yeast artificial chromosomes, and pulsed-field gel electrophoresis.

NCHGR also went through a number of leadership changes during this time. In 1992, Dr. Watson resigned as director, and Michael Gottesman was appointed acting director of the center. The following year, Francis S. Collins was recruited from the University of Michigan to be the new director.

By 1993, a majority of the goals laid out in the 1990 plan were already on or ahead of schedule. Efforts to construct human genetic maps and physical maps of genomes had been accelerated by technological improvements that could not have been anticipated even a few years earlier. Also, in the period since the original plan was published, leaders of the Human Genome Project had gained a better understanding of what needed to be done to reach the goal of obtaining the human genome sequence.

Consequently, the leaders revised and extended the project's goals to cover the first eight years (through September 1998) with the publication of "A New Five-Year Plan for the United States Human Genome Program" in the journal *Science*. Among the goals of the new plan were improving technology for rapid genotyping, developing higher resolution physical maps, moving towards a systematic large-scale sequencing strategy, and expanding ELSI goals to contemplate the potential widespread use of genetic testing.

Also in 1993, the NCHGR established a Division of Intramural Research (DIR), in which genome technology is developed and used to study specific diseases. DIR was charged with concentrating

its efforts on future applications of genomics. Over the division's 10-year history, NHGRI investigators have developed a variety of research approaches that accelerate the understanding of the molecular basis of disease. These advances include: DNA microarray technologies for large-scale molecular analyses, innovative computer software to study fundamental biological problems, animal models critical to the study of human inherited disorders and the clinical testing of new therapeutic approaches for genetic disease.

NHGRI's intramural investigators have directly been involved in research that has identified genes involved in Parkinson's disease, hereditary prostate cancer, breast cancer, Pendred syndrome (deafness), tumor suppression, neurological disorders, developmental disorders and, most recently, Hutchison-Gilford progeria syndrome, which is the most dramatic form of premature aging.

In 1994, the Human Genome Project's genetic mapping goal was achieved a year ahead of schedule and, in 1995, a physical map of chromosome 22 was published providing researchers with an important tool for finding genes on this chromosome. In 1996, pilot studies were launched that began the process of dramatically improving the technology needed for sequencing human DNA. That same year, the sequence of the first eukaryotic genome, *Saccharomyces cerevisiae* (brewer's yeast) was completed; a map pinpointing the locations of more than 16,000 human genes was published; and the International Human Genome Sequencing Consortium (IHGSC) made an historic decision to place all sequence data of 1 to 2 million bases into public databases within 24 hours for anyone to freely access.

The NCHGR received full institute status at NIH in 1997, being renamed the National Human Genome Research Institute (NHGRI) with Dr. Collins as its director. Having accomplished all major goals in the 1993-98 plan, NHGRI published a third five-year plan in 1998, again in the journal *Science*. All three plans had a set of interconnected goals that proved pivotal to achieving a completed sequence and maintaining progress to meet ambitious milestones.

Human DNA sequencing would become the major emphasis of the new plan and an audacious timetable was set forth for completing the sequence by April 2003 – more than two years ahead of previous projections. In addition, researchers would work to finish one-third of the human sequence during 2001 and publish a “working draft” by the end of the same year. A “working draft,” while not as accurate as a finished sequence, would contain 90 percent of the sequence and would provide researchers around the world with a useful tool for bringing important scientific projects to fruition much sooner than having to wait for the finished sequence to be completed. Other important goals included the studying human genome sequence variation, developing technology for functional genomics, completing the genomic sequences of the roundworm *Caenorhabditis elegans* and the fruitfly *Drosophila melanogaster*, and starting the sequencing of the mouse genome.

The task of building the “working draft” of the human sequence was delegated to the IHGSC. The three largest NIH-funded sequencing centers (the Whitehead Institute in Cambridge, Mass., Washington University at St. Louis, and Baylor College of Medicine in Houston), along with the Sanger Centre in Hinxton, England, and DOE's Joint Genome Institute, were responsible for sequencing 80 percent of the genome. International partners from France, Germany, Japan and China obtained the remainder of the sequence.

In 1999, the goal of producing a “working draft” seemed very far away, with less than 15 percent of the genome sequenced. If the accelerated goals had not already generated a sense of urgency in the consortium, a decision by the sequencing center leaders at a February meeting in Houston would. At the meeting, the leaders accepted Dr. Collins' challenge to ramp up their efforts to produce a “working draft” by spring of 2000.

By January 2000, the centers were collectively producing 1,000 base pairs a second, 24 hours a day, seven days a week, and 2 billion of the human genome's 3 billion base pairs were sequenced by March. At a White House ceremony hosted by President Bill Clinton in June 2000, Dr. Collins and J. Craig Venter of Celera Genomics, which had carried out its own sequencing strategy, announced that the majority of the human genome had been sequenced.

In February 2001, IHGSC researchers published the sequence and analysis of 90 percent of the human DNA sequence in the journal *Nature*. A simultaneous publication by Celera Genomics appeared in the journal *Science*. Surprises accompanying the sequence publication included: the relatively small number of human genes, perhaps as few as 30,000; the complex architecture of human proteins compared to their homologs – similar genes with the same functions – in worms and flies; and the lessons to be learned from repeated sequences of DNA.

On April 14, 2003 at a news conference at NIH, the IHGSC announced completion of a finished, reference version of the human genome sequence that has an accuracy of 99.99 percent and covers about 99 percent of the genome's gene-containing regions. In October 2004, IHGSC researchers published a scientific description in the journal *Nature* assessing the quality of the reference version of the finished human genome sequence produced by the Human Genome Project, confirming it has both the high coverage and accuracy needed to perform the most sensitive analyses. For instance, the improved accuracy of the finished human genome sequence, compared with earlier drafts, allowed researchers to lower the estimated number of human genes to 20,000-25,000.

When the Human Genome Project was launched in 1990, many in the scientific community were deeply skeptical about whether the project's audacious goals could be achieved, particularly given its hard-charging timeline and relatively tight spending levels. At the outset, the U.S. Congress was told the project would cost about \$3 billion in FY 1991 dollars and would be completed by the end of 2005. In actuality, the Human Genome Project was finished two and a half years ahead of schedule and, at \$2.7 billion in FY 1991 dollars, significantly under original spending projections.

In late 2001 through 2002, knowing that completion of a finished version of the human genome sequence was imminent, NHGRI gathered the world's leading genome researchers to chart the course of future research at two meetings called *Beyond the Beginning: The Future of Genomics I and II*. These meetings were supplemented with workshops throughout 2002 to discuss specific areas of genomic research, policy, education and ethics. The ideas and recommendations that arose from these sessions have informed plans for the next stage of genomic research, resulting in a vision document authored by the leadership at NHGRI: *A Vision for the Future of Genomics Research*, published in April 2003 in the journal *Nature*.

The overarching mission of NHGRI, however, remains the same: to understand the human genome and the role it plays in both health and disease. To that end, NHGRI has embarked on a new set of projects aimed at providing the scientific community with the next generation of tools needed to understand the underlying function and structure of the human genome sequence.

The International HapMap Project, launched in October 2002, is a partnership of scientists and funding agencies from Canada, China, Japan, Nigeria, the United Kingdom and the United States. The purpose of the project is to develop a public resource that will help researchers find genes associated with human disease and response to pharmaceuticals. The DNA sequence of any two people is 99.9 percent identical. However, the 0.1 percent variation among individuals may greatly affect disease risk. Sites in the DNA sequence where individuals differ by a single DNA base are called single nucleotide polymorphisms (SNPs). Sets of nearby SNPs on the same chromosome are inherited in blocks. This pattern of SNPs on a block is a haplotype.

Researchers trying to discover the genes that affect a disease, such as diabetes, will use the set of SNPs from the HapMap to compare a group of people with the disease to a group of people without the disease. Chromosome regions where the two groups differ in their haplotype frequencies might contain genes affecting the disease. The HapMap is expected take about three years to complete.

In 2003, NHGRI launched a pilot project called the ENCyclopedia Of DNA Elements (ENCODE), which will be carried out by an international consortium made up of scientists in government, industry and academia. Initially, research groups will work cooperatively to test a diverse set of existing and novel high-throughput technologies, techniques and strategies for identifying, locating and fully analyzing all of the functional elements contained in a set of DNA target regions that covers

approximately 30 megabases, or about 1 percent, of the human genome. If the pilot effort proves successful, the project will be expanded to cover the entire genome.

In addition to sequencing the 3 billion letters in the human genetic instruction book, researchers involved in the Human Genome Project sequenced the genomes of a number of important model organisms that are commonly used as surrogates in studying human biology. They were: the mouse, the rat, two species of puffer fish, two species of fruit flies, two species of sea squirts, two species of roundworms, baker's yeast and the bacterium *Escherichia coli*. By comparing genome sequences from carefully chosen organisms, scientists are able to identify specific DNA sequences that have been conserved throughout the evolution of different species, which is a strong indicator that these sequences reflect functionally important regions of the genome.

Comparative genomics will continue to play a pivotal role in the next stage of genomic research. In 2004 NHGRI-funded researchers deposited draft assemblies of the honey bee, chicken, dog and cow genomes into public databases. In addition, to aid in interpretation of the human genome, NHGRI approved plans to sequence a wide variety of other organisms, including the African savannah elephant, a snail, domestic cat, kangaroo, nine-banded armadillo and the orangutan.

Another project featured in NHGRI's vision paper and also appearing prominently in NIH's Roadmap for Medical Research is the initiative called "Molecular Libraries." The Molecular Libraries initiative will offer public sector biomedical researchers access to small organic molecules that can be used as chemical probes to study cellular pathways in greater depth. It will provide new ways to explore the functions of major components of the cell in health and disease. In the summer of 2004, as part of the Molecular Libraries initiative, NHGRI's Division of Intramural Research launched the NIH Chemical Genomics Center, the first center in a nationwide network that will produce innovative chemical "tools" for use in biological research and drug development.

The availability of molecular libraries has the potential to accelerate the development of new agents to detect and treat diseases by providing early stage compounds that encompass a broad range of novel targets and activities. These compounds will help validate new targets for drug therapy more rapidly, as well as enable other researchers in the public and private sectors to take these targets and compounds and move them through the drug-development pipeline.

Another of NHGRI's near-term goals is to lower the cost of sequencing a mammalian-sized genome to \$100,000, which would enable researchers to sequence the genomes of hundreds or even thousands of people as part of studies to identify genes that contribute to cancer, diabetes and other common diseases. Ultimately, NHGRI's vision is to cut the cost of whole-genome sequencing to \$1,000 or less, which would enable the sequencing of individual genomes as part of medical care. The ability to sequence each person's genome cost-effectively could give rise to more individualized strategies for diagnosing, treating and preventing disease. Such information could enable doctors to tailor therapies to each person's unique genetic profile.

The availability of such technologies will revolutionize healthcare in the future. In the meantime, NHGRI continues to develop the partnerships and tools necessary to make a difference in today's healthcare setting. For example, in November 2004, NHGRI partnered with the U.S. Surgeon General and other divisions of the Department of Health and Human Services to launch the Family History Initiative.

The Family History Initiative encourages all Americans to learn about their families' health histories as a way of promoting personal health and preventing disease. The centerpiece of this effort is a free web based tool called "My Family Health Portrait" (<http://www.hhs.gov/familyhistory/>), which can be used to record common diseases that run in a person's family. The family history can then be printed and taken to a health care professional to help determine whether a patient is at higher risk for disease.

Ethical, legal and social issues continue to occupy a central role in NHGRI's mission. In 2004, NHGRI's ELSI research program announced grants establishing the first Centers of Excellence in

ELSI Research, which will bring together investigators from multiple disciplines to address some of the most pressing ethical, legal and social questions raised by the rapidly expanding fields of genetics and genomics.

The completion of the sequence of the human genome in April 2003 represents a major milestone in the history of science. However, the challenges set forth in *A Vision for the Future of Genomics Research* will likely prove even more significant by advancing the effort to utilize the human genome sequence to benefit humankind. As medical research ventures further into the genome era, NHGRI will remain at the forefront of such research by providing the tools and information needed to understand human health and disease.

Biographical Sketch of NHGRI Director Francis S. Collins, M.D., Ph.D.

Francis S. Collins, M.D., Ph.D., a physician-geneticist noted for his landmark discoveries of disease genes and his leadership of the Human Genome Project, is director of the National Human Genome Research Institute (NHGRI).

With Dr. Collins at the helm, the Human Genome Project attained historic milestones, while consistently running ahead of schedule and under budget. A working draft of the human genome sequence was announced in June 2000, and an initial analysis was published in February 2001. Human Genome Project scientists continued working until a finished sequence of all 3 billion base pairs was achieved in April 2003. The vast trove of data generated by the public sequencing effort is now available to the medical research community without restrictions on access or use.

In addition, Dr. Collins founded a new NIH intramural research program in genome research, which has evolved into one of the nation's premier research units in human genetics in the country. The Collins research laboratory continues to be vigorously active, exploring the molecular genetics of adult-onset diabetes and other disorders.

Dr. Collins received a B.S. from the University of Virginia, a Ph.D. in Physical Chemistry from Yale University and an M.D. from the University of North Carolina. Following a fellowship in Human Genetics at Yale, he joined the faculty at the University of Michigan, where he remained until moving to NIH in 1993.

While at Yale and the University of Michigan, Dr. Collins developed innovative methods of crossing large stretches of DNA to identify disease genes. This gene-hunting approach, which he named "positional cloning," has become a powerful component of modern molecular genetics. In contrast with previous methods for finding genes, positional cloning enabled scientists to identify disease genes without knowing in advance what the functional abnormality underlying the disease might be.

Dr. Collins' research has led to the identification of genes responsible for cystic fibrosis, neurofibromatosis, Huntington's disease, multiple endocrine neoplasia type 1 and the M4 type of adult acute leukemia. Most recently, his lab, in collaboration with international researchers, found four gene variants that may combine with other unidentified genetic factors to predispose certain people to Type 2 diabetes.

Dr. Collins' accomplishments have been recognized by numerous awards and honors, including election to the Institute of Medicine and the National Academy of Sciences.

NHGRI Directors

Name	In Office From To	
James D. Watson	1989	April 10, 1992
Michael Gottesman (Acting)	April 10, 1992	April 1993
Francis S. Collins	April 1993	Present

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National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892



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National Institute on Aging

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Mission

In 1974 Congress authorized the establishment of the National Institute on Aging (NIA). The NIA is responsible for "conduct and support of biomedical, social, and behavioral research, training, health information dissemination, and other programs with respect to the aging process and diseases and other special problems and needs of the aged."

Important Events in NIA History

December 2, 1971 – The White House Conference on Aging recommends the creation of a separate National Institute on Aging (NIA).

May 31, 1974 – P.L. 93-296 authorizes the NIA and mandates the Institute develop a national comprehensive plan coordinating Department of Health, Education and Welfare agencies involved in aging research.

October 7, 1974 – The National Institute on Aging is established.

April 23, 1975 – The first meeting of the National Advisory Council on Aging is held.

July 1, 1975 – The Adult Development and Aging Branch and Gerontology Research Center becomes the core of the NIA.

December 8, 1976 – The national comprehensive research plan mandated by P.L. 93-296 is sent to Congress.

September 20, 1982 – The NIA Laboratory of Neurosciences Clinical Program admits its first inpatient to a new unit at the NIH Clinical Center.

September 9-11, 1983 – The Institute marks the 25th anniversary of the Baltimore Longitudinal Study of Aging. The first volunteers joined this unique study in 1958.

1984 – NIA funds Alzheimer's Disease Centers (ADC) nationwide to conduct research at medical institutions focused on curing and preventing AD while improving care and diagnosis.

November 14, 1986 – P.L. 99-660, section 951-952, authorizes the NIA's Alzheimer's Disease Education and Referral (ADEAR) Center as a part of a broad program to distribute information about Alzheimer's disease to health professionals, patients and their families, and the general public.

November 4, 1988 – P.L. 100-607 establishes the Geriatric Research and Training Centers (GRTC).

1988 – Congress authorizes NIA to make LEAD awards to researchers making significant contributions to Alzheimer's disease research.

1990 – The GRTCs are expanded and renamed the Claude D. Pepper Older American

Independence Centers and charged with conducting research about diseases that threaten independent living.

1993 – Six Edward Roybal Centers for Research on Applied Gerontology are authorized to convert research findings into programs that improve the lives of older people and their families.

NIA funds six Exploratory Centers for Minority Aging and Health Promotion in collaboration with the NIH Office of Research on Minority Health.

1994 – Nine demography of aging centers are funded to provide research on health, economics, and aging, and to make more effective use of data from several national surveys of health, retirement, and long-term care.

1995 – Three Nathan Shock Centers of Excellence in Basic Biology of Aging are established to further the study of the basic processes of aging.

The Federal Task Force on Aging Research report is published containing nearly 200 specific recommendations for increased emphasis in ten general areas of research.

1999 – As part of NIA's 25th anniversary celebration, a strategic plan is formulated and made available for public comment. The plan addresses scientific topics holding the greatest promise for advancing knowledge in areas such as the basic biology of aging, geriatrics, and social and behavioral functioning.

Biographical Sketch of NIA Director Richard J. Hodes, M.D.

Dr. Hodes was appointed NIA director on May 27, 1993. He received his B.A. from Yale University (summa cum laude) in 1965 and his M.D. from Harvard Medical School (magna cum laude) in 1971.

His postgraduate training included an internship and residency at Massachusetts General Hospital department of medicine. Before attending medical school, he was a research fellow at the Karolinska Institute in Stockholm, Sweden. Before joining NIA, he was senior investigator and chief of the immune regulation section at NCI's Experimental Immunology Branch.

In 1997 Dr. Hodes was elected as a fellow of the American Association for the Advancement of Science. He received a PHS Commendation Medal in 1977, a PHS Outstanding Service Medal in 1988, and a PHS Distinguished Service Medal in 1996. In 1999 Dr. Hodes was elected to membership in the Institute of Medicine of the National Academy of Sciences.

NIA Directors

Name	In Office From To	
Norman Kretchmer (Acting)	October 1974	July 1975
Richard C. Greulich (Acting)	July 1975	April 1976
Robert N. Butler	May 1, 1976	July 1982
Robert L. Ringler (Acting)	July 16, 1982	June 30, 1983
T. Franklin Williams	July 1, 1983	July 31, 1991
Gene D. Cohen (Acting)	July 1, 1991	May 31, 1993
Richard J. Hodes	June 1, 1993	Present

Research Programs

Intramural Research

NIA's Intramural Research Program (IRP) comprises eleven scientific laboratories, a clinical research branch and a research resources branch that include the scientific disciplines of biochemistry, cell and molecular biology, structural biology, genetics, behavioral sciences, epidemiology, statistics, and clinical research and the medical disciplines of neurobiology, immunology, endocrinology, cardiology, rheumatology, hematology, oncology, and gerontology. Medical problems associated with aging are pursued in-depth using the tools of modern laboratory and clinical research. The central focus of research is the understanding of age-related changes in physiology and the ability to adapt to environmental stress. This understanding is then applied to developing insight about the pathophysiology of age-related diseases. The program seeks to understand the changes associated with healthy aging and to define the criteria for evaluating when any change becomes pathologic. Thus, not only are the common age-related diseases under study (e.g., Alzheimer's disease, atherosclerosis, osteoarthritis, diabetes, cancer), but the determinants of healthy aging are also being defined.

Most IRP research is conducted at the Gerontology Research Center in Baltimore, Maryland. The section of *Brain Physiology and Metabolism* and the *Laboratory of Neurogenetics* are located in the Clinical Center on the NIH main campus in Bethesda, and the *Laboratory of Epidemiology, Demography & Biometry* is located in the Gateway Building in Bethesda.

The *Laboratory of Cellular and Molecular Biology* (LCMB) interests cover a wide range of topics devoted to understanding basic biological processes that contribute to the aging process, and to the development of age-related disabilities and diseases. The LCMB currently has five research programs. A common goal of these programs is the elucidation of biochemical and molecular events associated with various age-related deficits that could serve as targets for therapeutic strategies aimed at preventing or delaying the onset of disabilities and disease processes. These research programs, each of which is headed by either a tenure-track scientist or a senior investigator, are the *T Lymphocyte Signaling Unit*, the *Cancer Molecular Genetics Unit*, the *DNA Repair Unit*, the *RNA Regulation Section* and the *Gene Regulation Section*. Major areas of emphasis common to the individual programs include: 1) regulation and deregulation of gene expression, particularly as it pertains to human development and age-associated changes that result in disease; 2) the elucidation of signal transduction processes and genes involved in regulating cellular responses to environment signals such as growth factors, cytokines and stress stimuli; 3) the determination of mechanism that contribute to the maintenance of cellular homeostasis and cell cycle control; 4) the role of DNA damage and repair in age and age-related disease and these processes have direct relevance to our understanding of critical events associated with various age-related deficits and/or development of age-related diseases including cancer and inflammation. The ultimate goal of the programs is to uncover knowledge that can be applied to prevent or delay the onset of age-related disabilities and disease processes, and/or provide new strategies for their treatment. While individual research programs within the LCMB generally function as independent groups, they are highly interactive, conduct twice monthly joint meetings, and engage in collaborative projects. Combined, the programs within the LCMB provide extensive and broad expertise in the areas of biochemistry, cellular and molecular biology, and genetics. Specialized expertise in a variety of approaches used to analyze or manipulate gene expression is also available with the LCMB. The LCMB is equipped with state-of-the-art instrumentation and an extensive computer network.

The *Laboratory of Cardiovascular Sciences* (LCS), established in 1985, is presently organized into two sections: *Cardiac Function* and *Behavioral Hypertension*. The *Cardiac Function Section*, which comprised the entire LCS at its inception, is organized into nine functional units: the Cardiovascular Gene Therapy Unit, the Cardiovascular Biology Unit (Cardiac and Vascular Groups), the Calcium Signaling Unit, the Cardioprotection Unit, the Cellular Biophysics Unit, the Hypertension Unit, the Receptor Signaling Unit, the Human Cardiovascular Studies, and the Molecular Cardiology Unit. The *Behavioral Hypertension Section* was formerly part of the Laboratory of Behavioral Science and joined LCS in 1997.

The overall goals of the Laboratory of Cardiovascular Sciences are (1) to identify age-associated changes that occur within the cardiovascular system and to determine the mechanisms for these changes; (2) to study myocardial structure and function and to determine how age interacts with

chronic disease states to alter function; (3) to study basic mechanisms in excitation-contraction coupling and how these are modulated by surface receptor signaling pathways in cardiac muscle; (4) to determine the chemical nature and sequence of intermediate reactions controlling the chemical nature and sequence of intermediate reactions controlling the movement of ions through ionic channels and pumps present in myocardium, and how these are affected by aging and disease; (5) to determine mechanisms that govern neuro-hormonal behavioral aspects of hypertension; (6) to determine mechanisms of normal and abnormal function of vascular smooth muscle and endothelial cells; and (7) to establish the potentials and limitations of new therapeutic approaches such as gene transfer techniques. In meeting these objectives, studies are performed in human volunteers, intact animals, isolated heart and vascular tissues, isolated cardiac and vascular cells, and subcellular organelles. In the LCS environment, discoveries are integrated within and among individual research areas, and many projects become multi-faceted, spanning the range from humans to molecules.

The *Laboratory of Clinical Investigation* (LCI) conducts research on age changes and mechanisms underlying these changes in humans, laboratory animals, cellular, and molecular systems. It comprises 5 sections and 2 units: the *Bioanalytical Chemistry/Drug Discovery Section*, the *Diabetes Section*, the *Hematology/Oncology Section* with the *Cancer Immunology Unit*, the *Metabolism Section*, the *Molecular and Clinical Pharmacology Section*, and the *Nuclear Magnetic Resonance Unit*. The interests and goals of the LCI are most broadly defined as the identification of potential therapeutic targets for the treatment of age-related disease. The mission of LCI is to carry out the research needed to move these targets to drugs and treatments that can then be developed for clinical therapeutics. The *Bioanalytical Chemistry/Drug Discovery Section* studies receptor-ligand interactions using molecular modeling and immobilized receptor columns to characterize drug-receptor, drug-enzyme, and drug-transporter interactions to develop screening methods for drug candidates. It serves as a bioanalytical core for measurement of drugs and metabolites obtained during clinical and preclinical studies, and as a resource for structural characterization of large protein molecules. It has also begun the study of treatment of wasting syndromes (cancer cachexia) using enhancers of intermediary metabolism. The *Diabetes Section* studies mechanisms of pancreatic islet cell differentiation and has identified receptors of the gut peptides GLP-1 and GIP as therapeutic targets for the development of insulinotropic agents. Cellular, animal, and clinical studies are underway to identify potential new drugs that target these receptors for the treatment of type 2 diabetes mellitus. In addition studies of the molecular basis of insulin receptor signaling are undertaken to better understand changes in insulin signaling that occur in diabetes. The *Hematology/Oncology Section* studies tumor suppressor genes, and seeks to identify, explore, and conduct translation research on new therapeutic targets that are promising for the aging cancer patient. The *Cancer Immunology Unit* studies mechanisms of lymphocyte signaling and activation, and is clinically evaluating the use of bryostatin-1 for the treatment of cancer. It will begin to utilize 'mini' bone marrow transplantation in combination with other treatments to improve cancer treatments in the aged patient. The *Metabolism Section* studies the utility of diagnostic criteria for diabetes and the metabolic syndrome using the BLSA database and other longitudinal study sets. The *Molecular and Clinical Pharmacology Section* studies mechanisms of calcium channel gating in the L-type calcium channel, to define the effects of age and disease on the expression of splice variants and function of this channel, and to study the structural mechanisms that this channel transmits its signal to other cellular signaling and effector pathways. These studies include study of clinical surgical tissue to link the molecular findings to human atherosclerotic disease. In addition clinical studies of the effect of genetic polymorphisms of endothelial nitric oxide synthase and angiotensin converting enzyme on forearm vascular reactivity, heart rate variability and drug responses are underway. Clinical and laboratory studies of the role of muscle atrophy in the evolution of osteoarthritis are also underway. The *Nuclear Magnetic Resonance Unit* studies connective tissue biophysics (whole cartilage, chondrocytes in culture, and in vivo cartilage imaging), muscle metabolism under a variety of pharmacological and physiological conditions, and methodology development in imaging and spectroscopy. In vivo NMR is also conducted to define the phenotype of transgenic animals.

The *Laboratory of Epidemiology, Demography, and Biometry* (LEDB) conducts research on aging and age-associated diseases and conditions using population-based epidemiologic and biometric methods. Laboratory staff work collaboratively both within and among four sections: the

Epidemiology and Demography Section, the *Neuroepidemiology Section*, the *Geriatric Epidemiology Section*, and the *Biometry Section* and with other NIA and outside investigators. The mission of LEDB is to elucidate the etiology of diseases of old age by combining epidemiologic data with information from other disciplines; evaluate the consistency of epidemiologic data with etiologic hypotheses developed either clinically or experimentally; and to provide the basis for developing and evaluating preventive procedures and public health practices. These general principles have guided a research agenda that emphasizes three important and interrelated areas: Physical Function and Disability, Cognitive Function and Dementia, and Age-associated Diseases and Conditions - including successful or effective aging. In each area, studies are influenced by results of analytic efforts of current LEDB-sponsored studies and by opportunities created by advances in biology. The *Epidemiology and Demography Section* plans and conducts studies on chronic diseases, functional status and disability in the older population. The *Neuroepidemiology Section* conducts interdisciplinary research on the association of genetic, molecular, and behavioral factors in relation to brain disease in old age. The *Geriatric Epidemiology Section* carries out interdisciplinary studies of the association of molecular and genetic risk factors with health outcomes in old age, including discrete diseases, disability and mortality. The *Biometry Section* conducts research in the mathematical, statistical and numerical aspects of aging and health. This section provides statistical consulting, computing, graphics, and data management services to the other units within LEDB. Senior LEDB staff consult with other components within the IRP, NIA, other NIH Institutes, other Government agencies, and the private sector. LEDB research interests use data from the Established Populations for Epidemiologic Studies of the Elderly (EPESE), the Women's Health and Aging Study (WHAS), the Honolulu-Asia Aging Study (HAAS), Health and Body Composition (Health ABC) Study; InCHIANTI Study; Veterans' Study of Memory in Aging (VSMA); the MacArthur Studies of Successful Aging, and other epidemiologic studies.

The *Laboratory of Experimental Gerontology* is a new laboratory formed to create and supervise research in experimental models focused on interventions that retard aging processes. The laboratory currently comprises the *Behavioral Neuroscience Section* (BNS) and a *Nutritional and Molecular Physiology Unit* (NMPU); however, new organizational units are planned. A major project within the NMPU involves a longitudinal study to assess the beneficial effects of calorie restriction on aging in nonhuman primates. Other studies conducted in this unit utilize *in vivo* rodent models and *in vitro* cellular models to identify protective mechanisms invoked by calorie restriction. The LEG will also participate in a newly created program coordinated with the NIA extramural program designed to evaluate various aging interventions (pharmaceuticals, hormones, dietary supplements, genes) in mouse models to assess effects in a standardized fashion on lifespan, pathology, and functional capacity at older ages. Within the BNS, research is directed toward developing behavioral assays of aging in rodents and nonhuman primates with focus on motor and memory performance. Additional projects in the BNS involve identifying mechanisms of age-related decline in motor and memory performance and developing pharmacological, genetic, and nutritional interventions that improve function in the aging brain.

The *Laboratory of Genetics* (LG) comprises six units, with a *Human Genetics Section*; a *Human Genetics and Integrative Medicine Section*; a *Developmental Genomics and Aging Section*; a *Transcription Remodeling and Regulation Unit*, a *Gene Recovery and Analysis Unit*, and an *Image Informatics and Computational Biology Unit*. The interests of the laboratory are based on the view that aging has genetic determinants as an integrated part of human development, with a profound dependence on the interplay of synthetic and degradative processes that are initiated *in utero*. Major studies include: 1) transitions between immortal and mortal cells, such as the transition of immortal embryonic stem cells to mortal differentiating cells that is a fundamental feature of the initiation of aging in metazoans; 2) cohorts of genes involved in the development of selected "nonrenewable" systems. To understand and ultimately try to compensate for loss of cells and tissues during aging, the examples of skin appendage, connective tissue, and ovarian follicle development are being studied; and 3) genes involved in embryonic events that prefigure aging-related phenomena. This includes studies of overgrowth syndromes, in which the set-point of size of tissues and organs is determined in fetal life, and studies of premature ovarian failure, in which the aging phenomenon of early menopause is determined by an increased rate of follicular atresia during fetal life. 4) Genes involved in embryonic events that prefigure aging-related phenomena. For example, the Human Genetics Unit is involved in studies of overgrowth syndromes, in which the set point of size of

tissues and organs is determined in fetal life; studies of premature ovarian failure, in which the aging phenomenon of early menopause is determined by an increased rate of follicular atresia during fetal life; and studies by the HGIM focus on characteristics of heritable disorders of connective tissue including Ehlers-Danlos and Stickler syndromes, and various forms of dwarfism. 5) Genes involved in chromatin remodeling. The Transcription Remodeling and Regulation Unit is studying the action of the components of nuclear complexes that regulate chromatin accessibility and are affected in diseases, like Rett Syndrome, that correspondingly involve problems in chromatin structure and function. 6) The genetics of aging-related complex conditions is being approached by interactive studies of the "founder" population in Sardinia. Initial phenotypes to be studied along with epidemiological factors include arterial stiffness, selected psychiatric/psychological traits. For this project investigators from Cardiovascular Sciences (Edward Lakatta and Angelo Scuteri), Personality and Cognition (Paul Costa, Antonio Terracciano, and Alan Zonderman) are working with Antonio Cao and Giuseppe Pilia, human geneticists at the University of Cagliari, Sardinia. The Laboratory is equipped with state-of-the-art resources for genomic approaches in the *Gene Recovery and Analysis Unit*, including large-insert clones and recovery methods, high throughput sequencing, and nuclear fractionation; and the *Developmental Genomics and Aging Section* has built large cohorts of genes based on its capacity to make and analyze high-quality cDNA libraries from very few cells - for example, from subregions of embryos. An extension of technology is now being assessed in a major effort by the *Image Informatics and Computational Biology Unit*, devoted to comparative analyses of microscopic images, including database and algorithm development, to investigate protein distribution during cell division and tissue formation, and to facilitate automated screening for mutants.

The *Laboratory of Immunology* (LI) conducts studies to provide a greater understanding of the biological, biochemical, and molecular alterations in immune function that occur within individuals during both normal and pathology-associated aging processes. The Laboratory includes the *Clinical Immunology Section*, the *Lymphocyte Differentiation Unit*, and the *Lymphocyte Cell Biology Unit*. The common goal of these research programs is the elucidation of the age-related deficits in immune function that could be potentially targeted by various therapeutic strategies. The *Clinical Immunology Section* has concentrated its efforts on five major areas of research which include: (1) the molecular analysis of differentially-regulated genes involved in lymphoid organ and cell development, differentiation, and activation; (2) the study and use of biological response modifiers such as cytokines and hormones to optimize and control leukocyte trafficking, activation, and organ engraftment in normal and aging hosts; (3) the induction of antigen-specific tolerance for use in transplantation and autoimmunity; (4) the role of cholesterol and lipid rafts in cellular activation, trafficking, and HIV infectivity; and (5) the cellular and molecular dynamics involved in thymic involution and regeneration. The research interests of the *Lymphocyte Differentiation Unit* are focused mainly in three areas: (1) the molecular and cellular mechanisms of immunological memory; (2) the roles of telomere and telomerase in lymphocyte function, replicative lifespan, and aging; and (3) the mechanisms of age-associated loss of learning and memory formation in rodent. The research interests of the *Lymphocyte Cell Biology Unit* are focused in three major areas: (1) the role of T cell costimulatory pathways in the generation of GVHD and T-cell tolerance; (2) the factors involved in the regulation of tumor cell growth and division; and (3) the mechanisms of tumor-induced immunosuppression.

The *Laboratory of Molecular Gerontology* (LMG) investigates DNA related mechanisms such as genomic instability, DNA repair, DNA replication, and transcription. The *DNA Repair Section* examines the role of the increased DNA damage accumulation in senescence as the major molecular change with aging. The goal is to understand the underlying mechanisms involved in DNA damage formation and processing as well as the changes that take place with aging that make aging cells susceptible to cancer. Investigative focus is placed on investigating the molecular mechanisms involved in DNA repair and in genomic instability in normal, senescent and cancer cells. The human premature aging syndromes are primary targets of investigation. Studies are focused on the molecular functions and protein interactions of the premature aging proteins, Werner syndrome and Cockayne syndrome. The *DNA Helicases Unit* focuses on the roles of DNA helicases in genomic stability. The growing number of DNA helicases implicated in human disease suggests that these enzymes have vital specialized roles during replication, DNA repair, recombination, and transcription. RecQ DNA helicases are of particular interest because the human

hereditary disorders Werner syndrome (WS), Bloom syndrome, and Rothmund-Thomson syndrome all arise from mutations in genes of the RecQ helicase family. This unit focuses its efforts on understanding the cellular and molecular defects of WS, a premature aging disorder characterized by genomic instability. *The Gene Targeting Section* is developing oligonucleotides that can form a three-stranded DNA structure called a triple helix. The third strand lies in the major groove of an intact double helix and is stabilized by hydrogen bonds between the bases in the third strand and the purine bases in the duplex. These oligonucleotides can be linked to DNA reactive compounds and site-specific modification of DNA with these oligo-reagent conjugates has been demonstrated by many groups. Due to recent advances from this group of investigators, this approach can now be used to deliver additional DNA reactive compounds to specific genomic locations. Eventually this approach will be used to modulate genomic sequences with targeted gene knockout as a specific application. *The Antibody Diversity Unit* investigates the mechanism of somatic hypermutation. Somatic hypermutation of variable genes, which encode a portion of immunoglobulin molecules, occurs at a frequency that is a million times greater than mutation in other genes. Evidence points to a process that involves DNA repair events at sites of targeted strand breaks. In vertebrate cells, there are many recently identified DNA polymerases that inaccurately copy templates. This unit is studying the roles of DNA polymerases zeta, eta, and iota in the mechanism. In addition, work from this group includes examination of whether aging alters the frequency and pattern of hypermutation. *The Unit of Structure and Function in base excision Repair* investigates the mechanism involved in base excision repair, the removal of oxidative DNA lesions. The functions of the individual proteins are studied and their interactions are investigated. The approach is a combination of protein structure and function and with a view to how mutations and alterations in these proteins in the population change their function and cause disease. *The Unit of Oxidative DNA damage processing and mitochondrial function* focuses on mitochondrial DNA, and the studies seek to investigate the basis for the mitochondrial hypothesis of aging which states that accumulation of DNA damage with aging leads to the phenotypical changes that we observe in senescence and age-associated disease. The mechanisms of removal of oxidative DNA damage from mitochondria are investigated and how they are affected by increasing age or disease processes.

The overarching goal of research efforts in the *Laboratory of Neurosciences* (LNS) is to understand the cellular and molecular mechanisms that regulate neuronal plasticity and survival in the context of aging and age-related disease. It is assumed that there are fundamental mechanisms of aging that are shared among organisms at different levels of the phylogenetic tree, and that the lifespan of individuals is determined by the genes they express and environmental factors they encounter. A major focus of ongoing projects is to identify the factors that determine whether aging of the nervous system is successful, or whether a disease develops. There is therefore a strong emphasis placed on elucidating cellular and molecular alterations that lead to neuronal dysfunction and degeneration in disorders such as Alzheimer's disease (AD), Parkinson's disease (PD), stroke and amyotrophic lateral sclerosis (ALS). This is accomplished by studying human patients, cell culture and animal models relevant to human disease. Among the major areas of investigation are the signal transduction mechanisms that normally regulate cellular oxyradical, energy and ion homeostasis, and how they may be altered during aging and in age-related neurodegenerative disorders. Knowledge gained in such basic research is then being used in preclinical studies to develop approaches (diet, lifestyle, drugs and cell therapy) for preventing and treating these disorders. LNS comprises five sections which include: the *Cellular and Molecular Neurosciences Section*, the *Developmental Neurobiology Section*, the *Drug Design and Development Section*, the *Synaptic Physiology Unit*, and the *Invertebrate Molecular Genetics Unit*.

The fundamental scientific paradigm guiding research in the *Laboratory of Personality and Cognition* (LPC) is the analysis of individual differences. Few phenomena are more basic than the fact that human beings differ - in health, in rates of aging, in cognitive ability, in personality, in happiness, and in life satisfaction. The LPC conducts basic and clinical research on individual differences in cognitive and personality processes and traits. The laboratory investigates the influence of age on these variables and their reciprocal influence on health, well-being, and adaptation. It employs longitudinal, experimental, and epidemiological methods in the analysis of psychological and psychosocial issues of aging, including health and illness, predictors of intellectual competence and decline, models of adult personality, and correlates of disease risk factors. The *Personality, Stress,*

and Coping Section has conducted systematic basic research in personality guided by the Five Factor Model (FFM) which asserts that personality traits can be understood as aspects of five factors: Neuroticism, Extraversion, Openness to Experience, Agreeableness, and Conscientiousness. The FFM is now the prevailing conception of personality in psychological research. The unit on *Emotions and Psychophysiology* conducts research on the role of emotions and psychophysiology processes related to psychological adaptation and health. The *Cognition Section* conducts studies that attempt to distinguish pathological from healthy, age-related cognitive changes in a broad range of cognitive tasks, including short-term and long-term memory, visual/spatial rotation, attention, and decision tasks. Performance of Baltimore Longitudinal Study on Aging (BLSA) participants on the Benton Visual Retention Test has led to the test's identification as a potential early marker for Alzheimer's disease. That finding is being followed up using neuroimaging techniques. Work is ongoing to determine whether estrogen provides a protective effect on memory.

The goal of the *Laboratory of Neurogenetics* is to develop an understanding of neurodegenerative and neurologic diseases (Alzheimer's disease, Parkinson's disease, dystonia, ALS and stroke are current areas of research) based on genetic analysis. To this end, the group has four sections and two cores: a *Clinical Section* (shared with NINDS) who co-ordinate the identification and assessment of families and cases with the disease we are working on, a *Genetic Section* who spearhead gene and mutation identification for these diseases, a *Cell Biology Section* whose role is to define the cellular effects of pathogenic mutation and a *Transgenic Section* (for which recruitment is still ongoing) which will use mutant genes to develop animal models of disease. Underpinning this work is a *Genetic Linkage Core* which provides high throughput genotyping and sequencing and a *Bioinformatics Core* whose role is to develop our data in the context of the vast array of genomic and biologic data now available through computational analysis. The lab is in Bethesda and shares many projects with the Laboratory of Neurogenetics (NINDS), the Laboratory of Genetics (NHGRI) and the Laboratory of Epidemiology (NIA).

The *Molecular Dynamics Section* focuses on the interplay between structure and dynamics and how these influence biological function. The section is presently involved in studying the structural and dynamic factors in hemoglobin, which regulate the binding of oxygen as well as autoxidation with its associated release of superoxide. The finding that autoxidation of hemoglobin is appreciably enhanced at reduced oxygen pressures, has led to the proposal of a novel method for producing oxyradicals under hypoxic conditions. Studies are being performed on erythrocytes, interaction of erythrocytes with other tissues and with whole animals to determine to what extent this mechanism contributes to the pathophysiology of aging.

The *Brain Physiology and Metabolism Section* (BPMS) studies brain function, metabolism, and structure with regard to aging and disease, including Alzheimer's disease. Investigators are currently working to improve the sensitivity and specificity of diagnostic tools including Positron Emission Tomography (PET), functional Magnetic Resonance Imaging (fMRI), structural magnetic resonance imaging, magnetic resonance spectroscopy, as well as neuropsychological and behavioral assessment.

The *Clinical Research Branch* (CRB) is a newly formed Branch organized into the *Office of the Clinical Director* and five sections (*Longitudinal Studies Section, Health Disparities Research Section, Translational Research and Medical Services Section, Clinical Support Section* and the *Clinical Information and Data Management Section*). The overall goals of the CRB are: 1) the conduct of major longitudinal studies of aging including the BLSA and HANDLS studies and 2) to support and carry out translational research in the major areas of clinical research focus of NIA-IRP laboratories including longitudinal studies and interventional trials with a focus on cardiology, neurology, endocrinology and oncology disease areas. In the latter, the branch: 1) provides the infrastructure needed to promote high quality clinical research and to ensure patient safety including: protocol review, clinic infrastructure, nursing and physician support, clinical informatics, data and safety management; 2) monitors and maintains quality assurance of the intramural clinical research program; 3) develops and implements clinical program priorities, allocates clinical resources; 4) integrates the established research themes and projects with clinical relevance from various IRP laboratories and branches; 5) evaluates program effectiveness and represents the IRP in management and scientific decision-making meetings within the Institute; 6) coordinates the

credentialing of health care providers within the Institute; 7) coordinates and provides clinical research training for NIA staff and fellows and 8) develops novel approaches for carrying out translational research in an efficient and cost-effective manner. Ongoing research projects within the branch include: two large longitudinal studies, the Baltimore Longitudinal Study on Aging (BLSA) and the Healthy Aging in Nationally Diverse Longitudinal Samples (HANDLS); studies of factors predisposing patients to osteoarthritis and evaluation of muscular changes contributing to disability from this disease and studies of neuromuscular/ strength changes with aging. The NIA IRP *Cytapheresis Unit* is also a part of CRB. This unit conducts cytapheresis on BLSA participants and other normal volunteers providing important clinical research materials (T-cells, B-cells) to program investigators examining immunosenescence, the role of telomeres in human aging and other age related research. In addition, the CRB supports all other clinical studies conducted within the NIA-IRP through provision of Protocol Support, Pharmacy support and Clinical Core Laboratory support under the Office of the Clinical Director and Nursing support under the Clinical Support Section of the Branch.

Extramural Research

Office of Extramural Affairs

The *Office of Extramural Affairs* (OEA) manages NIA's extramural program activities. It often is the first point of contact for applicants requesting information on how to apply for federal support or who wish to know if their research ideas may be of interest to NIA. The OEA coordinates NIA's extramural programs and ensures that policies and procedures are implemented in a uniform and fair way. The Office has responsibility for oversight of grants and contract administration, scientific review, and committee management functions. The Office serves as primary liaison for NIA with the NIH Office of Extramural Research, and with other institutes that share research interests. It also has primary responsibility for NIA's extramural training programs, career development programs, small business initiatives, and other special programs. The Office handles appeals, and scientific integrity and other ethical issues involved in the conduct of research. The OEA organizes meetings of the National Advisory Council on Aging (NACA) and meetings of related groups. OEA has central responsibility for research training and career development activities at the institute, including policies related to different mechanisms, eligibility, and initiatives to increase the number of underrepresented students and researchers trained in aging research.

The *Scientific Review Office* (SRO) of the OEA is responsible for initial peer review of specific research applications assigned to the NIA. These include applications for grants to Centers, for program project initiatives, and for training and career development. Members of NIA's four review panels that correspond to the Institute's program areas and members of the Institute's special emphasis panels include non-government scientists who are themselves grantees and who are expert in the scientific areas of the applications they review.

While the SRO interacts with applicants prior to the award of grants, the *Grants and Contracts Management Office* (GCMO) works with scientists and institutional research administrators to issue, manage, and close awards when the research is completed. GCMO staff members provide guidance on administrative and fiscal policies and practices for the investigator and for the institutional research administrators. For example, they address questions about allowable costs and about major changes in staff or content of the research project. The GCMO has legal responsibility for the fiscal management of the Institute's extramural grants and contracts.

External Scientific Review

In support of research, research training, and career development related to aging, the NIA awards grants to universities, hospitals, and research organizations throughout the U.S. and abroad. Approximately 80 percent of the funds appropriated to the NIA are disbursed through these extramural awards. Competition for this funding is very high; for example, over the past ten years, NIA was able to fund fewer than one in three of the research project grant applications it received. To ensure that the research funded is of the highest quality and serves the health needs of the

nation, peer review committees comprised of external scientific experts are brought together to review proposed and ongoing research.

Extramural Grant Review

Extramural research investigators trigger the grant review process by submitting grant applications to the NIH Center for Scientific Review (CSR). Initial review of applications may be assigned to a Center review group or to NIA's initial review committee which reviews program project, center, research career, small, and institutional training grant applications, as well as applications submitted in response to RFAs issued by the NIA.

Applications clearly within NIA's mandate are forwarded to NIA for funding consideration. Whether the applications are reviewed at the Center for Scientific Review or at the NIA, committees of experts, including NIH grantees, assess the quality and originality of the proposed science. Reviewers also assess applications for the qualifications of the investigators, quality of the proposed facilities, treatment of animal models, if relevant, and, for research involving humans, the proposed plans for recruiting women and minorities to the studies. The judgment of the group on these parameters is summarized in a report (summary statement) and overall rating (priority score) of the application. These reports are provided to the applicants and to NIA officials. Among the applications assigned to the NIA, approximately the top half, as judged by initial review, are given a second level of review by the National Advisory Council on Aging.

National Advisory Council on Aging

Congress created the National Advisory Council on Aging (NACA) to provide advice on programmatic and policy matters; specifically:

"to advise, consult with, and make recommendations to the Secretary, DHHS, the Assistant Secretary for Health; the Director, NIH; and the Director, NIA; on matters relating to the conduct and support of biomedical, social, and behavioral research, training, health information dissemination, and other programs with respect to the aging process and the diseases and other special problems and needs of the aged."

Grant applications over \$50,000 must receive Council approval to be eligible for funding. In its deliberations, the NACA reviews summary statements to evaluate the fairness and appropriateness of the initial review of grant applications, and considers the scientific and public importance of the proposed work. In cases in which the applicant or NIA staff has concerns about the initial review of the application (special actions), NACA members can evaluate these concerns.

Council members also serve as a conduit for insights into the concerns and opinions of the research community, and assist in keeping the scientific community, Congress, and the public knowledgeable about the activities of the NIA.

The NACA meets three times each year, typically for a period of two days to review applications for grants and cooperative agreements for research and training. The group recommends funding of research applications that show significant promise of a) improving the quality of life and health care for the aged; or b) making valuable contributions to our scientific knowledge of the aging process.

The NACA consists of 18 members appointed by the DHHS Secretary and five non-voting ex officio members. Of the 18 appointed members, 12 are leading representatives of the health and scientific disciplines and are leaders in the fields of public health and the behavioral or social sciences relevant to the activities of the NIA, particularly with respect to biological and medical sciences relating to aging and public health. Six of the members are leaders from the general public in the fields of public policy, law, health policy, economics, and management. Members are invited to serve for overlapping four-year terms.

Once the Council provides its recommendations, the NIA Director may approve payment of applications that have been favorably reviewed and for which sufficient funds are available. Primary weight is given to the scientific quality of the application as judged by initial peer review. Consideration is also given to the proposed research's relevance to NIA priorities and to the timeliness of the research.

Biology of Aging Program

The program supports biomedical studies through various NIH grant mechanisms and contracts. The program plans, implements, and supports fundamental molecular, cellular and genetic research on the mechanisms of aging. It also supports resource facilities that provide aged animals and cell cultures for use in aging research.

Aging Research Technologies. The objective of this Program is to support research on emerging technologies useful in gerontological research.

Animal Models. The objective of the Animal Models Program is to identify and develop new animal models, both mammalian and lower organism, for use in aging research. This includes research on rats, mice, birds, fish, rabbits, non-human primates, insects, nematodes and yeast. Mutant and genetically engineered rodent models of both normal aging and specific age-related pathologies are of particular interest.

Cardiovascular Biology. The objectives of the Cardiovascular Biology Program are to support basic research on age-related changes in cardiovascular function, e.g. gene expression, and on factors affecting cell death in heart tissue.

Cell Structure and Function Program. The objectives of the Cell Structure and Function Program are to support research on the molecular basis of age-related changes in signal transduction mechanisms; microenvironment - ECM; replicative senescence/apoptosis/cancer; membranes and membrane receptors, and protein structure and function.

Endocrinology Program. Hormones secreted by the endocrine system play major roles in informing various organs of the status of other organ systems and in coordinating the functioning of various organ systems. As humans and various animal models age, average serum levels of some of these hormones decline while others rise, changing the overall hormonal milieu of the organism. Also, the sensitivity of some intracellular signaling pathways responsive to endocrine factors change with age, altering tissue response to hormonal signals. The purpose of the endocrinology of aging program is to support basic molecular and cellular research into the causes and effects of age-related changes in the endocrine system of humans and various animal models. Areas of investigation in this program include age-related changes in hormone production, metabolism, and action; Type II diabetes; reproductive aging: biology of menopause and animal models of menopause; age-related changes in control of prostate growth; and endocrine aspects of age-dependent tumors.

Genetics Program. The objectives of the Genetics Program are to support research on identification and characterization of longevity assurance genes (LAGs) and senescence assurance genes (SAGs); genome stability; telomere biology; genomics; mouse mutagenesis; single nucleotide polymorphisms/genetic epidemiology; and Werner syndrome.

Immunology Program. Changes in the immune system of older people may contribute to the increased incidence of infection and cancer in the elderly. Research directed towards understanding the age-related regulation of immune function in health and disease is supported by BAP. Areas of investigation in this program include regulation of lymphocyte proliferation; regulation of immune specificity; response of immune system to biochemical stimuli; autoimmune disease and other immunopathology; endocrine control of immune function; molecular basis of the age-related decline in immune function; and interventions to retard and/or correct age-related decline in immune function.

Metabolic Regulation. Areas of investigation in the Metabolic Regulation Program include nutrition and metabolism; age-related changes in mitochondrial function/mitochondrial dysfunction; mechanism of life span extension by caloric restriction; and generation of free radicals and oxidative stress.

Musculoskeletal Biology. The age-related change of function of various physiologic systems often negatively impacts the health of the elderly. The purpose of this program is to support high quality basic molecular and cellular research to understand the causes and effects of these changes, thereby encouraging the development of preventative and interventional strategies to extend the health span of the elderly. Areas of investigation in this program include age-related changes in osteoblast and osteoclast function and bone matrix; age-related changes in muscle structure and function; age-related changes in cartilage, connective tissue and skin; age-related changes in wound healing; molecular mechanisms of the above age-related changes; and molecular basis of osteoporosis and osteoarthritis.

The Biology of Aging Program also includes the *Office of Biological Resources and Resource Development*. Because most investigators have neither the facilities nor the resources needed to develop and maintain colonies of aged animals in a barrier facility, the NIA provides support for both rat and mouse colonies for use by the scientific community. The cost of these animals is partially subsidized by the NIA through contracts. Other NIA resources managed by this office include colonies of rhesus macaque monkeys, an Aged cell bank, and a Genetic Stock Center for nematode mutant strains.

Geriatrics and Clinical Gerontology Program

The NIA Geriatrics and Clinical Gerontology Program comprises three branches:

The *Geriatrics Branch* is focused primarily on health issues regarding the aged, and deals with research on disease and disability in older persons, including both specific conditions and issues related to multiple morbidity. Examples of current research areas addressed by this branch and future directions are:

- Multifactorial geriatric syndromes, such as falls, frailty, and various types of disability
- Effects of comorbidity and polypharmacy
- Effects of age-related changes on clinical or functional disease outcomes or treatment responses
- Effects of physical activity on disease and disability in older persons
- Elucidation, diagnosis, and treatment of previously unappreciated pathologic changes in old age (e.g., sarcopenia, vascular stiffening, diastolic dysfunction)

The *Clinical Gerontology Branch* is focused primarily on clinically related issues regarding aging, and deals with research on aging changes over the life span. A major focus is on the determinants of rates of progression of age-related changes that affect disease risk, particularly those affecting risk for multiple age-related conditions. Examples of current areas addressed by this branch and future directions are:

- Healthy aging across the life span, including exceptional longevity
- Protective factors against multiple age-related conditions
- Longitudinal studies of factors affecting aging changes at different points in the life span

- Translational human research to follow up findings from basic research on aging processes
- Long-term effects of current or new interventions that may be administered over a large part of the life span (e.g., antihypertensives, statins)
- Long-term effects of physical activity throughout the life span

The *Clinical Trials Branch* plans and administers clinical trials on age-related issues that require extensive specialized clinical trials expertise. Examples of current and possible future types of interventions for trials are:

- Interventions to prevent or treat "geriatric syndromes", disability, and complications of comorbidity or polypharmacy
- Trials to detect age- or comorbidity-related differences in responses to interventions against conditions found in middle age and old age
- Interventions for problems associated with menopause and other mid- and late-life changes
- Interventions that may affect rates of progression of age-related declines in function in early and mid-life
- Interventions with protective effects against multiple age-related conditions

Neuroscience and Neuropsychology of Aging Program

This program fosters and supports extramural and collaborative research and training to further the understanding of neural and behavioral processes associated with the aging brain. Research on dementias of old age - in particular Alzheimer's disease - is one of the highest program priorities.

Neurobiology of Aging. The Neurobiology of Aging Branch fosters research on age-related cellular, molecular, and behavioral changes in the structure or function of the nervous system. Studies of neuroimmunology, neurovirology, neuroendocrinology, neuropharmacology, sensory and motor processes, sleep, biorhythmicity, cell death and neural plasticity are of particular interest.

The *Fundamental Neuroscience Section* supports research at cellular, molecular, and behavioral levels that explore age-related structural and functional changes in brain, including cell death, energy and metabolic changes, synaptic plasticity, neural stem cells and neurogenesis.

The *Integrative Neurobiology Section* supports research on neural mechanisms underlying age-related changes in endocrine functions; neurodegenerative diseases of aging associated with infectious agents; and central nervous system, neuroendocrine system, and immune system interactions in aging.

The *Sleep and Biological Rhythms Section* focuses on studies of epidemiology, etiology, pathogenesis, diagnosis, treatment, and prevention of sleep disorders of older people, age-related mechanisms underlying sleep-wakefulness cycles and behavioral sequelae in the aged, and on biorhythmicity in the aging nervous system.

The *Sensory Processes Section* focuses on mechanisms of normal aging and disease-related alterations in visual, auditory, somatosensory, vestibular, and chemosensory functions, and pain from the level of the gene to the whole organism as well as epidemiological studies of populations.

The *Motor Function Section* supports research on proprioception, postural control, sensory motor

integration, vestibular, and movement disorders in aging, including Parkinson's disease.

Dementias of Aging. The Dementias Branch supports studies of etiology, pathophysiology, epidemiology, clinical course/natural history, diagnosis and functional assessment, drug design, drug development and trials, and behavioral management and intervention in the dementias of later life. It also supports the Alzheimer's Disease Centers Program.

The *Basic Research Section* supports research on Alzheimer's disease and other age-related neurodegenerative disorders, including identification of genetic loci associated with inherited forms of these diseases as well as risk factor genes for late-onset Alzheimer's disease; molecular changes leading to cell death and other neuropathologies, including chemical and molecular genetic analysis of the components of amyloid plaques, neurofibrillary tangles, and other abnormal structures found in the brains of persons with Alzheimer's disease; and development and testing of interventions in model systems.

The *Population Studies Section* supports research in the epidemiology of cognitive decline, mild cognitive impairment, and Alzheimer's disease including prevalence, incidence, and risk and protective factors and on models for large-area registries for Alzheimer's disease.

The *Clinical Studies Section* supports research on the diagnosis, treatment, and management of patients with cognitive decline or Alzheimer's disease. Research on diagnosis is aimed at the development and evaluation of reliable and valid multidimensional procedures and instruments for diagnosis, progression, and response to treatment.

Research in the treatment and management of Alzheimer's seeks to develop the knowledge required to interrupt the course of the disorder, to manage its behavioral manifestations, and to ultimately prevent it. Treatment approaches include clinical trials of pharmacologic agents and studies of behavioral and environmental interventions. Preclinical drug discovery, development, and animal testing studies are important aspects.

The *Research Centers Section* supports Alzheimer's Disease Research Centers and Alzheimer's Disease Center Core programs, which provide a multifaceted approach to research on Alzheimer's disease, including clinical and other core services, neuropathological evaluation, basic and clinical research, professional and public information, and educational activities. It also supports the National Alzheimer's Coordinating Center, the National Cell Repository for Alzheimer's Disease, and several multi-center collaborative research projects.

Neuropsychology of Aging. The Neuropsychology of Aging Branch emphasizes research, including the use of animal models, on the neural and psychological mechanisms underlying age-related changes in basic cognitive processes, including learning, memory, attention, and language. Studies of age-related changes in emotion also are supported. The use of neural modeling, and computational neuroscience approaches, and the integration of these approaches, to understanding these structural and dynamic brain changes and adaptations are encouraged.

Behavioral and Social Research Program

This program supports basic social and behavioral research and research training on the processes of aging at both the individual and societal level. It focuses on how people change over the adult life course, on the interrelationships between older people and social institutions, and on the societal impact of the changing age-composition of the population. Emphasis is placed upon the dynamic interplay between the aging of individuals and their changing biomedical, social and physical environments and on multi-level interactions among psychological, physiological, social and cultural levels.

BSR supports research, training, the developing of research resources and methodologies to produce a scientific knowledge base for maximizing active life and health expectancy. This

knowledge base is required for informed and effective public policy, professional practice, and everyday life, and BSR also encourages the translation of behavioral and social research into practical applications.

The BSR Program is administratively organized into two branches: (1) *Individual Behavioral Processes* and (2) *Population and Social Processes*, with substantial interactions between them. A section devoted to *Research Resources and Development* is housed within the *Office of the Associate Director*.

Individual Behavioral Processes Branch. This branch supports research and training on biopsychosocial processes linking health and behavior, cognitive functioning, human factors, and integrative approaches to the study of social, psychological, and physiological influences on health and well-being over the life course. Personality and social/interpersonal relationships are investigated as causal variables, and as mediators or moderators of the relationship between social/structural characteristics and health outcomes.

- *Behavioral Medicine and Interventions Section.* Focused on examining the dynamic interrelationships among aging, health, and behavior processes, this unit expands traditional studies in behavioral medicine by adding an aging perspective as well an emphasis on the influence of the socio-cultural environment on the development and maintenance of a wide range of health and illness behaviors (e.g., healthy lifestyle practices, medical self management, and coping with chronic illnesses and disabilities). Major research topics include: 1) disease recognition, coping and management, including physiological consequences of life stresses and burdens; and 2) social, behavioral and environmental interventions for health promotion, disease prevention, and disability postponement.
- *Cognitive Aging Section.* Supports research on changes in cognitive functioning over the life course. Studies are encouraged that: 1) examine the influence of contexts (behavioral, social, cultural, and technological) on the cognitive functioning and life performance of aging persons; 2) investigate the effects of age-related changes in cognition on activities of daily living, social relationships, and health status, and 3) develop strategies for improving everyday functioning through cognitive interventions. Major research topics include: higher-order cognitive processes (e.g., problem-solving, decision-making), social cognition, memory strategies, perceptual skills, and reading and speech comprehension. Research is also welcomed that explores the role of individual difference factors in cognitive functioning (e.g., motivation, self-efficacy, beliefs about aging, emotions, sensory limitations, experience and expertise). This unit collaborates with the NIA Neuroscience and Neuropsychology of Aging Program to encourage research at the intersection of behavior and neurocognition.
- *Psychological Development and Integrative Science Section.* Promotes research that applies an integrative approach to the study of health, behavior, stress and coping, and well-being over the life course. Studies are encouraged that combine diverse levels of analysis and examine reciprocal interactions among these levels. Examples include the effects of sociocultural, psychological (social, personality), biological, and genetic processes on behavioral and functional aging. Studies exploring factors that influence aging at a single level are welcomed.

Population and Social Processes Branch. This branch supports research and training on the antecedents and impact of changing social, demographic, economic, and health characteristics of the older population. Research on the consequences of particular health care organizations and settings, and studies of the effects of other social institutions upon the health, well-being, and functioning of people in the middle and later years are supported. Comparative research is often appropriate, and interconnections with individual behavioral processes are encouraged.

- *Demography and Epidemiology Section.* This unit embraces such topics as medical and biodemography; changes in the age-structure of populations, as well as studies on the

prevalence and incidence of disease and disability, and age trajectories of health; life expectancy and active life expectancy; forecasting functioning, disability, morbidity, and mortality; migration and geographic concentrations of older people; rural-urban comparisons; distributions of health services and the long-term care system; race, ethnic, and socioeconomic variations; genetic epidemiology and population genetics.

- *Health and Retirement Economics Section.* This unit concentrates on all aspects of the economics of aging, including but not limited to, economic and health antecedents and consequences of work and retirement; pensions and savings; health insurance and health care expenditures; Medicaid, Medicare, and Social Security; interrelationships between health and economic status, including issues related to wealth, poverty, productivity, human capital development, and economic development; the economic costs of disability; cost-effectiveness of interventions; taxation policies; and cross-national comparisons.
- *Health and Social Institutions Section.* This unit encourages research on the impact of a wide range of formal health care and related services, with particular emphasis on long-term care systems and settings and on the health and well-being of older persons. It also examines how social institutions (e.g., work, family, religion, community, living arrangements) influence health outcomes in the later years and the ways in which people influence and are influenced by the network of cultural and social institutions surrounding them.

The Office of Research Resources and Development (ORRD). This Office replaces the Office of Demography of Aging that was established in 1991. ORRD coordinates and implements initiatives related to research data and resources. The Office manages the Health and Retirement Study (HRS), the National Archive of Computerized Data on Aging (NACDA), and all Interagency Agreements. ORRD also serves as the administrative site for the Federal Interagency Forum on Aging-Related Statistics that was established in 1986 to encourage cooperation among federal agencies responsible for the collection, analysis, development, and dissemination of data on the aging population.

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The NIH Almanac – Organization

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National Institute on Alcohol Abuse & Alcoholism

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Mission

The National Institute on Alcohol Abuse and Alcoholism (NIAAA) provides leadership in the national effort to reduce alcohol-related problems by:

- Conducting and supporting research in a wide range of scientific areas including genetics, neuroscience, epidemiology, health risks and benefits of alcohol consumption, prevention, and treatment;
- Coordinating and collaborating with other research institutes and Federal programs on alcohol-related issues;
- Collaborating with international, national, state, and local institutions, organizations, agencies, and programs engaged in alcohol-related work;
- Translating and disseminating research findings to health care providers, researchers, policymakers, and the public.

NIAAA's vision is to support and promote the best science on alcohol and health for the benefit of all. NIAAA uses multidisciplinary and transdisciplinary approaches to:

- Increase understanding of normal and abnormal biological functions and behavior relating to alcohol use;
- Improve the diagnosis, prevention, and treatment of alcohol use disorders;
- Enhance quality health care.

Important Events in NIAAA History

December 31, 1970 – NIAAA was established under authority of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (P.L. 91-616) with authority to develop and conduct comprehensive health, education, training, research, and planning programs for the prevention and treatment of alcohol abuse and alcoholism.

May 14, 1974 – P.L. 93-282 was passed, establishing NIAAA, NIMH, and NIDA as coequal institutes within the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA).

July 26, 1976 – NIAAA's research authority was expanded to include behavioral and biomedical etiology of the social and economic consequences of alcohol abuse and alcoholism under authority of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act amendments of 1976 (P.L. 94-371).

August 1981 – The Omnibus Budget Reconciliation Act of 1981 (P.L. 97-35) was passed, transferring responsibility and funding for alcoholism treatment services to the states through the creation of an Alcohol, Drug Abuse, and Mental Health Services block grant administered by ADAMHA and strengthened NIAAA's research mission.

October 27, 1986 – A new Office for Substance Abuse Prevention in ADAMHA was created through the Anti-Drug Abuse Act of 1986 (P.L. 99-570), which consolidated the remainder of NIAAA's nonresearch prevention activities with those of NIDA and permitted NIAAA's total commitment to provide national stewardship to alcohol research.

1989 – NIAAA launched the Collaborative Studies on Genetics of Alcoholism (COGA) with the goal of identifying the specific genes underlying vulnerability to alcoholism as well as collecting clinical, neuropsychological, electrophysiological, and biochemical data, and establishing a repository of immortalized cell lines.

1991 – NIAAA began the National Longitudinal Alcohol Epidemiologic Survey, designed to study drinking practices, behaviors, and related problems in the general public.

July 10, 1992 – NIAAA became a new NIH research institute under authority of ADAMHA Reorganization Act (P.L. 102-321).

May 3, 1995 – NIAAA celebrated its 25th anniversary.

April 8, 1999 – NIAAA organized the first National Alcohol Screening Day (NASD), created to provide public education, screening, and referral for treatment when indicated. The program was held at 1,717 sites across the United States, including 499 college sites.

1999 – NIAAA co-sponsored the launch of the *Leadership to Keep Children Alcohol Free*, a unique coalition of state Governors' spouses, Federal agencies, and public and private organizations that targets prevention of drinking in young people ages 9- to 15-years old.

April 9, 2002 – NIAAA published *A Call to Action: Changing the Culture of Drinking at U.S. Colleges, the Final Report of the Task Force on College Drinking*, which was developed by a panel convened by NIAAA's National Advisory Council to conduct a comprehensive review of research on college drinking and the effectiveness of methods to prevent it.

June 2004 – Publication of the results from the 2001-2002 National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), a longitudinal survey that is a representative sample of the United States population with data on alcohol and drug use; alcohol and drug abuse and dependence; and associated psychiatric and other medical comorbidities.

Dr. Ting-Kai Li, M.D.

Dr. Ting-Kai Li was appointed to the position of the Director of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) in November 2002. Born in Nanjing, China, Dr. Li earned his undergraduate degree from Northwestern University and his M.D. from Harvard University. He completed his residency training at Peter Bent Brigham Hospital in Boston, where he was named chief medical resident in 1965.

Dr. Li received his research training at Harvard University Medical School and conducted research at the Nobel Medical Research and Karolinska Institutes in Stockholm, Sweden before becoming deputy director of the department of biochemistry at the Walter Reed Army Institute of Research. He joined the faculty at Indiana University as professor of medicine and biochemistry in 1971. He subsequently was named the school's John B. Hickam Professor of Medicine and Professor of Biochemistry and, later, Distinguished Professor of Medicine. In 1985 he became director of the Indiana Alcohol Research Center (IARC) at the Indiana University School of Medicine, where he also was the Associate Dean for Research. Dr. Li is also the recipient of Honorary D.Sc. degrees awarded by Northeast Ohio Universities Colleges of Medicine (1998) and by Indiana University and Purdue University (2003).

Throughout his distinguished research career, Dr. Li has been at the center of advances that have transformed both the way alcoholism is understood and the means of investigating alcohol's effects on the body and brain. A major focus of Dr. Li's research has been to characterize the structure and functional characteristics of the multiple genetic variants of alcohol dehydrogenase (ADH), the enzyme that catalyzes the first step in the metabolism of ethanol, and the differences among individuals in the physiology of these enzymes. Dr. Li also pioneered the development of animal models in which marked differences in the level of voluntary alcohol consumption could be observed, paralleling the same inborn variation seen in human behavior. The development of these animal lines helped cement the once radical notion that alcohol consumption behavior was genetically influenced.

Dr. Li is the author of more than 400 journal articles and book chapters, has been invited to deliver many major lectureships in countries all over the world, and is the recipient of numerous prestigious awards for his scientific accomplishments, including the Jellinek Award, the James B. Isaacson Award for Research in Chemical Dependency Diseases and the R. Brinkley Smithers Distinguished Science Award. Dr. Li has also served in many prominent leadership and advisory positions including past President of the Research Society on Alcoholism (RSA), and as a member of the National Advisory Council on Alcohol Abuse and Alcoholism and the Advisory Committee to the Director, NIH. Dr. Li was elected to membership in the Institute of Medicine of the National Academy of Sciences in 1999 and is an honorary fellow of the United Kingdom's Society for the Study of Addiction.

NIAAA Directors

Name	In Office From To	
Morris E. Chafitz	1972	September 1, 1975
Ernest P. Noble	February 1976	April 1978
Loran Archer (Acting)	April 1978 November 1981 January 1986	April 1979 July 1982 October 1986
John R. DeLuca	May 1979	October 1981
William E. Mayer (Acting)	August 1982	July 1983
Robert G. Niven	August 1983	December 1985
Enoch Gordis	November 1986	January 2002
Raynard Kington (Acting)	January 2002	November 2002
Ting-Kai Li	November 2002	Present

Programs and Activities

NIAAA conducts and supports research through its Division of Intramural Clinical and Biological Research and through its four extramural divisions that provide grants to scientists at leading research institutions across the country. In addition, findings from these research endeavors are made available through a variety of research translation and dissemination programs and activities. More information on NIAAA programs can be found at NIAAA's Web site at <http://www.niaaa.nih.gov>.

Intramural Research

The overall goal of the NIAAA's Division of Intramural Clinical and Biological Research is to understand the mechanisms by which alcohol produces intoxication, dependence, and damage to vital body organs, and to develop tools to prevent and treat those biochemical and behavioral processes. Areas of study include identification and assessment of genetic and environmental risk factors for the development of alcoholism; the effects of alcohol on the central nervous system, including how alcohol modifies brain activity and behavior; metabolic and biochemical effects of alcohol on various organs and systems of the body; noninvasive imaging of the brain structure and

activity related to alcohol use, development of animal models of alcoholism; and the diagnosis, prevention, and treatment of alcoholism and associated disorders.

NIAAA utilizes a combination of clinical and basic research facilities, which enables a coordinated interaction between basic research findings and clinical applications in pursuit of these goals. A 12-bed inpatient ward and a large outpatient program are located in the NIH Clinical Research Center in Bethesda, Maryland.

NIAAA intramural researchers investigate a number of areas, including –

- research focused on investigating and identifying the vulnerability and protective genes that underlie alcoholism's heritability;
- studies seeking a better understanding of the underlying factors of alcoholic liver disease;
- investigating the biological functions of essential fatty acids and the adverse effects of alcohol on these functions;
- studies to determine how alcohol interacts with nerve cells and the brain's signaling system to improve our understanding of the molecular basis of alcohol dependence and lead to development of treatments and prevention strategies.

Extramural Research

Division of Epidemiology and Prevention Research

Alcohol epidemiology provides the foundation for monitoring the role of alcohol in various health outcomes in the population, for the development and evaluation of prevention and treatment of alcohol-related problems, and for the establishment of alcohol-related social policies.

Epidemiology Research – NIAAA conducts and supports epidemiologic research to study the distribution and determinants of alcohol use and its associated health and social consequences. These include alcohol abuse and dependence, fatal and non-fatal alcohol-related intentional and unintentional injuries (e.g. motor vehicle injuries and deaths, assaults, drownings, homicides, and suicides), medical diseases for which alcohol is a contributing factor (e.g. cancer, heart disease), and alcohol-related negative social outcomes (e.g. family violence, school failure). Alcohol-related epidemiologic research also includes studies of co-occurring disorders (e.g. psychiatric disorders, other drug abuse/dependence) as well as studies of the risks and benefits of moderate alcohol consumption. Methodological studies focused on improving measurement and assessment in all of the above areas of research also play an important role.

Prevention Research – NIAAA supports community-based controlled intervention trials to prevent alcohol-related trauma (including violence), underage drinking, and, drinking and driving. These include studies of school/parent/community-focused interventions among economically and ethnically diverse populations, media advocacy strategies, strategies to enhance voluntary and enforced compliance with underage drinking laws, and a variety of community-mobilization techniques.

College-Focused Research and Other Special Emphasis Programs – Several studies are addressing alcohol problems on college campuses, including "binge" drinking. Epidemiologic studies are exploring various aspects of drinking by college students. Other studies are testing the efficacy and effectiveness of preventive interventions designed to reduce drinking and problem drinking among college students.

Other projects addressing special areas of emphasis include studies on rural underage drinking, research to measure the impact of alcohol advertising on youth and adults, and studies on the effectiveness of various sanctions and treatments to prevent recidivism for DWI (drinking while intoxicated).

Health Services Research – NIAAA supports a program of health services research that seeks to expand understanding of how alcohol treatment and prevention services are organized, managed, financed, and delivered and how these factors influence the availability, quality, cost, utilization, effectiveness, and efficiency of these services.

HIV/AIDS – NIAAA supports a program of research studying the relationship of alcohol use and HIV/AIDS in infected and uninfected drinkers with regard to risk, prevention and treatment. This includes studies on –

- domestic and international epidemiologic studies to characterize modes of transmission related to alcohol use, abuse, and dependence (including genetic variations) and other factors such as other substance use, mental illness, and homelessness;
- the interactions between individual and social, structural, and cultural factors and contexts that contribute to the co-occurrence of HIV/AIDS;
- the effectiveness of interventions to reduce alcohol-related HIV infection
- exploring how alcohol influences testing for HIV, getting into treatment for HIV/AIDS, responding to and complying with treatment regimens, and health care utilization among infected persons.

Division of Metabolism and Health Effects

Chronic alcohol use affects every organ and system of the body and can lead to life threatening medical disorders, including liver cirrhosis, pancreatitis, and cardiomyopathy. Heavy alcohol use is also an important factor for co-morbid conditions, such as hepatitis C, osteoporosis, type 2 diabetes, and certain cancers. The NIAAA supports a wide range of research to elucidate the genetic, metabolic, and immunologic mechanisms of alcohol-induced tissue injury that contribute to the initiation and progression of these disorders.

Basic research studies are identifying the molecular pathways through which alcohol causes organ damage with the goal of identifying the targets for drug discovery to prevent or treat alcohol-related disorders. The potential for tissue repair and regeneration following damage from chronic heavy drinking through stem cell therapy, gene targeting, and metabolic manipulations is being explored.

Metabolic research in the field of alcohol abuse and alcoholism is accordingly broad in nature, encompassing: enzymes, proteins, substrates, substrate adducts, co-factors, vitamins, nucleic acids, sugars and other metabolites which may be affected by alcohol or alcohol by-products.

Other basic investigations seek to identify biomarkers for the early stages of disease using genomic, proteomic, and metabolomic approaches that will facilitate early identification and treatment before diseases become irreversible.

The NIAAA also supports research to elucidate the mechanism of alcohol's potential beneficial effects. These include studies related to coronary heart disease and other inflammatory diseases.

Recently, the NIAAA has developed a multidisciplinary team on the mechanisms of alcohol action and injury with a focus on the integration of genetic, cellular, and animal models research with patient-oriented research on alcohol metabolism, pharmacokinetics, pharmacodynamics, developmental effects, and organ damage/benefit.

The knowledge gained from the research described above will inform the development of new therapeutic strategies to prevent or slow the progression of diseases caused by excessive drinking.

Division of Neuroscience and Behavior

NIAAA supports research in two broad categories. The first concerns the effects of acute and chronic alcohol consumption on the structure and function of the nervous system. Basic research

seeks to understand the acute effects of alcohol on neuronal processes, gene transcription, and behavioral responses. These changes result from alcohol exposure but the response varies depending on the pattern of alcohol consumption. Chronic exposure results in structural and functional neuroadaptations leading to prolonged and excessive alcohol consumption. Studies of pathological changes after prolonged alcohol use that result in cognitive decline and neurodegeneration are actively being pursued.

Of particular concern are –

- the consequences of alcohol use during pregnancy that produces fetal alcohol syndrome disorders (FASD); and
- the effects of alcohol drinking on the adolescent brain and throughout the lifespan.

The acute and chronic effects of alcohol exposure encompasses study at multiple levels ranging from molecular through cellular and genetic to neural pathways and circuits that mediate behavioral responses such as tolerance, dependence, sensitization and relapse.

A second category of emphasis concerns the neurobiological mechanisms underlying the motivation for alcohol consumption leading to excessive drinking. A high priority is research to identify the genetic components and environmental influences such as stress that increase vulnerability to alcohol use, dependence, and relapse. Such studies will inform medications development strategies as well as prevention-intervention studies.

Division of Treatment and Recovery Research

NIAAA continues to emphasize research to improve treatment of alcohol use disorders through a program of both solicited and investigator initiated research on behavioral and pharmacologic treatments, health services research, and use of epidemiologic data bases to assess national trends and potential needs.

Division staff participate in a number of NIAAA's *Trans-divisional Research Emphasis and Resource Development Teams*. These include the following:

Behavioral and Environmental Interventions – NIAAA supports research to improve the efficacy and cost-effectiveness of preventive and behavioral treatment interventions at the individual, family, and broader community levels. NIAAA support has been crucial in the development and testing of effective school-based and community prevention programs. Addressing underage drinking especially on college campuses is a central goal. NIAAA-supported studies have demonstrated that brief interventions delivered in primary care health settings are effective for reducing alcohol consumption in heavy drinkers. Large multi-site NIAAA-funded trials comparing psychotherapy approaches to treating alcohol use disorders have provided valuable information concerning the efficacy of alcohol treatment. Future research efforts will focus on improving understanding of natural recovery; the role of spirituality in recovery; understanding the mechanisms of action of behavior therapies; and adolescent treatment.

Genes and Environment – Alcoholism has long been recognized as a familial disorder, and NIAAA-supported twin, family, and adoption studies have indicated major roles for both genetic and environmental factors in its etiology. Twin and family studies are defining more precisely those aspects of the risk for alcoholism that are inherited. Vulnerability to alcoholism is influenced by multiple genes and gene variants. In order to identify these genes, the NIAAA supports studies in affected individuals and their families drawn from diverse populations from various ethnic backgrounds.

The largest of such studies has been the Collaborative Study on the Genetics of Alcoholism (COGA), initiated in 1989. Researchers identified candidate genes and

published data providing suggestive evidence for the locations of several other relevant genes and gene variants, based on detailed diagnostic evaluations of more than 20,000 individuals drawn from families with a high incidence of alcoholism, and genotyping of more than 3,000 individuals selected from that sample population.

NIAAA also supports studies using naturally occurring and induced genetic variations in animals as a tool for identifying the genes associated with various features of the vulnerability to alcohol abuse and the response to alcohol, such as sensitivity, stimulation, aggression, tolerance, sedation, and withdrawal. Animal models have been used to identify genetic factors associated with variation in many alcohol-related behavioral traits and physiological and biochemical variation relevant to the alcohol response. Gene mapping has resulted in the identification of more than a hundred chromosomal regions associated with alcohol-related traits and has identified candidate genes and gene variants associated with alcohol dependence. NIAAA continues to encourage data sharing and bioinformatics approaches to increase understanding of genetic variation in alcohol response.

Identification of genes predisposing to risk for alcoholism and the physiological pathways mediating the development of this disorder will provide us with clues to biomarkers for risk and injury and medications for prevention, treatment, and mitigation of alcohol-induced injury. Moreover, knowledge of the genes predisposing to alcoholism will permit the design of more powerful studies to determine which gene-gene and gene-environment interactions influence this disease.

NIAAA also supports studies of the interaction of genes and environment that contribute to an individual's susceptibility to alcohol-related medical disorders such as liver cirrhosis, pancreatitis, cardiomyopathy, fetal alcohol spectrum disorders, and cancers related to alcohol exposure.

Mechanisms of Alcohol Action and Injury – NIAAA support in this area is focused on the integration of genetic, cellular, and animal models research with patient-oriented research on alcohol metabolism, pharmacokinetics, pharmacodynamics, developmental effects, and organ damage/benefit.

Medications Development – NIAAA is strongly committed to the development of pharmacological interventions to diminish the craving for alcohol, reduce risk of relapse, and safely detoxify dependent individuals undergoing treatment. Pharmacologic agents are at various stages of development ranging from preclinical research to clinical application for the treatment of alcoholism, including two promising medications: naltrexone and acamprosate. Naltrexone, an opioid antagonist, has been approved by U.S. Food and Drug Administration (FDA) as a safe and effective adjunct to psychosocial treatment for alcoholism. Acamprosate, a medication that interacts with the glutamate receptor, was recently approved by the FDA for treating alcohol dependent individuals seeking to continue to remain alcohol-free after they have stopped drinking.

Since alcohol-seeking behavior is complex and involves several neurotransmitter systems and neurohormones, NIAAA is exploring a range of medications to modify drinking behavior, including topiramate, a GABA enhancer and glutamate inhibitor, and ondansetron, a serotonin₃ (5-HT₃) blocker. Related topics of interest are medication compliance, differential effect of pharmacotherapies on subtypes of alcoholics, effects of medications when used in concert with psychosocial interventions, and two (or more) medications in combination. The medications development program also seeks to develop compounds to treat alcohol-related medical disorders as well as to promote tissue regeneration in organs damaged by alcohol. The safety and efficacy of medications to treat adolescents with alcohol disorders is a new area of research.

Research on Underage Drinking – Underage drinking presents an enormous public health issue. Alcohol is the drug of choice among children and adolescents. As the lead Federal agency for supporting and conducting basic and applied research on alcohol problems, NIAAA is spearheading an initiative to intensify research, evaluation, and outreach efforts regarding underage drinking. NIAAA also supports the Leadership to Keep Children Alcohol Free, a unique coalition of State Governors' spouses, Federal agencies, and public and private organizations that targets prevention of drinking in young people ages 9- to 15-years old. Additional information is available at <http://www.niaaa.nih.gov/about/underage.htm>.

Additional teams are focused on developing technology and analysis resources and supporting the multi-site projects, such as the Alcohol Research Centers, and programs for training the next generation of investigators to carry out alcohol-related studies.

Research Translation and Dissemination

NIAAA also supports collaborations with other organizations through the Office of Research Translation and Communications. The following are highlights from selected program activities:

Alcohol and Pregnancy – NIAAA supports research to determine why and how alcohol consumption during pregnancy results in adverse consequences for the fetus, the most serious of which is fetal alcohol spectrum disorders (FASD) characterized by reduced growth; facial abnormalities; and neurological, cognitive, and behavioral impairment. NIAAA chairs the Interagency Coordinating Committee on Fetal Alcohol Syndrome (ICCFAS), which was created in 1996 in response to a report by an expert committee of the Institute of Medicine (IOM). For details, visit the ICCFAS Web site at <http://www.niaaa.nih.gov/FAS/TOC.html>.

In 2003 NIAAA launched the Collaborative Initiative on Fetal Alcohol Spectrum Disorders (CIFASD), a program to inform and develop effective interventions and treatment approaches for the full spectrum of neurological disorders caused by fetal alcohol exposure. CIFASD comprises highly integrated, multidisciplinary research projects.

Alcohol Screening –The Institute's screening programs have a number of important goals: to increase public and professional involvement in identifying individuals who would benefit most from alcohol prevention and treatment; to increase the visibility of alcohol problems and the importance of incorporating screening into routine practice in medical and other health professional settings in the U.S., and to heighten awareness of the consequences of at-risk drinking.

National Alcohol Screening Day (NASD) provides an opportunity for the public to receive basic information about alcohol consumption. Screening is performed annually during the month of April in thousands of public, college, primary care, clinic, and government settings across the U. S.

Alcohol Health and Science Education Programs – The Institute supports several initiatives to better prepare health professionals to identify, prevent, and treat alcohol problems in their patient populations. This is accomplished by developing and disseminating research-based curricula and state-of-the-art faculty training programs. Curricula have been developed for medical education and professional social workers.

The NIAAA also develops, disseminates, implements, and evaluates innovative educational programs regarding the science of alcohol for K-12 science education and public education programs.

Research Dissemination –NIAAA maintains a communications program aimed at informing health care practitioners, researchers, policy makers, and the general public about findings from supported research programs. Scientific communications include vehicles such as:

- Alcohol Research & Health, a peer-reviewed journal available by both subscription and full text on the NIAAA's web site.
- the Alcohol Alert series, bulletins designed to quickly disseminate research findings to health professionals.
- FrontLines, a newsletter reporting on current findings from alcohol-related health services research and other critical issues of interest to science, practitioner, policy-making, and general audiences.
- the NIAAA Newsletter, featuring news, events, and updates on research initiatives, organizational changes, new publications and resources, and other information for the alcohol research community.
- Public service announcements, videos, posters, brochures, pamphlets, fact sheets, Web pages, and other materials as well as coordinated public education campaigns to inform the public about alcohol misuse and related research topics.

Online Resources – Research findings and resources are also shared with the alcohol and general health care communities through the NIAAA Web site, <http://www.niaaa.nih.gov>. The Web site features publications, news releases, grant and contract information, conferences and workshops, databases, frequently asked questions for the public, and links to other resources.

NIAAA also hosts www.TheCoolSpot.gov, a unique interactive for site middle-school students that uses quizzes, games, and graphics to deliver important messages about the risks of underage drinking and ways to resist peer pressure.

This page was last reviewed on August 18, 2005 .

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National Institute of Allergy and Infectious Diseases

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Mission

The National Institute of Allergy and Infectious Diseases (NIAID) conducts and supports research to study the causes of allergic, immunologic, and infectious diseases, and to develop better means of preventing, diagnosing, and treating these illnesses.

Following is a brief description of the major areas of investigation.

- *Acquired Immunodeficiency Syndrome (AIDS)*. NIAID is responsible for conducting and supporting basic research on the pathogenesis of the human immunodeficiency virus (HIV), which causes AIDS; developing new drug therapies; conducting clinical trials of promising experimental drugs for HIV infection and related opportunistic infections and cancers; carrying out epidemiologic studies to assess the impact of HIV on the populations most severely affected by the epidemic; and developing and testing HIV vaccines and other prevention strategies.
- *Asthma and Allergic Diseases*. NIAID supports programs to examine the causes, pathogenesis, diagnosis, treatment, and prevention of asthma and allergic diseases. Examples of such programs include the Inner-City Asthma Consortium and the Food Allergy Research Consortium.

In 2005, NIAID opened a pediatric allergy clinic at the NIH Clinical Center to serve as a focal point for translational research conducted in collaboration with NIAID intramural laboratories and clinical trials of novel therapies.

- *Biodefense*. To meet the challenges posed by bioterrorism affecting the civilian population, NIH supports research in basic research into microbial biology and host response and the development of (1) rapid, accurate diagnostics for natural and bioengineered microbes; (2) effective antimicrobial and antitoxin medicines to treat those individuals affected; and (3) protective vaccination for individuals at risk of exposure. Basic research provides the essential underpinnings for the other research areas. The program embraces the concept that bioterrorism and emerging infectious diseases are related public health issues.
- *Radiation Exposure*. In 2004, the HHS Office of Public Health Emergency Preparedness charged NIH with designing and implementing a national research program for the development of medical countermeasures appropriate for civilian use that can be used against radiological and nuclear attack. As the lead institute for research on immune homeostasis and immune reconstitution, NIAID is tasked with developing a robust research program in this area. With the input of government and non-government experts, NIAID has developed the NIH Strategic Plan and Research Agenda for Medical Countermeasures against Radiological and Nuclear Threats (see: <http://www3.niaid.nih.gov/research/topics/radnuc>)

- *Emerging and Re-emerging Infectious Diseases.* New diseases are arising worldwide and old diseases are re-emerging as infectious agents evolve or spread, and as changes occur in ecology, socioeconomic conditions, and population patterns. NIAID conducts and supports research on influenza, West Nile virus, hepatitis C, tuberculosis, and other emerging and re-emerging diseases to develop new or improved diagnostics, treatments, and vaccines.
- *Enteric Diseases.* Worldwide, diarrheal diseases such as cholera and rotavirus infection are major causes of illness and death in infants and children. In contrast, viral hepatitis in its various forms, can cause severe disease in older children and adults, although it produces few symptoms among younger age groups. NIAID supports basic research on how enteric agents cause illness as well as studies aimed at developing and testing vaccines to prevent enteric infections.
- *Genetics and Transplantation.* NIAID's basic immunology and genetics research seeks to define the effects of gene expression on immune function and to determine the manner in which the products of gene expression control the immune response to foreign substances, such as transplanted organs and cells. NIAID supports studies to further develop methods and reagents needed for precise tissue typing to ensure that transplant recipients receive the best-matched donor organs available. Research programs in genetics and transplantation include HLA Region Genetics in Immune-Mediated Diseases, the Genomics of Transplantation, and Clinical Trials in Organ Transplantation.
- *Immune-Mediated Diseases.* NIAID supports basic, pre-clinical, and clinical research on immune-mediated diseases, including: asthma and allergic diseases, autoimmune disorders, primary immunodeficiency diseases, and the rejection of transplanted organs, tissues, and cells. Efforts are underway to evaluate the safety and efficacy of tolerance induction strategies for treating immune-mediated diseases, as well as clinical trials to assess the efficacy of hematopoietic stem cell transplantation for treating severe autoimmune disorders. These programs include the Autoimmunity Centers of Excellence, the Immune Tolerance Network (<http://immunetolerance.org>), Autoimmune Diseases Prevention Centers, Clinical Trials in Organ Transplantation, and the Primary Immunodeficiency Diseases Consortium (<http://www.usidnet.org/>).

The NIAID chairs the NIH Autoimmune Diseases Coordinating Committee (ADCC), established in FY 1998 at the request of Congress, to increase collaboration among the many NIH Institutes, private groups, and other federal agencies interested in these diseases and to facilitate the development of coordinated research plans. The ADCC Autoimmune Diseases Research Plan, which was mandated by the Children's Health Act of 2000 (Public Law 106-310), was presented to Congress in late 2002. In March 2005, the ADCC submitted *Progress in Autoimmune Disease Research*, its third report to Congress.

- *Malaria and Other Tropical Diseases.* Diseases such as malaria, filariasis, trypanosomiasis, and leprosy disable and kill millions of people worldwide. NIAID's research efforts in tropical medicine are conducted by U.S. and foreign investigators receiving Institute support and by NIAID intramural scientists in Bethesda.. NIAID supports a number of centers for tropical medicine research in countries where such diseases are endemic.
- *Pathogen Genomics.* NIH is also working to sequence the entire genomes of pathogenic microbes and invertebrate vectors of infectious diseases. Pathogen gene sequencing efforts are enabling scientists to identify genes that may lead to potential new vaccine candidates and drug targets so that infectious diseases can be accurately diagnosed, prevented and treated. In addition, knowing a pathogen's genetic sequence will help researchers better understand how mechanisms of pathogenesis and pathogen mutations contribute to drug resistance.

- ***Sexually Transmitted Infections (STIs).*** More than 15 million Americans each year acquire infectious diseases other than AIDS through sexual contact. Such STIs as gonorrhea, syphilis, chlamydia, genital herpes, and human papillomavirus can have devastating consequences, particularly for young adults, pregnant women, and newborn babies. NIAID-supported scientists in STI Cooperative Research Centers, NIAID laboratories, and other research institutions are developing better diagnostic tests, improved treatments, and effective vaccines.
- ***Vaccine Development.*** Effective vaccines have contributed enormously to improvements in public health in the United States during the last century. Research conducted and supported by NIAID has led to new or improved vaccines for a variety of serious diseases, including rabies, meningitis, whooping cough, hepatitis A and B, chickenpox, and pneumococcal pneumonia, to name a few. NIAID supports vaccine evaluation units for the testing of new vaccines in people at a number of U.S. medical centers.
- ***Drug Research and Development.*** The development of therapies to treat infectious and immunologic diseases is a key component of NIAID's mission. In collaboration with industry, academia, and other government agencies, NIAID has established research programs to facilitate drug development, including capacity databases to screen chemicals for their potential use as therapeutic agents, facilities to conduct preclinical screening/testing of promising drugs, and clinical trials networks to evaluate the safety and efficacy of drugs and therapeutic strategies in humans.
- ***Antimicrobial Resistance.*** NIAID funds a diverse portfolio of grants and contracts to study antimicrobial resistance in major viral, bacterial, fungal, and parasitic pathogens. Projects include basic research into the disease-causing mechanisms of pathogens, host-pathogen interactions, and the molecular mechanisms responsible for drug resistance, as well as applied research to develop and evaluate new or improved products for disease diagnosis, intervention, and prevention. NIAID-supported clinical trials networks with capacity to assess new antimicrobials and vaccines relevant to drug-resistant infections include the Adult AIDS Clinical Trials Groups, the Bacteriology and Mycology Study Group, the Collaborative Antiviral Study Group, and Vaccine and Treatment Evaluation Units.
- ***Minority and Women's Health.*** Some of the diseases studied by NIAID disproportionately affect women and minority populations. The Institute remains committed to the inclusion of minorities and women in every aspect of its scientific agenda, from recruitment of special populations into clinical studies to the conduct of biomedical research by minority researchers. NIAID's Office of Special Populations and Research Training sponsors activities aimed at eliminating the continuing health disparities among these populations. The Office also develops innovative training initiatives to increase the number of minority scientists by supporting undergraduate, graduate, and postgraduate research training in immunologic and infectious diseases. NIAID research results are disseminated to underserved minority communities through the Institute's outreach activities, which have focused to date on AIDS, asthma, and autoimmune diseases.

Important Events in NIAID History

1948 – The National Microbiological Institute was established November 1. The Rocky Mountain Laboratory and the Biologics Control Laboratory, both dating to 1902, were incorporated into the new institute, together with the Division of Infectious Diseases and the Division of Tropical Diseases of NIH.

1951 – An institute-supported grants program was initiated, and a branch was established to administer research, training, and fellowship grants. Grant applications were reviewed by the National Advisory Health Council until 1956.

1953 – The Clinical Research Branch was renamed the Laboratory of Clinical Investigation.

1955 – The National Microbiological Institute became the National Institute of Allergy and Infectious Diseases on December 29. The Biologics Control Laboratory was detached from the institute and expanded to division status within NIH.

1956 – The first meeting of the National Advisory Allergy and Infectious Diseases Council was held March 7-8.

1957 – The Laboratory of Immunology was established in January to meet the growing need for research on the mechanisms of allergy and immunology.

The Middle America Research Unit was established in the Canal Zone jointly by NIAID and the Walter Reed Army Institute of Research as a temporary field station, made permanent in 1961. Important tropical diseases studies were done there for 15 years. NIAID transferred its part of the program to the Gorgas Memorial Institute in 1972.

1959 – The Laboratory of Parasitic Diseases was established, formerly a part of the Division of Tropical Diseases.

1962 – A collaborative research program funded mainly by contracts was established within the institute to plan, coordinate, and direct nationwide projects on infectious diseases, vaccine development, transplantation immunology, research reagents, and antiviral substances.

1967 – The Laboratory of Viral Diseases was established.

1968 – With the dissolution of NIH's Office of International Research and creation of the Fogarty International Center on July 1, 1968, programs formerly managed by OIR were transferred to NIAID to be administered by the Geographic Medicine Branch. These included the U.S.-Japan Cooperative Medical Science Program – initiated in 1965 by the President and the Japanese Prime Minister to explore the health problems of Asia, and the International Centers for Medical Research and Training – a 1960 congressional initiative to advance the status of U.S. health sciences through international research.

1971 – The first seven Allergic Disease Centers were established to translate basic concepts of the biomedical sciences into clinical investigations.

1974 – The first centers for the study of sexually transmitted diseases and of influenza were established.

1977 – The NIAID Extramural Research Program was reorganized into three areas: Microbiology and Infectious Diseases; Immunology, Allergic and Immunologic Diseases; and Extramural Activities. An intramural Laboratory of Immunogenetics was formed.

1978 – The first maximum containment facility (P4) for recombinant DNA research was opened in Frederick, Md. International program project grants and international exploratory/development research grants programs were established. Centers were created for interdisciplinary research on immunologic diseases.

1979 – The Office of Recombinant DNA Activities was transferred from the NIGMS to NIAID. The International Collaboration in Infectious Diseases Research Program superseded the International Centers for Medical Research and Training established in 1960.

The Rocky Mountain Laboratory was reorganized into the Laboratory of Persistent Viral Diseases to deal with both host and viral mechanisms leading to slow or persistent viral infections; the Laboratory of Microbial Structure and Function, directed at bacterial diseases, particularly sexually

transmitted diseases; and an Epidemiology Branch.

1980 – The Laboratory of Immunoregulation was established to provide a means for applying new knowledge in immunology to the clinical diagnosis and treatment of patients with immunological disorders.

1981 – The Laboratory of Molecular Microbiology was created to exploit new techniques in recombinant DNA methodology and other molecular studies to expand the institute's interests in both bacterial and viral pathogenesis and virulence.

1984 – The Office of Tropical Medicine and International Research (OTMIR) was established to coordinate NIAID's intramural and extramural research activities in tropical medicine and other international research. OTMIR works with other Federal agencies and international organizations active in these areas.

1985 – The Laboratory of Immunopathology was established. At Rocky Mountain Laboratories, the Epidemiology Branch was renamed the Laboratory of Pathology.

1986 – An Acquired Immunodeficiency Syndrome (AIDS) Program was established in January to coordinate the institute's extramural research efforts in HIV/AIDS.

1987 – The Laboratory of Cellular and Molecular Immunology was established.

1988 – The Immunology, Allergic and Immunologic Diseases Program was reorganized and renamed the Allergy, Immunology, and Transplantation Program.

The Office of Recombinant DNA Activities transferred from NIAID to the NIH Office of the Director.

1989 – NIAID's programs became divisions: Intramural Research; Microbiology and Infectious Diseases; Allergy, Immunology, and Transplantation; Acquired Immunodeficiency Syndrome; and Extramural Activities.

1990 – At Rocky Mountain Laboratories, a section of the Laboratory of Microbial Structure and Function became the Laboratory of Intracellular Parasites. The name of the Laboratory of Pathobiology was changed to the Laboratory of Vectors and Pathogens.

1991 – The Laboratory of Host Defenses was established.

1994 – The Laboratory of Allergic Diseases was established.

The Office of Research on Minority and Women's Health was created.

At Rocky Mountain Laboratories, the Laboratory of Vectors and Pathogens was renamed the Microscopy Branch.

1999 – The Dale and Betty Bumpers Vaccine Research Center was launched – a research program jointly funded by NIAID, NCI, and the NIH Office of AIDS Research.

2000 – The Children's Health Act of 2000 (P.L. 106-310) codified the NIH Autoimmune Diseases Coordinating Committee in law. The ADCC is chaired by the NIAID.

2001 – Malaria Vaccine Development Unit dedicated.

2002 – Laboratory of Parasitic Diseases reorganized; Laboratory of Malaria and Vector Research

established.

The Office of Biodefense Research Affairs was established within the Division of Microbiology and Infectious Diseases to coordinate the planning, implementation, and evaluation of DMID-wide biodefense research.

NIAID awards its first Partnership grants to support collaboration between private industry, academia and government to accomplish critical infectious disease and biodefense research goals.

2003 – NIAID establishes an intellectual and physical infrastructure for biodefense research through awards to support National and Regional Biocontainment Laboratories (NBLs and RBLs) and Regional Centers of Excellence (RCEs) for Biodefense and Emerging Infectious Diseases.

2004 – The Laboratory of Molecular Immunology was established.

2005 – The Laboratory of Zoonotic Pathogens was established.

The Laboratory of Bacterial Diseases was established.

NIAID makes its first awards using authorities granted under Project Bioshield legislation to support development of new therapeutics and vaccines against some of the most deadly agents of bioterrorism including anthrax, botulinum toxin, Ebola virus, pneumonic plague, smallpox and tularemia.

NIAID Legislative Chronology

November 1, 1948 – The National Microbiological Institute was established under authority of section 202 of the Public Health Service Act, as implemented by General Circular No. 55, Organization Order No. 20, dated October 8, 1948.

December 29, 1955 – NIAID was established (replacing the National Microbiological Institute) under authority of the Omnibus Medical Research Act (P.L. 81-692, 64 Stat. L. 443) as implemented by PHS Briefing Memorandum of November 4, 1955, from the Surgeon General to the Secretary of Health, Education, and Welfare.

November 4, 1988 – NIAID was provided with additional authorities under title II of the Health Omnibus Programs Extension Act of 1988 (P.L. 100-607), the first major law to address AIDS research, information, education, and prevention.

August 14, 1991 – The PHS act (P.L. 102-96), the "Terry Beirn Community Based AIDS Research Initiative Act of 1991" reauthorized NIAID's Community Programs for Clinical Research on AIDS (CPCRA) for another 5 years.

June 10, 1993 – The PHS act was amended by P.L. 103-43, the National Institutes of Health Revitalization Act of 1993. This comprehensive legislation required NIAID to include research on tropical diseases in its mission statement and directed the Secretary, DHHS, to ensure that individuals with expertise in chronic fatigue syndrome or neuromuscular diseases are appointed to appropriate NIH advisory committees.

December 14, 1993 – The Preventive Health Amendments of 1993 were passed, which included provisions requiring the director, NIAID, to conduct or support research and research training regarding the cause, early detection, prevention, and treatment of tuberculosis. (The institute already had authority to conduct such research under its authorities in Title IV, PHS act.)

October 7, 1998 – Rep. Anne Northup (Ky.), on behalf of herself and Rep. Bill Young (Fla.),

introduced H.C.R. 335, a resolution recognizing NIAID's 50th anniversary. On October 9, Sen. Richard Durbin (Ill.), on behalf of himself and Sen. Connie Mack (Fla.), introduced a companion measure, S.C.R. 127. Both pieces of legislation were submitted to "demonstrate the support of the U. S. Congress for the NIAID, the NIH and all of the dedicated professionals who have devoted their lives to improving the quality of the Nation's health."

October 17, 2000 – The Children's Health Act (Public Law 106-310) required the Directors of NIAID and the National Institute of Arthritis and Musculoskeletal and Skin Diseases to expand and intensify the activities of their Institutes with respect to research and related activities concerning juvenile arthritis and related conditions.

November 13, 2000 – The Public Health Improvement Act (Public Law 106-505) authorized the NIAID Director to establish a program of clinical research and training awards for sexually transmitted diseases.

July 21, 2004 – The Project BioShield Act (Public Law 108-276) authorized the NIAID Director to provide grants for the modernization and construction of biomedical and behavioral research facilities and increased the Federal share of such NIAID-funded projects. The law also authorized the Secretary, DHHS, to employ other procedures to respond to pressing needs in the research and development of countermeasures against biological, chemical, radiological, and nuclear threats, including expediting peer review procedures in certain instances, contracting with experts or consultants, and appointing professional and technical employees to positions at the NIH.

Biographical Sketch of NIAID Director Anthony S. Fauci, M.D.

Anthony S. Fauci, M.D., became the Director of NIAID in 1984. He received his undergraduate degree from Holy Cross College in 1962 and his medical degree from Cornell University Medical College in 1966. He completed his internship and residency at The New York Hospital Cornell Medical Center and joined NIAID in 1968 as a clinical associate in the Laboratory of Clinical Investigation. In 1980, Dr. Fauci became Chief of the Laboratory of Immunoregulation, a post he continues to hold. Dr. Fauci serves as one of the key advisors to the White House and Department of Health and Human Services on global AIDS issues, and on initiatives to bolster medical and public health preparedness against possible future bioterrorist attacks.

Dr. Fauci has made many contributions to basic and clinical research on the pathogenesis and treatment of immune-mediated and infectious diseases, including human immunodeficiency virus (HIV) disease. In 2003, an Institute for Scientific Information study indicated that in the twenty year period from 1983 to 2002, Dr. Fauci was the 13 th most-cited scientist among the 2.5 to 3 million authors in all disciplines throughout the world who published articles in scientific journals during that time frame.

Dr. Fauci has received 28 honorary doctorate degrees from universities in the United States and abroad. A member of the National Academy of Sciences and many other professional organizations, Dr. Fauci is the author, coauthor, or editor of more than 1,000 scientific publications, including several textbooks.

Directors of NIAID

Name	In Office From	To
Victor H. Haas	November 1, 1948	April 1957
Justin M. Andrews	April 1957	October 1, 1964
Dorland J. Davis	October 1, 1964	August 1975
Richard M. Krause	August 1975	July 1984
Anthony S. Fauci	November 1984	Present

Research Programs

NIAID is composed of four extramural divisions: the Division of AIDS; the Division of Allergy, Immunology and Transplantation; the Division of Microbiology and Infectious Diseases; and the Division of Extramural Activities. In addition, NIAID scientists conduct intramural research in laboratories located in Bethesda, Rockville and Frederick, Maryland, and in Hamilton, Montana. More information on NIAID programs, committees, and initiatives can be found on NIAID's web site at www.niaid.nih.gov.

Division of AIDS

The Division of Acquired Immunodeficiency Syndrome (DAIDS) was formed in 1986 to address the national research needs created by the advent and spread of the HIV/AIDS epidemic. Specifically, DAID's mission is to help end the HIV/AIDS epidemic by increasing basic knowledge of the pathogenesis, natural history, and transmission of HIV disease and to support research that promotes progress in its detection, treatment, and prevention. DAIDS accomplishes this through planning, implementing, managing, and evaluating programs in (1) fundamental basic research, (2) discovery and development of therapies for HIV infection and its complications, and (3) discovery and development of vaccines and other prevention strategies. *Edmund C. Tramont, M.D., Director.*

Division of Microbiology and Infectious Diseases

The Division of Microbiology and Infectious Diseases (DMID) supports extramural research to control and prevent diseases caused by virtually all human infectious agents except HIV. DMID supports a wide variety of projects spanning the spectrum from basic biomedical research, such as studies of microbial physiology and antigenic structure, through applied research, including the development of diagnostic tests, experimental drugs and vaccines, to conduct of clinical trials to test the safety and efficacy of new disease prevention strategies. NIAID also funds projects to sequence the full genomes of a number of medically important microbes, which can be exploited in many ways, for example, to trace microbial evolution, to locate targets for vaccine and drug development, and to identify mutations that contribute to drug resistance. *Carole A. Heilman, Ph.D., Director.*

Division of Allergy, Immunology, and Transplantation

The Division of Allergy, Immunology, and Transplantation (DAIT) promotes and supports a broad range of research that seeks to further our understanding of the immune mechanisms underlying immune-mediated diseases and translating this basic knowledge to clinical applications that will benefit individuals affected by these diseases. The ultimate goal of DAIT's research program is the development of effective approaches for the treatment and prevention of immune-mediated diseases. *Daniel Rotrosen, M.D., Director.*

Division of Intramural Research

The Division of Intramural Research (DIR) is composed of 17 laboratories and 5 branches that conduct biomedical research programs covering a wide range of disciplines relating to immunology, allergy, and infectious diseases. This includes the subdisciplines of virology, microbiology, biochemistry, parasitology, epidemiology, mycology, molecular biology, immunology, immunopathology, and immunogenetics. In addition, DIR supports a large clinical effort to conduct patient-centered research in allergy, immunology, and infectious diseases. *Thomas Kindt, Ph.D., Director.*

Dale and Betty Bumpers Vaccine Research Center

The Vaccine Research Center (VRC) conducts research that facilitates the development of effective vaccines for human disease. The primary focus of research will be the development of vaccines for AIDS. In addition to its work on HIV, the VRC has expanded the scope of its activities to include

research on developing improved smallpox vaccines, effective vaccines for Ebola and other viral hemorrhagic fevers, for West Nile virus, and for SARS-associated coronavirus. Goals of the VRC include: (1) Scientific design and rational development of effective vaccine candidates; (2) Evaluation and optimization of immune responses generated by candidate vaccines; and (3) Advancement of promising vaccine candidates into vaccine trials in people. *Gary Nabel, M.D., Ph.D., Director.*

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The NIH Almanac – Organization

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National Institute of Arthritis and Musculoskeletal and Skin Diseases

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Until May 19, 1972, the National Institute of Arthritis and Metabolic Diseases; until June 23, 1981, the National Institute of Arthritis, Metabolism, and Digestive Diseases; until April 8, 1986, the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases.

Mission

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) was established in 1986. The mission of NIAMS is to support research into the causes, treatment, and prevention of arthritis and musculoskeletal and skin diseases; the training of basic and clinical scientists to carry out this research; and the dissemination of information on research progress in these diseases.

The Institute also conducts and supports basic research on the normal structure and function of joints, muscles, bones, and skin. Basic research involves a wide variety of scientific disciplines, including immunology, genetics, molecular biology, structural biology, biochemistry, physiology, virology, and pharmacology. Clinical research includes rheumatology, orthopaedics, dermatology, metabolic bone diseases, heritable disorders of bone and cartilage, inherited and inflammatory muscle diseases, and sports and rehabilitation medicine.

Important Events in NIAMS History

November 20, 1985 – The Health Research Extension Act of 1985 (P.L. 99-158) authorized the establishment of the National Institute of Arthritis and Musculoskeletal and Skin Diseases.

April 8, 1986 – NIAMS was established.

February 18, 1987 – The first meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council was held.

April 15, 1996 – NIAMS held a 10th anniversary symposium: “Progress and Promise in Chronic Disease.”

NIAMS Legislative Chronology

August 1950 – An arthritis program was established within the National Institute of Arthritis and Metabolic Diseases under P.L. 81-692.

May 1972 – The Institute was renamed the National Institute of Arthritis, Metabolism and Digestive Diseases, P.L. 92-305.

1973 – Senator Alan Cranston introduced legislation that would eventually lead to the National Arthritis Act. Companion legislation was introduced in the House by Congressman Paul Rogers.

January 1975 – The National Arthritis Act (P.L. 93-640) established the National Commission on Arthritis and Related Musculoskeletal Diseases to study the problem of arthritis in depth and to develop an arthritis plan. The act also established the position of associate director for arthritis and related musculoskeletal diseases and authorized an interagency arthritis coordinating committee, community demonstration project grants, an arthritis data bank, an information clearinghouse, and comprehensive centers for research, diagnosis, treatment, rehabilitation, and education.

April 1976 – After a year of study and public hearings, the commission issued a comprehensive plan aimed at diminishing the physical, economic, and psychosocial effects of arthritis and musculoskeletal diseases. It laid the groundwork for a national program encompassing research, research training, education, and patient care.

October 1976 – P.L. 94-562, the Arthritis, Diabetes, and Digestive Diseases Amendments of 1976, established the National Arthritis Advisory Board to review and evaluate the implementation of the Arthritis Plan, prepared in response to the National Arthritis Act (P.L. 93-640).

December 1980 – P.L. 96-538 changed the name of the Institute to the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases.

1982 – The Department conferred bureau status on the Institute, resulting in creation of the Division of Arthritis, Musculoskeletal, and Skin Diseases and the appointment of a division director.

November 1985 – The Health Research Extension Act of 1985, P.L. 99-158, established the National Institute of Arthritis and Musculoskeletal and Skin Diseases to bring increased emphasis to research on these disorders. The legislation provided for the development of a plan for a national arthritis and musculoskeletal diseases program, and establishment of two interagency coordinating committees, one on arthritis and musculoskeletal diseases and one on skin diseases. It also expanded the activities of the National Arthritis Advisory Board to include musculoskeletal and skin diseases.

September 1993 – The NIH Revitalization Act of 1993 (P.L. 103-43) called on NIAMS to establish “an information clearinghouse on osteoporosis and related bone disorders to facilitate and enhance knowledge and understanding on the part of health professionals, patients, and the public through the effective dissemination of information.”

October 2000 – The Children’s Health Act of 2000 (P.L. 106-310) called on NIAMS to expand and intensify research programs on juvenile arthritis and related conditions, in coordination with other NIH Institutes and the Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee. Further language stipulated that the Institute’s current information clearinghouse include resources on juvenile arthritis and associated conditions.

November 2000 – The Lupus Research and Care Amendments of 2000, which passed as part of the Public Health Improvement Act (P.L. 106-505), required NIAMS to expand and intensify research and related activities regarding lupus, and to coordinate such efforts with other NIH Institutes, as appropriate. Among other provisions, the bill called for information and education programs for health professionals and the public.

December 2001 – The Muscular Dystrophy Community Assistance, Research and Education Amendments of 2001, or the MD-CARE Act (P.L. 107-84), called on several components of NIH, including NIAMS, to enhance research on muscular dystrophy, including establishing Centers of Excellence.

February 2003 – The Office of the Secretary, Department of Health and Human Services (DHHS), was called on to establish a Federal working group on lupus for the purpose of exchanging information and coordinating Federal efforts regarding lupus research and education initiatives (P.L. 108-7, Omnibus Appropriations Act for FY 2003). The NIAMS, as the lead institute at the NIH for

lupus research, was asked to lead this Federal working group. The group is comprised of representatives from all relevant DHHS agencies and other Federal departments having an interest in lupus.

Biographical Sketch of NIAMS Director Stephen I. Katz, M.D., Ph.D.

Dr. Katz earned a B.A. degree *cum laude* in history from the University of Maryland, College Park; an M.D. degree *cum laude* from Tulane University Medical School, New Orleans, LA; and a Ph.D. degree in immunology from the University of London, England. He completed a medical internship at Los Angeles County Hospital, CA; a residency in dermatology at the University of Miami School of Medicine, FL; military service at Walter Reed General Hospital in Washington, DC; and postdoctoral work at the Royal College of Surgeons of England.

In 1974 he joined the National Institutes of Health (NIH) as a senior investigator in the Dermatology Branch of the National Cancer Institute (NCI), becoming acting chief in 1977 and chief from 1980 to 2001. He is still an active senior investigator. From 1989 to 1995, he also served as Marion B. Sulzberger professor of dermatology at the Uniformed Services University of the Health Sciences in Bethesda. On August 1, 1995, he was appointed Director of NIAMS.

Dr. Katz's studies of Langerhans cells and epidermally derived cytokines have demonstrated that skin is a critical component of the immune system both in its normal function and as a target in immunologically mediated diseases. He has also made seminal discoveries in the field of inherited and acquired blistering skin diseases.

At NCI, he has led a program of investigations in fundamental biological and clinical problems in neoplastic and inflammatory diseases of the skin. He has trained a large number of immunodermatologists from the United States and abroad. These individuals are now leading their own independent research programs.

Dr. Katz has received many Government- and private-sector honors and awards, including the Lifetime Achievement Award from the American Skin Association, the Presidential Distinguished Rank Award, Presidential Executive Meritorious Rank Award, PHS Superior Service Award, NIH Director's Award, Sulzberger Lecture Award from the American Academy of Dermatology, Martin Carter Mentor Award from the American Skin Association, Alfred Marchionini Gold Medal, Outstanding Alumnus Award of Tulane University School of Medicine, Stephen Rothman Memorial Award of the Society for Investigative Dermatology (SID), Inflammatory Skin Disorders Research Award, Scleroderma Foundation's Messenger of Hope Award, honorary membership in many international dermatologic societies, and election into the Institute of Medicine of the National Academy of Sciences.

He has served many scientific organizations in leadership positions such as president of SID, membership on the board of directors of SID and of the Association of Professors of Dermatology, secretary-general of the World Congress of Dermatology, and secretary-treasurer of the Clinical Immunology Society. In addition, he was named president of the International League of Dermatological Societies in 1997, for a 5-year term.

Dr. Katz has also served on the editorial boards of most clinical and investigative dermatology journals and many immunology journals. He has authored or coauthored more than 200 scientific articles and 60 book chapters and edited several conference proceedings and books.

NIAMS Directors

Name	In Office From	To
Lawrence E. Shulman	April 1986	October 1994
Michael D. Lockshin (Acting)	November 1994	July 1995

Stephen I. Katz

August 1995

Present

Research Programs

NIAMS supports a multidisciplinary program of basic, and clinical, and translational investigations, epidemiologic research, research centers, and research training for scientists within its own facilities as well as grantees at universities and medical schools nationwide. It also supports the dissemination of research results and information through the National Institute of Arthritis and Musculoskeletal and Skin Diseases Information Clearinghouse and through the NIH Osteoporosis and Related Bone Diseases'~ National Resource Center.

The *NIAMS Extramural Program* supports research via grants and contracts in four branches: Rheumatic Diseases, Musculoskeletal Diseases, Skin Diseases, and Muscle Biology. Support also is provided for the Epidemiology/Data Systems Programs and the Centers Program. A wide array of basic, and clinical, and translational research and research training in the fields of rheumatology, muscle biology, orthopaedics, bone and mineral metabolism, and dermatology are being pursued through these programs.

The *Intramural Research Program of NIAMS* conducts innovative basic, translational, and clinical research relevant to the health concerns of the Institute and provides training for investigators interested in careers in these areas. The ultimate goals are 1) to provide new insights into the normal function of bones, joints, skin, and muscles and diseases that affect them; and 2) to generate a cadre of well-trained investigators to continue toward a complete understanding of these structures and the disease conditions that affect them adversely.

Extramural Research Program

Rheumatic Diseases Branch

The mission of this program is to promote and support research leading to prevention, diagnosis, and improved treatments of rheumatic and related diseases. The Branch supports basic, epidemiologic, clinical, and translational research on etiology, pathogenesis, course, interventions, and outcomes in rheumatic and related diseases.

Immunology and Inflammation Program. This program supports basic research aimed at understanding the etiology, pathogenetic mechanisms, and systems affected in rheumatoid arthritis, adjuvant and chemically induced inflammatory arthritis, systemic lupus erythematosus, systemic scleroderma, and general autoimmunity. Relevant research comes from the areas of genetics, biochemistry, cellular and molecular biology, biophysics, enzymology, immunology, pathology, and physiology.

Cartilage and Connective Tissue Program. This program supports research aimed at understanding normal function of cartilage and components of connective tissues, and etiology and pathogenic mechanisms in osteoarthritis and heritable disorders of connective tissue.

Behavioral and Prevention Research Program. This program seeks to foster basic and clinical biopsychosocial research in arthritis, systemic lupus erythematosus, fibromyalgia, and related diseases. Research supported includes examination of behavioral, psychological, and social factors and their interaction with physiological processes in the prevention, etiology, course, management, and outcomes of disease. Multidisciplinary collaboration is encouraged.

Genetics and Clinical Studies Program. This program supports genetic studies in rheumatic diseases, both in animal models and in humans; clinical trials and complex clinical studies, including epidemiology, outcomes, and prevention of rheumatic and

related diseases; and research on Lyme disease and infection-related arthritis.

Musculoskeletal Diseases Branch

This program supports studies of the skeleton and associated connective tissues. Broad areas of interest include skeletal development, metabolism, mechanical properties, and responses to injury and treatment. Research on osteoporosis and osteoarthritis, two diseases affecting many of the Nation's growing population of older people, are major areas of emphasis. Other diseases and skeletal disorders under investigation are osteogenesis imperfecta, a genetic disorder that leads to fragile, easily fractured bones; Paget's disease, which results in irregular bone formation and subsequent deformity; and disorders of bone growth and development, such as rickets and osteomalacia.

Other studies focus on orthopaedic issues including the causes and treatment of acute and chronic injuries, including carpal tunnel syndrome, repetitive stress injury, and low back pain. The program supports development of technologies with the potential to improve treatment of skeletal disorders and facilitate the repair of trauma in the normal skeleton. These include drugs and nutritional interventions, joint replacement, bone and cartilage transplantation, and gene therapy. Sports medicine and musculoskeletal fitness are also areas of special research emphasis.

Research areas supported through this branch include:

- Bone diseases: epidemiology and development of disease; environmental and genetic risk factors; and treatment, prevention, and diagnosis
- Bone biology: mechanisms of bone resorption; hormone, growth-factor, and cytokine effects on bone-resorbing and bone-forming cells; regulation of bone growth and development; interactions among proteins, minerals, and cells in bone; and mechanisms of mineralization
- Orthopaedic research: skeletal architecture and mechanical properties; mechanisms of fracture repair; musculoskeletal tissue engineering; biomaterials, orthopaedic devices, and joint replacement and repair; rehabilitation; occupational and recreational/sports injuries; and clinical orthopaedic and sports medicine
- Osteoarthritis Initiative and diagnostic imaging: clinical studies of osteoarthritis; bone quality; and macro- and micro-scale imaging of bones and joints

Muscle Biology Branch

The mission of this program is to promote and support research to increase understanding of mechanisms underlying normal and abnormal skeletal muscle function and development. An important emphasis is basic and clinical research on the pathogenesis of, and interventions for, muscular dystrophy and other muscle disorders.

Muscle Structure and Function. This program supports basic research increasing understanding of skeletal muscle function and use of energy. Topics include the molecular structure of muscle, the molecular mechanisms that produce force and motion, and the assembly of muscle components, including those responsible for contraction and regulation of muscle action.

Specific research covered by the program includes:

- Skeletal muscle physiology
- Processes of muscle self-assembly
- Structure and function of muscle and of individual muscle proteins
- Molecular and atomic mechanisms of muscle contraction and force generation
- Structure and mechanical properties of muscle membranes and mechanisms of membrane maintenance and repair
- Electrophysiology of muscle membranes and regulation of activity

- Musculoskeletal fitness and adaptive biology, including metabolism and exercise physiology

Muscle Disorders and Therapies Program. This program supports research on genetic diseases that specifically affect skeletal muscle, such as Duchenne/Becker muscular dystrophy, facioscapulohumeral dystrophy, myotonic dystrophy, myotonias, and malignant hyperthermia. Additional disorders of interest include disuse atrophy and muscle injury. Translational and clinical research leading to effective treatments for these diseases and disorders is especially encouraged.

Specific research covered by the program includes:

- Molecular basis of genetic muscle diseases, such as muscular dystrophy
- Inflammatory muscle diseases and inflammation resulting from exercise or injury
- Development of more satisfactory methods of treatment for muscle diseases and disorders
- Effects of therapeutic drugs and abused substances on basic muscle processes
- Cellular basis for impaired muscle function in disease
- Molecular mechanisms of muscle repair and regeneration
- Muscle development and specialization, including genetic processes of muscle assembly
- Role of growth factors and hormones
- Sports medicine, and muscle injury and repair

Skin Diseases Branch

Research studies supported by this program are increasing understanding of the mechanisms underlying normal and abnormal skin function and development. Research investigations are conducted on the molecular structures of various skin cells, the immunologic functions of the skin in normal and disease conditions, and the development of diagnostic tests and effective therapies for an array of skin diseases that can cause discomfort, disfigurement, and/or chronic disability. The range of skin diseases includes keratinizing disorders such as psoriasis and ichthyosis, atopic dermatitis and other chronic inflammatory skin disorders, blistering diseases such as epidermolysis bullosa and pemphigus, disorders of pigmentation such as vitiligo, and disorders of the hair and nails.

Basic science and disease areas in skin research include:

- Metabolic studies of skin
- Immunologically mediated skin disorders
- Disorders of keratinization, pigmentation, and hair growth
- Photobiology, photoallergy, and phototoxic reactions
- Bullous diseases and the basement membrane of skin
- Acne and physiologic activity of sebaceous glands
- Skin manifestations of diffuse connective tissue disorders
- Heritable connective tissue diseases
- Skin manifestations of HIV infection and AIDS

Centers Mechanisms

NIAMS supports three types of Center mechanisms to advance the NIAMS mission and to meet the needs of the public and the research communities. The science of the centers is now aligned with the scientific program areas.

The *Centers of Research Translation (CORT) (P50)* encompasses a multidisciplinary approach to one disease-targeted theme within the NIAMS mission. A minimum of three projects, with at least one basic and one clinical project as well as an administrative core, form the basic elements of the CORT.

The *Multidisciplinary Clinical Research Center (MCRC) (P60)* focuses on assessment and improvement of clinical outcomes for patients with arthritis and musculoskeletal and skin diseases. Patient-oriented research is derived from many disciplines, and the center director is a clinician/scientist.

Each *Research Core Center (RCC) (P30)* is directed to one of three research areas: skin diseases, musculoskeletal disorders, or rheumatic diseases. RCCs have a minimum of two research cores and include a pilot and feasibility program.

Intramural Research Program

The NIAMS Intramural Research Program (IRP) consists of 11 main components: Office of the Clinical Director, Office of Science and Technology, Arthritis and Rheumatism Branch, Autoimmunity Branch, Cartilage Biology and Orthopaedics Branch, Genomics and Genetics Branch, Molecular Immunology and Inflammation Branch, Laboratory of Muscle Biology, Laboratory of Skin Biology, Laboratory of Structural Biology Research, and Protein Expression Laboratory.

The *Office of the Clinical Director* implements innovative clinical research programs that relate to the broad field of rheumatologic, musculoskeletal, and skin disorders. Through specific programs in translational research, rheumatology fellowship training, and health partnership, the Office of the Clinical Director plays an important role in establishing innovative therapeutic paradigms, in providing medical education in the field of rheumatology, and in reaching out to the community to reduce health care disparities and to improve the understanding of rheumatic and related diseases.

Translational Research Program: The Bridge Between Basic Research and Clinical Disease

A goal of clinical investigation is to bridge information gained from laboratory research with that afforded by clinical experience. Carefully designed observational and interventional studies provide opportunities to verify basic biological understanding of disease. These studies then bring back to the laboratory new insight into the biology of the human body.

Rheumatology Fellowship Program

The NIAMS/NIH Rheumatology Fellowship Training Program is dedicated to the clinical and research training of physicians wishing to pursue careers in biomedical or translational research related to the rheumatic diseases. The fellowship program is 2 years in duration, with extensions available for individuals interested in advanced research training. The program is accredited by the Accreditation Council for Graduate Medical Education (ACGME), and graduates are eligible to sit for the certifying examination in the subspecialty of rheumatology.

NIAMS Community Health Center

The NIAMS Community Health Center is a health information and medical center providing health care services to people affected by arthritis, lupus, and other rheumatic diseases. The health center offers patient care with access to a specialist, health information and education programs, and referral to clinical investigations for the prevention and treatment of rheumatic diseases. The health center is located in upper northwest Washington, DC.

The *Office of Science and Technology* encompasses an infrastructure of research and support facilities designed to enhance the research capabilities of all scientists of the IRP. In addition,

members advise the Scientific Director, Laboratory and Branch Chiefs, and other key officials on collaborative and cooperative activities, training programs, and proper use of laboratory animals; and negotiate and facilitate scientific collaborations that involve trans-institute and trans-NIH initiatives and agreements. The *Career Development Section* serves as a resource to all NIAMS students, fellows, and their sponsors to ensure that NIAMS continues to attract the best fellows and provide them with a genuine growth experience. The *Flow Cytometry Section* provides state-of-the-art multiparameter analytic and sorting capabilities for IRP investigators. The *Laboratory Animal Care and Use Section* provides support to all IRP branches and laboratories using animals. The *Light Imaging Section* functions as a core facility, offering IRP scientists access to state-of-the-art light imaging equipment and expertise in light imaging techniques. The *Scientific Interchange Section* facilitates intramural-extramural interchange on scientific and programmatic levels. The *Biodata Mining and Discovery Section* assesses the scientific computing needs of IRP scientists, and develops strategies and designs computational support for researchers. The *X-Ray Crystallography Facility* is an NIAMS core facility that provides equipment, training, assistance, and technological innovations to determine three-dimensional structures of protein and other macromolecules (large biological molecules). The *Macromolecular Biophysics Section* conducts research on the role of macromolecules in biological systems using radiation inactivation analysis and the direct action of ionizing radiation on biological macromolecules.

The *Arthritis and Rheumatism Branch (ARB)* conducts a variety of basic and clinical investigations. The historical focus of the ARB has been the study of the autoimmune rheumatic diseases, particularly rheumatoid arthritis, systemic lupus erythematosus, and myositis. Current studies focus on inflammatory and genetic diseases affecting the musculoskeletal system.

The *Autoimmunity Branch (AB)* conducts basic and clinical research to develop new insights into the molecular basis of autoantibody formation. Autoimmune diseases such as lupus are characterized by the formation of tissue-affecting autoantibodies. The basis of this formation is not known. Branch scientists are using molecular and cell-biologic techniques as well as multiparameter flow cytometry (a technique that allows large numbers of individual cells to be characterized in detail) to analyze autoantibody formation in patients with lupus and other autoimmune diseases.

The *Cartilage Biology and Orthopaedics Branch (CBOB)*, consisting of the *Cartilage Molecular Genetics, Developmental Biology, Orthopaedics, and Tissue Engineering Sections*, conducts basic and clinical research directed towards understanding the mechanisms regulating cartilage function, the basis of cartilage and orthopaedic diseases (such as osteoarthritis), and the development of functional cartilage tissue substitutes. Researchers are using cellular, molecular, bionomic, and bioengineering approaches to analyze cartilage development, growth, diseases, and aging, as well as applying the emerging technology of tissue engineering for functional cartilage replacement.

The *Genetics and Genomics Branch (GGB)* identifies and characterizes susceptibility genes for rheumatic and inflammatory diseases. This includes the study of Mendelian autoinflammatory diseases such as Familial Mediterranean Fever (FMF), tumor necrosis factor- associated periodic syndrome (TRAPS), neonatal onset multisystem inflammatory disease (NOMID), and the syndrome of pyogenic arthritis with pyoderma gangrenosum and acne (PAPA). The Branch also studies genetically complex conditions such as rheumatoid arthritis. Included in the Branch are the Inflammatory Biology Section and the Genomics Section.

The *Molecular Immunology and Inflammation Branch (MIIB)* conducts basic and clinical investigations on the molecular mechanisms underlying immune and inflammatory responses in rheumatic and autoimmune diseases. A major focus is the study of receptor-mediated signal transduction and how these events link to the regulation of genes involved in inflammatory responses. Included in the Branch are the Lymphocyte Cell Biology, Chemical Immunology, and Molecular Inflammation Sections.

The *Laboratory of Muscle Biology (LMB)* conducts a broad range of research in muscle and structural biology. This includes the molecular mechanisms of contraction, muscle elasticity and plasticity, differentiation and assembly of muscle cells, pathobiology of muscle diseases, and the

development and application of emerging technologies in proteomics and nanotechnology in muscle research.

The *Laboratory of Skin Biology (LSB)* conducts basic research on the skin and its diseases, emphasizing the epidermis.

The *Laboratory of Structural Biology Research (LSBR)* conducts research into the structural basis of the assembly and functioning of macromolecules and their complexes (such as viruses, machines, and cytoskeletons), and the mechanisms and proteins that control their assembly. These studies make extensive use of cryoelectron microscopy and three-dimensional image processing in studies of virus infection and replication; renewal of the epidermis, with maintenance of barrier function; prionogenesis (structural transitions of infectious proteins called prions); and intracellular protein quality control by energy-dependent proteases.

The *Protein Expression Laboratory (PEL)* plans and conducts research on the expression, purification, and structural characterization of Human Immunodeficiency Virus (HIV) and HIV-related proteins. Laboratory scientists also collaborate with NIH intramural researchers studying the structure and function of HIV and HIV-related proteins. The lab serves as a support and resource group for the expression and purification of these proteins.

Communications

The *Office of Communications and Public Liaison (OCPL)* leads the NIAMS efforts in information dissemination, public input, and health education. OCPL disseminates health and research news and updates, creates print and Web publications, manages the NIAMS Web site, coordinates outreach and promotion, and serves as a point of contact for the media, the public, and public organizations. OCPL oversees the NIAMS Information Clearinghouse, which operates a toll-free service to provide information and information sources on arthritis and rheumatic diseases, musculoskeletal and connective tissue disorders, and skin diseases. OCPL also oversees the NIH Osteoporosis and Related Bone Diseases~National Resource Center, which disseminates information on bone diseases.

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National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892



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National Institute of Biomedical Imaging and Bioengineering

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Mission

The mission of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) is to improve health by leading the development and accelerating the application of biomedical technologies. The Institute is committed to integrating the physical and engineering sciences with the life sciences to advance basic research and medical care. This is achieved through: research and development of new biomedical imaging and bioengineering techniques and devices to fundamentally improve the detection, treatment, and prevention of disease; enhancing existing imaging and bioengineering modalities; supporting related research in the physical and mathematical sciences; encouraging research and development in multidisciplinary areas; supporting studies to assess the effectiveness and outcomes of new biologics, materials, processes, devices, and procedures; developing technologies for early disease detection and assessment of health status; and developing advanced imaging and engineering techniques for conducting biomedical research at multiple scales.

NIBIB extramural research is organized into four divisions: Discovery Science and Technology, Applied Science and Technology, Inter-Disciplinary Training, and Program Coordination and Integration.

The Institute supports basic research and research training through investigator-initiated grants, contracts, program project and center grants, and career development and training awards.

NIBIB Legislative History

December 29, 2000 — The National Institute of Biomedical Imaging and Bioengineering Establishment Act (H.R. 1795) is signed into law by President William Jefferson Clinton.

Important Events in NIBIB History

April 20, 2001 — The NIBIB Establishment Plan is approved by the Secretary of DHHS, Mr. Tommy G. Thompson.

April 26, 2001 — Dr. Donna J. Dean is named as Acting Director of the NIBIB.

August 28, 2001 — The National Advisory Council for Biomedical Imaging and Bioengineering is established.

September 19, 2001 — The NIBIB assumes administration of the NIH's Bioengineering Consortium (BECON).

October 1, 2001 — The NIBIB web site is launched.

January 9, 2002 — A working group is established to review and recommend the transfer of grants to NIBIB.

January 11, 2002 — The NIBIB receives its first budget appropriation (FY 2002) in the amount of \$112 million.

February 21, 2002 — The NIBIB announces its first two Requests for Applications.

April 8, 2002 — The NIBIB announces the award of its first research grants.

September 23, 2002 — Dr. Roderic Pettigrew, Professor of Radiology, Medicine (Cardiology) and Bioengineering, and Director of the Emory Center for MR Research, Emory University School of Medicine, assumes the position of Director of NIBIB.

September 23, 2002 — Dr. Donna Dean becomes the first Deputy Director of NIBIB.

January 9, 2003 — The National Advisory Council for Biomedical Imaging and Bioengineering meets for the first time in Bethesda, Maryland.

May 13, 2003 — A new NIBIB organization is announced by Dr. Roderic Pettigrew.

September 17, 2003 — The National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel is established.

December 19, 2003 — Dr. Belinda Seto is named the Deputy Director of NIBIB.

February 2, 2004 — The NIBIB initiates its Strategic Planning process.

February 17, 2004 — The NIBIB and the Center for Devices and Radiological Health (FDA) sign an interagency agreement establishing the joint Laboratory for the Assessment of Medical Imaging Systems.

September 17, 2004 — The NIBIB hosts a Blue Ribbon Panel on Intramural Research to provide recommendations on the planning and development of an intramural research program.

September 27, 2004 — NIBIB and Howard Hughes Medical Institute announce a partnership to support the HHMI/NIBIB Interfaces Initiative for Interdisciplinary Graduate Research Training.

October 1, 2004 — The Positron Emission Tomograph (PET) Radiochemistry Group joins the Institute as the NIBIB intramural research program.

November 9, 2004 — NSF and NIBIB sponsor a conference on “Research at the Interface of the Life and Physical Sciences: Bridging the Sciences.

January 13, 2005 — NIBIB issues draft Strategic Plan and invites public comment.

April 21, 2005 — NIBIB holds its first Regional Grantsmanship Seminar in Troy, New York.

October 11, 2005 — NIBIB launches re-designed website.

[Biographical Sketch of NIBIB Director Roderic I. Pettigrew, Ph.D., M.D.](#)

Roderic I. Pettigrew, Ph.D., M.D. began his appointment as the first director of the NIBIB in

September 2002. Prior to his appointment at NIBIB, he was a Professor of Radiology, Medicine (Cardiology) and Bioengineering and Director of the Emory Center for MR Research, Emory University School of Medicine, Atlanta, Georgia.

Dr. Pettigrew is known for his pioneering work at Emory University involving dynamic three-dimensional imaging of the heart using magnetic resonance (MRI). He also was co-developer of the first computer software package specifically designed for cardiac imaging using MRI.

Dr. Pettigrew graduated cum laude from Morehouse College with a B.S. in physics, where he was a Merrill Scholar; has an M.S. in nuclear science and engineering from Rensselaer Polytechnic Institute; and a Ph.D. in applied radiation physics from the Massachusetts Institute of Technology, where he was a Whitaker Harvard-MIT Health Science Scholar. After completing his Ph.D., he received an M.D. from the University of Miami School of Medicine in an accelerated two-year program. He did his internship and residency in internal medicine at Emory University and completed a residency in nuclear medicine at the University of California, San Diego. Dr. Pettigrew spent a year as a clinical research scientist with Picker International, the first manufacturer of MRI equipment. In 1985, he joined Emory as a Robert Wood Johnson Foundation Fellow with an interest in non-invasive cardiac imaging.

Dr. Pettigrew, a member of Phi Beta Kappa, is the recipient of numerous awards, including the Bennie Award (Benjamin E. Mays) for Achievement in 1989. Also in 1989, when the Radiological Society of North America celebrated its 75th Diamond anniversary scientific meeting, the largest medical meeting in the world, it selected Dr. Pettigrew to give the keynote Eugene P. Pendergrass New Horizons Lecture. In 1990, he was named the Most Distinguished Alumnus of the University of Miami. He has served as chairman of the Diagnostic Radiology Study Section, Center for Scientific Review, NIH, and has received multiple grants from the NIH for his research on cardiac imaging. He is on numerous editorial boards, scientific societies' Boards of Directors, and is a frequent invited lecturer at international scientific meetings. Dr. Pettigrew has also been elected a Fellow of the American Heart Association, the American College of Cardiology, the International Society of Magnetic Resonance in Medicine, and the American Institute of Medical and Biomedical Engineering.

NIBIB Directors

Name	In Office From	To
Donna J. Dean (Acting)	April 26, 2001	September 22, 2002
Roderic I. Pettigrew	September 23, 2002	Present

This page was last reviewed on January 4, 2006 .

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National Institute of Child Health and Human Development

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Mission

The mission of the National Institute of Child Health and Human Development (NICHD) is to ensure that every person is born healthy and wanted, that women suffer no harmful effects from the reproductive process, and that all children have the chance to fulfill their potential to live healthy and productive lives, free from disease or disability, and to ensure the health, productivity, independence, and well-being of all people through optimal rehabilitation.

In pursuit of this mission, the NICHD conducts and supports laboratory research, clinical trials, and epidemiological studies that explore health processes; examines the impact of disabilities, diseases, and defects on the lives of individuals; and sponsors training programs for scientists, doctors, and researchers to ensure that NICHD research can continue.

NICHD research programs incorporate the following concepts:

Events that happen prior to and throughout pregnancy, as well as during childhood have a great impact on the health and well-being of adults. The Institute supports and conducts research to: advance knowledge of pregnancy, fetal development, and birth for developing strategies that prevent maternal, infant, and childhood mortality and morbidity; identify and promote the prerequisites of optimal physical, mental, and behavioral growth and development through infancy, childhood, and adolescence; and contribute to the prevention and amelioration of mental retardation and developmental disabilities.

Human growth and development is a life-long process that has many phases and functions. Much of the research in this area focuses on cellular, molecular, and developmental biology to build understanding of the mechanisms and interactions that guide a single fertilized egg through its development into a multi-cellular, highly organized adult organism.

Learning about the reproductive health of women and men and educating people about reproductive practices is important to both individuals and societies. Institute-supported basic, clinical, and epidemiological research in the reproductive sciences seeks to develop knowledge that enables women and men to overcome problems of infertility, and to regulate their fertility in ways that are safe, effective, and acceptable for various population groups. Institute-sponsored behavioral and social science research in the population field strives to understand the causes and consequences of reproductive behavior and population change.

Developing medical rehabilitation interventions can improve the health and well-being of people with disabilities. Research in medical rehabilitation seeks to develop improved techniques and technologies, with respect to the rehabilitation of individuals with physical disabilities resulting from diseases, disorders, injuries, or birth defects.

The Institute also supports research training across all its programs, with the intent of adding to the

cadre of trained professionals who are available to conduct research in areas of critical public health concern. In addition, an overarching responsibility of the NICHD is to disseminate information that emanates from Institute research programs to researchers, practitioners, other healthcare professionals, and the public.

Important Events in NICHD History

January 12, 1961 – The report of the Task Force on Health and Social Security calls for the establishment, by administrative action of the surgeon general, of a National Institute of Child Health within the National Institutes of Health (NIH).

January 30, 1961 – The Department of Health, Education, and Welfare (DHEW) general counsel declares that existing legislation (enacted in 1950) limited the creation of new Institutes to those focusing on a disease or group of diseases, and that new legislation would be required to establish the Institute called for in the Task Force report.

February 17, 1961 – The surgeon general establishes a Center for Research in Child Health in the Division of General Medical Sciences.

October 17, 1962 – Public Law 87-838 authorizes the establishment of the NICHD.

January 30, 1963 – Secretary of DHEW Anthony J. Celebrezze approves the establishment of the NICHD, with a provision that the Center for Research in Child Health and the Center for Research in Aging (established in 1956) be transferred from the Division of General Medical Sciences to the new Institute.

May 14, 1963 – The surgeon general appoints members of the National Advisory Child Health and Human Development (NACHHD) Council.

November 14, 1963 – The NICHD holds the first meeting of the NACHHD Council.

December 2, 1965 – A major NICHD reorganization, approved by the surgeon general, emphasizes four program areas: reproduction, growth and development, aging, and mental retardation.

April 18, 1967 – A second reorganization of the NICHD, approved by the surgeon general, acknowledges the Institute's intramural research programs by separating responsibility for intramural and extramural research and creating seven intramural laboratories. The reorganization brings the NICHD administrative structure into line with that of other NIH Institutes.

August 9, 1968 – The DHEW secretary establishes the Center for Population Research (CPR) within the NICHD. The Center is responsible for contract and grant programs in population and reproduction research and is designated by the president as the federal agency primarily responsible for population research and training.

1970 – The NICHD's Epidemiology and Biometry Branch, created during the Institute's second reorganization in 1967, becomes the Epidemiology and Biometry Research Program. The change allows the Program to conduct epidemiologic, behavioral, and biometric studies relating to reproductive, maternal, and child health.

May 27, 1975 – The federal government establishes the Center for Research for Mothers and Children (CRMC) within the NICHD as the focal point for research and research training on the special health problems of mothers and children. The Center also has responsibility for increasing knowledge about pregnancy, infancy, childhood, adolescence, and adulthood, and for administering grant and contract programs related to these areas.

June 30, 1975 – The Adult Development and Aging Branch and the Gerontology Research Center, with their programs for support and conduct of research in the field of aging, are transferred from the NICHD to the newly established National Institute on Aging (NIA).

1978 – NICHD intramural researchers become the first to successfully clone a mammalian gene, a critical first step in obtaining large amounts of medically important proteins.

December 1983 – NICHD grantees Ralph Brinster and Richard Palmiter become the first to transplant human genes into animals. Their accomplishment, transplanting the gene for human growth hormone into mice, provides an important new means to study the function of human genes, as well as the foundation of the new biotechnology industry.

1985 – The NICHD forms research networks of Neonatal Intensive Care Units and Maternal-Fetal Medicine Units. The sites, which perform large clinical trials, provide the Institute with a faster, more effective system of evaluating neonatal intensive care and maternal-fetal treatments.

December 1989 – The NICHD announces the establishment of the country's first research centers that combine the biomedical and behavioral sciences to focus specifically on learning disabilities.

September 1990 – The Institute begins a congressionally initiated national program of Child Health Research Centers. The goal is to expedite the application of findings from basic research to the care of sick children.

November 16, 1990 – Congress establishes the National Center for Medical Rehabilitation Research (NCMRR) within the NICHD to conduct and support programs for the rehabilitation, health, and well being of individuals with physical disabilities.

1991 – The NICHD expands its Epidemiology and Biometry Research Program to create the Division of Epidemiology, Statistics, and Prevention Research (DESPR), part of its intramural research component. DESPR's portfolio includes research in the fields of reproduction and maternal and child health.

1994 – The NICHD launches the *Back to Sleep* campaign, a program designed to teach parents and caregivers the importance of putting babies on their backs to sleep, to help reduce the risk of sudden infant death syndrome (SIDS).

January 1, 1994 – In response to the need for appropriate drug therapy for pediatric patients, the NICHD establishes the Pediatric Pharmacology Research Unit Network. The Network's mission is to facilitate and promote pediatric labeling of new drugs or drugs already on the market, to ensure the safe and effective use of drugs in children.

September 1996 – Two NICHD scientists, Drs. John Robbins and Rachel Schneerson, receive the 1996 Albert Lasker Clinical Medical Research Award for the landmark development of a polysaccharide-protein conjugate vaccine for *Hemophilus influenzae* type b (Hib). Also in 1996, Robbins and Schneerson receive the World Health Organization Children's Vaccine Initiative Pasteur Award for Recent Contributions in Vaccine Development for their Hib vaccine breakthrough.

1997 – The NICHD launches the *Milk Matters* calcium education campaign, designed to educate people about the importance of getting enough calcium during the childhood and teenage years to help prevent osteoporosis and fragile bones in adulthood.

June 1997 – The NICHD and the National Institute on Deafness and Other Communication Disorders establish the Network on the Neurobiology and Genetics of Autism, composed of ten Collaborative Programs of Excellence in Autism (CPEAs). The CPEA Network is a multi-million dollar, international effort that seeks to solve the puzzle of autism through research.

September 1997 – The NICHD initiates the first phase of its National Longitudinal Study of Adolescent Health (called the Add Health Study). The study's main premise is that social context – such as relationships with families, friends, and peers – influences the health-related behaviors of young people, and that understanding this context is essential to guide efforts to modify health behaviors.

March 1998 – Using sophisticated brain imaging technology, NICHD-funded researchers reveal a brain map of the physical basis of dyslexia. This finding may provide the basis for screening techniques that will help identify dyslexia, allowing treatment to start earlier in a person's development.

June 1998 – In the largest, most comprehensive analysis of its kind, NICHD-funded research finds that pregnant women who are infected with HIV can reduce the risk of transmitting the virus to their infants by about 50 percent if they deliver by elective cesarean section before they have gone into labor and before their membranes have ruptured.

July 1998 – The Food and Drug Administration approves an NICHD-developed DTaP (diphtheria-tetanus-acellular pertussis) vaccine for use in immunization against these diseases.

September 30, 1999 – NICHD-funded researchers announce the discovery of the gene for Rett syndrome, a disorder in which healthy infant girls gradually lose their language capabilities, mental functioning, and ability to interact with others.

January 2000 – The Bill and Melinda Gates Foundation joins the NICHD in developing and supporting an international research network to improve the health of women and children throughout the world. The NICHD will match the Foundation's \$15 million to help the network establish self-sustaining, international, and medical research institutions, which are urgently needed to address many of the world's health concerns.

2000 – NICHD researchers demonstrate that inhaled nitric oxide is an effective therapy for respiratory failure in critically ill term infants in whom aggressive conventional therapy had failed. The findings, which resulted from the first definitive, randomized clinical trial of nitric oxide use in human neonates, may further reduce the long-term costs of caring for such children and improve their quality of life by reducing their risk for chronic respiratory insufficiency and central nervous system ischemia.

April 13, 2000 – The National Reading Panel, established by the NICHD, releases findings of the largest, most comprehensive, evidence-based review ever conducted of research related to how children learn to read. The independent Panel concludes that the most effective way to teach children to read is through instruction that includes a combination of methods and addresses alphabets (phonemic awareness and phonemic instruction), reading fluency, reading comprehension, teacher education, and computer technology.

October 5, 2000 – An NICHD-funded study, conducted by researchers from Thailand, France, and the United States, shows that transmission of HIV from a mother to her child can be reduced nearly as effectively with shorter treatments of the drug AZT, as with longer AZT treatments. The findings may allow women in developing countries to better afford the treatment that can reduce their babies' chances of contracting AIDS.

2000 – NICHD researchers evaluating data from the Fels Longitudinal Study, the oldest and largest growth study in the world, find that obesity in childhood tracks from age three onward, into adulthood, and that obesity in adolescence is more likely to lead to adult obesity than obesity earlier in childhood. Data from the Study, which the NICHD has supported since 1974, may allow researchers to ascertain the segregation of growth patterns over three generations, to detect linkage of candidate genes to various phenotypes of growth and to permit the discovery of new descriptors of normal growth and underlying genetic mechanisms.

October 11, 2000 – An NICHD grantee, Dr. James J. Heckman of the University of Chicago, is one of two NIH researchers to receive the Bank of Sweden Prize in Economic Sciences in memory of Alfred Nobel. Dr. Heckman is awarded the Nobel Prize in Economics for his pioneering work in accounting for unknown factors affecting statistical samples. Much of his work has been applied to understanding how early life events contribute to individuals' later earning potential and economic standing.

February 2001 – The NICHD establishes three Fragile X research centers to conduct and support research related to improving the diagnosis and treatment of, and finding a cure for, Fragile X and Fragile X Syndrome. This initiative was mandated under Public Law 106-310, the Children's Health Act, passed in October 2000.

April 2001 – A typhoid vaccine developed by NICHD scientists showed a 91.5 percent effectiveness rate, the highest reported for any typhoid vaccine, in clinical trials done in Vietnam. More than 16 million people worldwide are affected by typhoid every year. This highly effective vaccine could prevent the more than 600,000 deaths that result from typhoid fever every year around the world.

February 2002 – NICHD scientists, in conjunction with the biologics firm Nabi, develop the first vaccine against *Staphylococcus aureus*, a major cause of infection and death in hospital patients. *S. aureus*, which can cause illness ranging from minor skin infections to life-threatening pneumonia, meningitis, and infections of the heart, attacks people whose immune systems are compromised. This new vaccine provides a powerful new way to prevent these infections, a finding which could save thousands of lives every year.

June 2002 – Findings from the NICHD's Women's Contraceptive and Reproductive Experiences Study (Women's CARE) reveal no association between oral contraception use and an increased risk of breast cancer. The study, which focuses on women age 35 to 64 because they are more likely to develop breast cancer than younger women, provides scientific evidence that past or present oral contraception use does not significantly increase breast cancer risk.

2003 – In a first-of-its-kind collaboration, the NICHD, National Coalition of 100 Black Women, the Women in the NAACP, and Alpha Kappa Alpha Sorority, Inc., embark on a year-long program to spread the safe sleep message in African American communities. At regional summits held in Tuskegee, Los Angeles, and Detroit, the partners conduct SIDS risk-reduction training and activities to equip members and community leaders with educational techniques, strategies, and promotional materials so they can conduct outreach activities to reduce the risk of SIDS among African American infants.

June 2003 – The NICHD establishes the Center for Developmental Biology and Perinatal Medicine. The Center strives to advance fundamental and clinical knowledge about maternal health and problems of child development, such as preterm birth, mental retardation and developmental disabilities, congenital defects and genetic disorders, fetal growth restriction, and other conditions.

June 2004 – Reorganization within the NICHD's CRMC establishes the Obstetric and Pediatric Pharmacology Branch (OPPB) to meet the increased demand for research leadership and support of legislation passed to ensure the safety of drugs used to treat children. The new Branch, which includes the NICHD Pediatric Pharmacology Research Units Network, the Obstetric-Fetal Pharmacology Research Network, and NICHD Best Pharmaceuticals for Children Act activities, provides a focus for managing DHHS-wide efforts to address this important topic.

November 2004 – The NICHD and its partner agencies announce the 96 recruitment locations for the National Children's Study, a national, longitudinal study of environmental influences on child health mandated in the Children's Health Act of 2000. The Study, led by a consortium of federal agencies, including DHHS (the NICHD and the National Institute of Environmental Health Sciences, within NIH, as well as the Centers for Disease Control and Prevention) and the U.S. Environmental

Protection Agency, will be the largest and most comprehensive study of its kind. Study coordinators also publish a Study Plan, which outlines objectives, methodologies, and measures related to the first years of the Study, as well as requests for proposals for institutions to manage initial Study sites and a coordinating center.

NICHD Legislative Chronology

October 17, 1962 – Public Law 87-838 authorizes the surgeon general, with approval of the secretary of the DHEW, to "establish in the Public Health Service (PHS) an institute for the conduct and support of research and training relating to maternal health, child health and human development, including research and training in the special health problems and requirements of mothers and children and in the basic sciences relating to the processes of human growth and development, including prenatal development."

October 31, 1963 – Public Law 88-164 provides grants to support the construction of research centers for mental retardation and related disabilities. The NICHD remains closely associated with some 12 centers installed prior to June 30, 1967, when the authority expires.

December 24, 1970 – Public Law 91-572 adds Title X to the PHS Act to authorize grants and contracts for research and research training in family planning and population problems. The DHEW secretary delegates the authority to the NICHD, where the program is administered by the CPR.

April 22, 1974 – Public Law 93-270 assigns the task of conducting research on SIDS and reporting on it to the congress to the DHEW secretary and, ultimately, to the NICHD.

July 29, 1975 – Title II of Public Law 94-63, the Family Planning and Population Research Act of 1975, amends Title X of the PHS Act. Thereafter the PHS can conduct and support population research. Title X becomes the sole authority for population research appropriations.

August 13, 1981 – The Budget Reconciliation Act of 1981, Public Law 97-35, repeals sections 1004(b)(1) and 1004(b)(2) of the PHS Act. Once enacted, authority for supporting research in human reproduction and the population sciences derives from the broad provisions of sections 301 and 441 of the PHS Act.

November 20, 1985 – The Health Extension Act of 1985 directs the NICHD to appoint an Associate Director for Prevention, "to coordinate and promote the programs in the Institute concerning the prevention of health problems of mothers and children."

November 16, 1990 – Section 3 of the NIH Amendments of 1990, Public Law 101-613, establishes the NCMRR. The Center will conduct and support programs with respect to the rehabilitation of individuals with physical disabilities that result from congenital defects, diseases, or disorders of the neurological, musculoskeletal, cardiovascular, pulmonary, or any other physiological system.

June 10, 1993 – The National Institutes of Health Revitalization Act of 1993, Public Law 103-43, mandates the NICHD to do the following: 1) establish contraception research centers to improve methods of contraception; establish infertility research centers to improve methods of diagnosis and treatment of infertility; and establish an educational loan repayment program for extramural and intramural health professionals who agree to conduct contraception or infertility research; 2) establish and maintain an intramural laboratory and clinical research program in obstetrics and gynecology within the Institute; 3) establish and support a program of Child Health Research Centers; and 4) undertake a national prospective, longitudinal study of adolescent health and well-being.

October 17, 2000 – President Clinton signs Public Law 106-310, the Children's Health Act, which designates the NICHD as the lead organization on a number of research initiatives, including establishment of a pediatric research initiative, expansion of autism-related and Fragile X syndrome

research activities, and authorization for NICHD to lead other federal agencies in conducting a national longitudinal study of environmental influences on child health.

December 18, 2001 – President Bush signs Public Law 107-84, the Muscular Dystrophy Community Assistance, Research and Education Amendments of 2001, which directs the NIH director, in coordination with the National Institute of Neurological Disorders and Stroke, the National Institute of Arthritis and Musculoskeletal and Skin Diseases, and the NICHD, to expand research activities at NIH pertaining to various types of muscular dystrophy. This expansion is to include the formation of an inter-agency coordinating committee and the establishment of centers of excellence to conduct research. The law also mandates a contract with the Institute of Medicine to study and report on the impact of and need for centers of excellence at the NIH.

January 4, 2002 – The Best Pharmaceuticals for Children Act (Public Law 107-109) seeks to improve the safety and efficacy of pharmaceuticals for children. The law authorizes funding for the NIH to conduct testing of drugs already on the market, including at federally funded facilities, such as the NICHD's Pediatric Pharmacology Research Units.

January 8, 2002 – The President signs the No Child Left Behind Act (Public Law 107-110). Among the education legislation's many provisions is authorization for programs that build upon the reading readiness research funded by the NICHD, as well as on findings from the National Reading Panel, established and supported by the NICHD.

December 3, 2003 – The President authorizes the Pediatric Research Equity Act (Public Law 108-155), which codifies a policy of requiring pharmaceutical companies to test new drugs in pediatric populations, if the drugs are likely to be used to treat children, and to provide the data to the federal government. This law complements the Best Pharmaceuticals for Children Act, in which the NICHD plays a central role.

Biographical Sketch of NICHD Director Duane Alexander, M.D.

Duane Alexander, M.D., was named NICHD Director on February 5, 1986, after serving as Acting Director. Dr. Alexander also served a four-year term as the Institute's Deputy Director and was the Assistant to the Director, beginning in 1978.

Much of his career has been with the NICHD. After receiving his undergraduate degree from Pennsylvania State University, Dr. Alexander earned his medical degree from Johns Hopkins University School of Medicine. Following his internship and residency at the Department of Pediatrics at Johns Hopkins Hospital, Dr. Alexander joined the NICHD in 1968, as a clinical associate in the Children's Diagnostic and Study Branch. Following his tenure with the Branch, Dr. Alexander returned to Johns Hopkins as a fellow in pediatrics (developmental disabilities) at the John F. Kennedy Institute for Habilitation of the Mentally and Physically Handicapped Child.

His interests brought him back to the NICHD in 1971, when Dr. Alexander became Assistant to the Scientific Director and directed the NICHD National Amniocentesis Study. The study established the safety and accuracy of prenatal diagnosis using amniocentesis, now widely used to detect numerous genetic defects and inborn errors of metabolism.

From 1974 to 1978, Dr. Alexander served as medical officer in the Office of the Assistant Secretary for Health, in what is now the Department of Health and Human Services (DHHS). During that time, he was also the physician on the staff of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, whose recommendations form the basis of current DHHS regulations that protect human subjects in research.

Dr. Alexander is a diplomate of the American Board of Pediatrics and a member of the American Academy of Pediatrics (AAP), the American Pediatric Society and the Society for Developmental Pediatrics. For more than a decade, he also served as the United States' observer on the Steering

Committee on Bioethics for the Council of Europe. As an officer in the Public Health Service (PHS), Dr. Alexander has received numerous PHS awards, including a Commendation Medal in 1970, a Meritorious Service Medal, and a Special Recognition Award in 1985. He also received the Surgeon General's Exemplary Service Medal in 1990.

In 2002, Dr. Alexander received the Arnold J. Capute award from the AAP, to commend him on his contributions to the health and well-being of children with disabilities through service and/or advocacy on local, state, and national levels. In 2004, the American Medical Association (AMA) commended Dr. Alexander for his leadership in research on Sudden Infant Death Syndrome by awarding him the Dr. Nathan Davis Award for Outstanding Government Service. The award, named for the AMA's founder, recognizes federal, state, and municipal officials whose contributions promote the art and science of medicine and the betterment of the public health.

In addition, Dr. Alexander is the author of numerous articles and book chapters, most of which relate to his research in developmental disabilities.

Directors of NICHD

Name	In Office From	To
Robert A. Aldrich	March 1, 1963	October 1964
Donald Harting	July 8, 1965	1966
Gerald D. LaVeck	October 9, 1966	September 1, 1973
Gilbert L. Woodside (Acting)	September 1, 1973	September 1, 1974
Norman Kretchmer	September 1, 1974	September 30, 1981
Betty H. Pickett (Acting)	September 30, 1981	June 30, 1982
Mortimer B. Lipsett	July 1, 1982	January 7, 1985
Duane Alexander	February 5, 1986	Present

Organization

The NICHD's major components include both extramural programs, which support research via grants and contracts, and intramural programs, which conduct research at various laboratories, branches, units, and sections. The Division of Scientific Review provides additional support for NICHD activities. Descriptions of the major components and their functions are outlined below. For more information on the NICHD, its mission, its components, and its research, please visit <http://www.nichd.nih.gov>.

Center for Population Research (CPR)

The CPR is the federal government's focal point for population research. Through grants and contracts, the Center supports: fundamental biomedical research on reproductive processes that influence human fertility and infertility; development of better methods for regulating fertility and for preventing the spread of sexually transmitted diseases (STDs), including HIV; evaluation of the safety and effectiveness of contraceptive methods now in use; and behavioral and social science research on the reproductive behavior of individuals, sexual transmission of HIV, and the causes and consequences of population change.

The Center also supports an extensive training program for individuals interested in all aspects of reproduction and population research through its three branches:

- Contraception and Reproductive Health Branch
- Demographic and Behavioral Sciences Branch
- Reproductive Sciences Branch

Center for Developmental Biology and Perinatal Medicine (CDBPM)

The CDBPM provides support for basic, clinical and applied research and research training in maternal, fetal, and infant health, and disorders of human development. The Center seeks to advance fundamental and clinical knowledge about maternal health and problems of child development, such as preterm birth, mental retardation and developmental disabilities, congenital and genetic disorders, fetal and infant morbidity and mortality (including fetal growth restriction, stillbirth, SIDS, fetal therapy, and disorders of the high risk neonate), and other conditions. Areas of emphasis include, but are not limited to: biology of high-risk pregnancies and premature birth; low birth weight; mental retardation and developmental disabilities, including autism and fragile X syndrome; heritable diseases; birth defects; prenatal and neonatal screening; immunodeficiencies ; and mechanisms and factors in teratogenesis and developmental biology, including basic studies of processes in embryonic development and the development and use of animal models to study developmental processes and genetic diseases.

The Center achieves its mission through the efforts of three branches:

- Developmental Biology, Genetics, and Teratology Branch
- Mental Retardation and Developmental Disabilities Branch
- Pregnancy and Perinatology Branch

Center for Research for Mothers and Children (CRMC)

The CRMC is a major source of research and research training in child health and in the health of mothers. The Center and its programs focus on maximizing growth and development, preventing transmission of HIV/AIDS in various populations, and improving knowledge about children's behavior and behavioral outcomes. Areas of emphasis include, but are not limited to: behavioral, social, and emotional adaptation from infancy through adolescence and early adulthood; learning disabilities; nutrition; endocrine disorders and growth retardation; and preconceptional, prenatal, and postnatal infectious diseases and HIV/AIDS. In addition, the CRMC plays a lead role in the following initiatives: the Global Network for Women's and Children's Health, the activities of the Best Pharmaceuticals Act for Child and Pediatric Pharmacology Research Unit Network, examinations of reading and math outcomes and how to improve them, and accident and injury prevention.

The Center achieves its mission through the efforts of its branches:

- Endocrinology, Nutrition, and Growth Branch
- Child Development and Behavior Branch
- Pediatric, Adolescent, and Maternal AIDS Branch

National Center for Medical Rehabilitation Research (NCMRR)

The NCMRR funds research training and projects to develop the scientific knowledge needed to promote the health, productivity, independence, and quality of life for people with disabilities. A primary goal of the Center is to bring the health-related problems of people with disabilities to the attention of the nation's best scientists, to capitalize upon the myriad advances occurring in the biological, behavioral, and engineering sciences.

The NCMRR supports a number of research programs:

- Behavioral Sciences and Rehabilitation Engineering Technology Program
- Biological Sciences and Career Development Program
- Pediatric Critical Care and Rehabilitation Program
- Spinal Cord and Musculoskeletal Disorders and Assistive Technology Program

Division of Epidemiology, Statistics, and Prevention Research (DESPR)

DESPR, an intramural research program, provides the Institute with skills in four disciplines: biostatistics, epidemiology, computer sciences, and prevention research. DESPR relies solely on contracts to fund its research – not grants. Within DESPR are three branches:

- Biometry and Mathematical Statistics Branch
- Epidemiology Branch
- Prevention Research Branch

In response to the Children's Health Act of 2000, DESPR initiated the planning phase of the *National Children's Study*, a national, longitudinal study of environmental influences on child health, in 2001. The Study, led by a consortium of federal agencies, including DHHS (the NICHD and the National Institute of Environmental Health Sciences, within NIH, as well as the Centers for Disease Control and Prevention) and the U.S. Environmental Protection Agency, will span more than two decades and will follow approximately 100,000 children. DESPR staff continue to be integral in Study planning and progress. In November 2004, DESPR staff and the Study's partner agencies announce the 96 locations for the Study, release the Study Plan, and publish the request for proposals for the Study sites. Recruitment for the study is anticipated to begin in 2006.

Division of Intramural Research (DIR)

The DIR is broadly concerned with the biological and neurobiological, medical, and behavioral aspects of normal and abnormal human development. The Division's clinical research projects admit a limited number of research patients under guidelines established by the Director of the NIH Clinical Center. Patients must be referred by a physician to participate. In addition to clinical research and training programs in the areas of genetics, endocrinology, and maternal-fetal medicine, a diverse range of developmental models are under study in research laboratories and branches. For more information about the DIR, visit <http://dir2.nichd.nih.gov/>.

DIR Basic Research

- Cell Biology and Metabolism Branch
- Endocrinology and Reproduction Research Branch
- Laboratory of Cellular and Molecular Biophysics
- Laboratory of Cellular and Molecular Neurophysiology
- Laboratory of Cellular and Synaptic Neurophysiology
- Laboratory of Developmental Biology
- Laboratory of Gene Regulation and Development
- Laboratory of Integrative and Medical Biophysics
- Laboratory of Mammalian Genes and Development
- Laboratory of Molecular Genetics
- Laboratory of Molecular Growth Regulation
- Laboratory of Physical and Structural Biology
- Section on DNA Replication, Repair, and Mutagenesis

DIR Clinical Research

- Bone and Extracellular Matrix Branch
- Developmental Endocrinology Branch
- Heritable Disorders Branch
- Laboratory of Clinical Genomics
- Laboratory of Comparative Ethology
- Laboratory of Developmental and Molecular Immunity
- Reproductive Biology and Medicine Branch
- Perinatal Research Branch

The Research Animal Management Branch and the Unit on Biologic Computation also provide support and resources for DIR research and activities.

Division of Scientific Review (DSR)

The DSR is responsible for a broad range of functions related to the review of grant applications for research and training, and of contract proposals for research. The Division also provides policy direction and coordination for planning and conducting initial scientific and technical merit reviews of applications for numerous types of grant applications, including small research grants, program projects, centers, institutional training grants, career development, and conference grants. In addition, the DSR coordinates and conducts the review of grant applications that are received by the NICHD in response to requests for applications, which are published with the aim of fostering work in a research area of particular relevance to the mission of the Institute. The Division also manages the technical evaluation of contract proposals that arrive in response to requests for proposals issued by the Institute.

To review grant applications, the DSR relies on subcommittees of the Child Health and Human Development (CHHD) Initial Review Group (IRG) or, where appropriate, a Special Emphasis Panel that is convened for its expertise in a specific area of science. The CHHD IRG includes subcommittees on the following scientific areas: pediatrics; developmental biology; biobehavioral and behavioral sciences; population sciences; obstetrics and maternal-fetal biology; reproduction, andrology, and gynecology; and function, integration, and rehabilitation sciences. In addition to managing the subcommittees, scientific review administrators also recruit extramural scientists to serve as peer-reviewers, while maintaining oversight of all aspects of the peer-review process. Further, Special Emphasis Panels, which are convened as technical evaluation groups, also evaluate contract proposals.

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National Institutes of Health (NIH)
9000 Rockville Pike
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The NIH Almanac – Organization

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National Institute on Deafness and Other Communication Disorders

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Mission

The National Institute on Deafness and Other Communication Disorders (NIDCD) conducts and supports research and research training on disorders of hearing and other communication processes, including diseases affecting hearing, balance, smell, taste, voice, speech, and language through:

- Research performed in its own laboratories and clinics
- A program of research grants, individual and institutional research training awards, career development awards, center grants, and contracts to public and private research institutions and organizations
- Cooperation and collaboration with professional, academic, commercial, voluntary, and philanthropic organizations concerned with research and training that is related to deafness and other communication disorders, disease prevention and health promotion, and the special biomedical and behavioral problems associated with people having communication impairments or disorders
- The support of efforts to create devices which substitute for lost and impaired sensory and communication functions
- Ongoing collection and dissemination of information to health professionals, patients, industry, and the public on research findings in these areas.

Important Events in NIDCD History

October 28, 1988 – Public Law 100-553 authorized the formation of the National Institute on Deafness and Other Communication Disorders.

June 26, 1989 – The NIDCD Advisory Board held its first meeting.

September 18, 1989 – The Advisory Council of NIDCD convened for the first time.

February 11, 1990 – James B. Snow, Jr., M.D., was appointed as the first Director, NIDCD.

September 21, 1990 – The NIDCD established the Office of Administrative Branch, Financial Management Branch, Personnel Management Branch, and Program and Health Reports Branch.

December 5, 1990 – Division of Intramural Research established labs and branches within the

division.

December 6, 1990 – The Information Systems Branch was created.

March 1, 1991 – The NIDCD Information Clearinghouse was established.

April 4, 1991 – The Board of Scientific Counselors of NIDCD held its first meeting.

November 19, 1991 – The Deafness and Other Communication Disorders Interagency Coordinating Committee met for the first time.

December 29, 1991 – David J. Lim, M.D., appointed as Scientific Director.

May 8, 1992 – NIDCD/American Academy of Otolaryngology–Head and Neck Surgery sponsored a live interactive satellite conference, "Warning! The Impact of Pollution on the Upper Alimentary and Respiratory Tracts," to inform scientists, physicians and the public about health problems associated with pollution and identify areas of needed research.

August 21, 1992 – NIDCD/Department of Veterans Affairs directors signed a Memorandum of Understanding which established a collaboration to expand and intensify hearing aid research and development.

October 23, 1992 – NIDCD/National Aeronautics and Space Administration (NASA) established formal scientific collaboration to enhance basic knowledge and understanding of vestibular function in both clinical and normal states and provide investigators access to NASA's unique ground-based research facilities and to space flight.

March 1-3, 1993 – Consensus Development Conference, "Early Identification of Hearing Impairment in Infants and Young Children," evaluated current research and provided recommendations regarding hearing assessment from birth through 5 years of age.

October 25, 1993 – NIDCD commemorated its fifth anniversary, "A Celebration of Research in Human Communication."

January 18, 1994 – The Division of Communication Sciences and Disorders established the Hearing and Balance/Vestibular Sciences Branch and the Voice, Speech, Language, Smell, and Taste Branch.

May 1994 – The NIDCD Advisory Board held its final meeting.

August 5, 1994 – The Division of Communication Sciences and Disorders was changed to the Division of Human Communication.

February 14, 1995 – "The Partnership Program" began, designed to maximize opportunities for underrepresented students to participate in fundamental and clinical research in the NIDCD research areas, with four academic centers: Morehouse School of Medicine; University of Puerto Rico School of Medicine; University of Alaska System, Fairbanks; and Gallaudet University.

March 1, 1995 – James F. Battey, Jr., M.D., Ph.D., was appointed as Director of the Division of Intramural Research.

May 15-17, 1995 – Consensus Development Conference, "Cochlear Implants in Adults and Children," summarized current knowledge about the range of benefits and limitations of cochlear implantation.

September 11-13, 1995 – First biennial conference, "Advancing Human Communication: An Interdisciplinary Forum on Hearing Aid Research and Development," was held.

September 13, 1997 – James B. Snow, Jr., M.D., retires as the first Director, NIDCD. James F. Battey, Jr., M.D., Ph.D., becomes Acting Director of NIDCD.

September 22-24, 1997 – The second biennial hearing aid research and development conference took place.

February 10, 1998 – James F. Battey, Jr., M.D., Ph.D., appointed as the new Director, NIDCD.

March 13, 1998 – The NIDCD Working Group on Early Identification of Hearing Impairment's second workshop identified some research opportunities offered by neonatal hearing screening programs, specifically in diagnostic strategies for characterizing hearing impairment and in the intervention strategies for remediating hearing impairment.

August 13-14, 1998 – The Working Group on Single and Multiple Project Grants held its first meeting.

December 20, 1998 – Robert J. Wenthold, Ph.D., appointed as Scientific Director.

January - February 1999 – The NIDCD convened a group of distinguished scientists and members of the public to provide recommendations for a Strategic Plan.

May 25, 1999 – The NIDCD working group on "Communicating Informed Consent to Individuals Who Are Deaf or Hard-of-Hearing," met to clarify issues of informed consent, develop guidelines for use by scientists, and propose new, needed materials for improving communication about informed consent.

December 11, 2000 – NIDCD signs a Memorandum of Understanding with the Center for Comparative and Evolutionary Biology of Hearing, University of Maryland, College Park to establish a program for training graduate students in the hearing sciences.

March 22-23, 2001 – The Division of Intramural Research, NIDCD, held its first retreat at St. Michael's, Maryland.

May 24, 2001 – Dr. Battey announced the Institute's new logo at the Advisory Council meeting.

September 2002 – Dr. Battey was appointed as Chair of the NIH Stem Cell Task Force by NIH Director Dr. Zerhouni.

October 21, 2002 – NIDCD hosts first health literacy lecture, "Babel Babble: What is the Doctor Saying? What is the Patient Understanding?" for health communication professional who develop health materials and communication strategies for a range of diverse audiences

June 12, 2003 – Dr. Battey opens First NIH Symposium on Human Embryonic Stem Cells, Bethesda, Maryland

December 2003 – NIDCD's WISE EARS!® national campaign to prevent noise-induced hearing loss turned five years old. The campaign is a coordinated effort among NIDCD, the National Institute on Occupational Safety and Health (NIOSH), and a coalition of organizations who care about hearing.

October 2004 – NIDCD-funded investigator, Dr. Linda Buck, wins the 2004 Nobel Prize in Physiology and Medicine.

Biographical Sketch of NIDCD Director James F. Battey, Jr., M.D., Ph.D.

Dr. Battey became the new NIDCD director on February 10, 1998. He served as acting director since the retirement of the Institute's first director in September 1997. He is responsible for the planning, implementation and evaluation of Institute programs to conduct and support biomedical and behavioral research, research training, and public health information in human communication.

He received his education at the California Institute of Technology, where he earned his B.S. with honors in physics. He earned his M.D. and Ph.D. in biophysics at Stanford University where he had residency training in pediatrics. His postdoctoral fellowship at Harvard Medical School was under the direction of the eminent scientist, Dr. Philip Leder. While working with Dr. Leder, he was part of a team that cloned the genes encoding the IgE immunoglobulin constant region domains. In addition, he isolated and characterized the human c-myc gene, a key growth regulatory nuclear proto-oncogene that contributes to cancer formation when inappropriately expressed.

Dr. Battey has been with NIH since 1983, first on the staff of NCI where he rose from senior staff fellow to senior investigator. In his work at the NCI-Navy Medical Oncology Branch, he collaborated in the isolation and characterization of human N-myc and L-myc, two additional members of the human myc gene family, important in human neoplasms. He became interested in neuropeptides and their receptors at this time because of their dual function as growth factors and regulatory peptides. His group isolated cDNA and genomic clones for mammalian bombesin-like peptides, key regulators of secretion, growth and neuronal firing.

In 1988 he moved to NINDS as chief of the molecular neuroscience section in the Laboratory of Neurochemistry. In 1992 he returned to the NCI to head the molecular structure section of the Laboratory of Biological Chemistry where his laboratory cloned and characterized the genes for three subtypes of mammalian receptors for bombesin-like peptides. His team at NCI's Laboratory of Biological Chemistry was among the first to clone the gene encoding cdk5, a member of the cyclin-dependent kinase family, where important proteins are involved in cell cycle control. Dr. Battey was appointed as director of the Intramural Research Program for NIDCD in 1995 by Dr. Snow, the first NIDCD director. The PHS has honored him with its PHS Commendation Medal in 1990 and the Outstanding Service Medal in 1994. He is author or co-author of over 130 research articles and is co-author with Leonard Davis and Michael Kuehl of *Basic Methods in Molecular Biology*.

NIDCD Directors

Name	In Office From	To
Jay Moskowitz (Acting)	October 31, 1988	February 1990
James B. Snow, Jr.	February 1990	September 13, 1997
James F. Battey, Jr.	September 14, 1997	Present

Research Programs

NIDCD supports and conducts research and research training in the normal and disordered processes of hearing, balance, smell, taste, voice, speech, and language through a program of grants and contracts in basic, clinical, and translational research. They are conducted in public and private institutions across the country and around the world and within the laboratories and clinics at the National Institutes of Health in Bethesda, Maryland.

Division of Intramural Research conducts basic and clinical research in human communication disorders, which is within the mission of the Institute. Research objectives include: studies of electromechanical processes responsible for fine tuning in the cochlea; identification, characterization, and cloning of genes responsible for hereditary hearing impairment; electromotility of the outer hair cell; molecular bases of mechanosensory transduction mechanisms in the organ of Corti; molecular bases for G-protein signaling with emphasis on sensory signaling processes in the

chemical senses; development of vaccines for otitis media; molecular mechanisms underlying the development and function of the mammalian taste system; mechanisms responsible for the development of the inner ear; molecular mechanisms underlying auditory system function with emphasis on neurotransmission and neuromodulation; identification of genes associated with neoplasms affecting human communication; identification of the genetic component of stuttering; neuroimaging of brain function in physiologic and pathophysiologic states; pathophysiology and etiology of voice and speech disorders; and epidemiological and biometric research studies of communication disorders.

Division of Extramural Activities (DEA) provides leadership and advice in developing, implementing, and coordinating extramural programs and policies. It represents the Institute on NIH committees on extramural program policies and oversees compliance with such policies within the NIDCD. The Division provides grant management and processing services for all of the Institute's grants and conducts initial scientific merit review of a large array of grant mechanisms and R&D contract proposals. In addition, the DEA coordinates the Institute's committee management activities, research integrity activities, and Certificates of Confidentiality, and manages the meetings of the National Deafness and Other Communication Disorders Advisory Council. The Division has two components: Grants Management Branch and Scientific Review Branch.

- *Grants Management Branch (GMB)* — focal point for all business-related activities associated with the negotiation, award, and administration of grants and cooperative agreements within the NIDCD. GMB plays a critical role of bridging among the various NIH offices (review, program, financial management, and policy), institutional offices of sponsored programs, and principal investigators.
- *Scientific Review Branch (SRB)* — coordinates the initial scientific peer review applications for the following mechanisms of support: research project grants, clinical center and core center grants, research training and career development grants, multi-site clinical trials, and cooperative agreements, as well as all proposals for research and development contracts. SRB also coordinates receipt and referral issues with the Center for Scientific Review, represents NIDCD on NIH's overall committee for review policies, and manages all aspects of NIDCD's peer review process.

Division of Scientific Programs (DSP) of NIDCD is responsible for coordinating a broad range of activities and functions to assure sound and efficient management of NIDCD's extramural activities that include a program of research grants, career development awards, individual and institutional research training awards, center grants, and contracts to public and private research institutions and organizations. DSP also plans and directs a program of grant and contract support for research and research training in the normal processes and diseases and disorders of hearing, balance, smell, taste, voice, speech, and language to insure maximum utilization of available resources in attainment of Institute's objectives; assesses needs for research and research training in program areas; establishes program priorities and recommends funding levels for programs to be supported by grants; and sets priorities and funding levels for research to be supported by contracts.

Hearing

The fields of cellular and molecular biology have furthered hearing research. A multitude of genes for syndromic and nonsyndromic forms of hearing impairment including autosomal dominant and recessive, X-linked and mitochondrial modes of transmission have been located in specific regions of the human genome. In addition, clinically relevant genes essential for normal auditory development and/or function are being identified and cloned at a rapid pace.

Other cochlear-specific genes have been isolated from enriched membranous labyrinth cDNA libraries. New technology, including the development of detailed maps of expressed sequence tags (EST) coupled with the use of inner ear specific cDNA libraries, exon trapping and cDNA library enrichment procedures, have facilitated gene cloning. Once cloned, the molecular biology of hearing and the role of particular proteins in the development and/or maintenance of the inner ear can be

determined. Mouse models of hereditary hearing impairment have been instrumental in mapping and cloning many deafness genes. Because of the utility of the mouse for such studies, additional mouse models of deafness are being created through mutagenesis and screening programs as well as targeted mutation of deafness genes found in man. In addition, mouse models are being used to study the function of the proteins encoded by deafness genes and to test therapeutic approaches. These advances offer researchers many opportunities to study the characteristics of deafness, hereditary factors involved in hearing loss, and genes that are critical for the development and maintenance of the human ear. Great strides are being made in the study of properties of auditory sensory cells, and of characteristics of the response of the inner ear to sound.

Scientific advances have also been translated into cochlear implants, digital hearing aids, and tactile devices that provide information by stimulating the skin. Great strides are being made in the study of properties of auditory sensory cells, and of characteristics of the response of the inner ear to sound. Research has verified that despite substantial variability in the performance of children who have received cochlear implants, most demonstrate marked improvements in speech perception and production. Speech produced by children who use multichannel cochlear implants is usually more accurate than the speech produced by children with comparable hearing impairment using vibrotactile devices or hearing aids. Cochlear implants also positively influence children's receptive and expressive language skills. The longer children use their implants, the greater their language ability.

To achieve the most benefit from their implants, however, children generally need extensive oral-auditory training following implantation and also benefit from periodic audiological assessments. Cochlear implants have benefited children who are congenitally deaf as well as those who are postlingually deaf. The vast majority of adult implant recipients derive substantial benefit in conjunction with speechreading, and many can communicate effectively without speechreading and are able to communicate by telephone. Dedication to research on cochlear implants throughout the world will improve the capabilities of current implant users and improve our understanding of the auditory system.

New insights have been gained concerning the encoding of complex signals transmitted from the auditory nerve to the brain. The relationship between the neural codes for sound intensity, frequency, duration and temporal characteristics of auditory signals and the perception of the stimulus variables has been further clarified. Valuable progress has been made in understanding the structure and function of efferent feedback pathways to the inner and middle ear. There is now good evidence that this system may aid in the detection of signals in noisy environments and serve to protect the ear from acoustic injury.

Gains have been made about the ways in which the brain creates maps of auditory space and how the maps interact with visual space. This research may have implications in treatment of children who acquire hearing loss in infancy or early childhood. Further, psychoacoustic and electrophysiologic studies of infants and children are providing important new insights into the development of functional hearing.

In the aging auditory system, discoveries have been made demonstrating changes in the regulation of fluid composition and autoregulation of cochlear blood flow which may underlie some of the biologic effects of aging on auditory function. Improved behavioral and electrophysiological techniques for measuring auditory function are providing more accurate assessments of the peripheral and central components of age-related hearing impairment.

Recent development of animal models for bacterial and viral infections hold promise for new diagnostic and therapeutic approaches to sensorineural hearing loss caused by infections. Antiviral drugs may find rapid application in the treatment for these conditions with the advent of suitable animal models in which to test efficacy. In addition, models will allow a greater understanding of why and to what degree infants and children are susceptible to ototoxic drugs used in the treatment of infections.

Otitis media continues to be a significant focus of research because of its prevalence and cost to society. Important risk factors have been identified. Studies of the eustachian tubes have provided new information on tubal mechanics, surfactant-like (fluid) substances and middle ear pressure regulation. The role of bacterial biofilms in chronic otitis media is a new and promising area of investigation. State-of-the-art molecular, genetic and genomic techniques are being used to identify genes that may predispose an individual to chronic otitis media. These techniques are also being used to define the specific molecular changes that allow viral and bacterial infection of the middle ear as well as the host/pathogen interactions that facilitate the disease process.

Balance

NIDCD supports research on balance and the vestibular system. Balance disorders affect a large proportion of the population, particularly the elderly. The vestibular system, with its receptor organs located in the inner ear, plays an important role in the maintenance of one's orientation in space, the control of balance while the body is immobile and in motion, and visual fixation of objects during head movement. Vestibular disorders can therefore yield symptoms of imbalance, vertigo (the illusion of motion), disorientation, instability, falling and visual blurring (particularly during motion). Deficits in vestibular function result from diverse disease processes, including infection, trauma, toxicity, impaired blood supply, autoimmune disease, impaired metabolic function and tumors.

In addition to its role in the stabilization of gaze and balance, recent findings from NIDCD-supported studies suggest that the vestibular system plays an important role in regulating blood pressure. The information emerging from these studies holds potential clinical relevance for the understanding and management of orthostatic hypotension (lowered blood pressure related to a change in body posture).

The linear acceleration detectors of the vestibular system, the otolithic organs, detect the forces produced by head tilt and by linear (forward-to-aft, side-to-side) head movements. How the vestibular apparatus and the nervous system resolve gravitational from linear accelerations in order to accurately perceive motion and control balance is currently under active study by NIDCD-supported investigators.

Investigations supported by the NIDCD are characterizing the genes essential to normal development and function in the vestibular system. The genetic bases of several inherited cerebellar syndromes of imbalance and incoordination are currently being investigated.

The institute supports research to develop and refine tests of balance and vestibular function. Computer-controlled systems measuring eye movement and body postural responses activated by stimulating specific parts of the vestibular sense organ and nerve have been developed and validated for clinical use. Also, tests of functional disability and physical rehabilitative strategies currently being applied in clinical and research settings will have important implications for refining the rehabilitation of patients with balance and vestibular disorders.

Recently, a prototype vestibular neural prosthesis has been developed by a team of NIDCD-funded investigators. Early-stage studies with this device demonstrates that the function of the inner ear balance system can be partially restored through electrostimulation of the vestibular nerve. Research is progressing in earnest to refine the vestibular prosthesis and to determine its viability for application to vestibular-deficient humans.

Smell and Taste

NIDCD investigators study the chemical senses of olfaction (smell) and gustation (taste) to enhance our understanding of how individuals communicate with their environment. Smell and taste play important roles in preferences and aversions for aromas, specific foods and flavors. Sweet-tasting substances are generally consumed and contribute to caloric intake and proper nutrition; bitter-tasting substances are typically avoided because bitterness is often associated with toxic

compounds that cause illness. The NIDCD is supporting research on the development of bitter-taste blockers in an effort to identify compounds that can mask the bitter taste of essential medications, especially for children.

Both the olfactory and gustatory systems offer special approaches for the understanding of the fundamental mechanisms of neural plasticity. NIDCD scientists have found that smell and taste receptor cells are continually replaced and have the further capacity to replace themselves rapidly in response to injury. With every hard sneeze and with every burnt tongue from a hot cup of coffee, olfactory and taste receptor cells are destroyed and are then replaced. These are the only known mammalian sensory cells with this native regenerative capability, and the olfactory system is now used as a model system in the study of the biology of multi-potent stem cells. Unfortunately, the plasticity of the olfactory system declines with age, with important consequences to the increasingly aged population. The perceived quality of foods moves towards blandness in the elderly and this affects food intake, diet and overall nutrition, and health status. Prevention of this age-related decline in olfactory sensitivity is being studied by NIDCD investigators.

Advances in molecular and cellular biology, biophysics and biochemistry of the olfactory and gustatory systems are paving the way for improved diagnosis, prevention, and treatment of chemosensory disorders. The vertebrate olfactory receptor neuron has become an important model system in molecular and cellular biology. The olfactory receptor gene family has been described in several mammalian species, including humans, and may contain as many as 1,000 members. NIDCD scientists are presently characterizing genetic mechanisms of olfaction, which will provide the opportunity to study the molecular pharmacology of the process of smell. More recently, a family of about 80 taste receptor genes has been identified by NIDCD investigators. Interestingly, both olfactory and sweet and bitter taste receptors are structurally similar and activate similar second messenger signal transduction cascades, which ultimately generates neural activity in the central nervous system. The characterization of these receptor genes was greatly facilitated by the genetic database provided by the NIH's human and mouse genome projects.

The molecular biological studies of olfactory and taste receptor cells have provided essential information about the sensitivities of the chemical senses at the first level of neural integration. The coding of odorants and tastants by the central nervous system begins at the level of the receptor cell. In addition, in both the olfactory and gustatory systems, odor and taste quality coding is further refined by a synthetic process of the central nervous system. NIDCD-funded projects are examining the nature of the central coding. In the olfactory system, odor coding appears very complex because of the numerous types of odors that must be detected and because of the complicated neuroanatomical organization of the olfactory system. We are just beginning to understand the nature of the olfactory code. On the other hand, in the taste system, significant progress has been made in our understanding of how the four taste qualities of sweet, salty, sour, and bitter are coded centrally. Recent work suggests a fifth taste quality, umami, which is familiar to many as the taste of monosodium glutamate (MSG). The nature of the gustatory code and the high degree of central processing makes the gustatory system very resistant to damage. Consequently, the taste system is less often affected by aging as is the olfactory system.

Voice, Speech and Language

Studies of voice and speech disorders focus on determining the nature, causes, treatment and prevention of disorders such as stuttering, speech-sound acquisition disorders, and motor speech disorders. Oral speech communication may not be a realistic option for individuals with severe dysarthria. Substantial progress has been made in the development of augmentative communication devices to facilitate the expressive communication of persons with severe communication disabilities. An investigation of conversational performance by augmentative communicative device users is in progress. Other funded research evaluates whether a low-cost, laser-activated keyboard for accessing personal computers is feasible. By providing access to computers, individuals with disabilities can immediately use personal computer software programs and speech synthesizers for augmentative communication.

NIDCD funded investigators are exploring the use of non-viral gene transfer for the delivery of growth factors applied to re-innervation of laryngeal muscles in an animal model. This will have direct relevance towards creating a more practical treatment strategy for human disorders, including treatment of laryngeal paralysis and other peripheral nerve injuries. Others are studying the limbic and motor system interaction in laryngeal function using an animal model to better understand mechanisms of voice disorders and speech disorders and their recovery.

Spasmodic dysphonia is a unique voice disorder with significant physical and emotional burden. A phase 1 randomized prospective clinical trial comparing Botox injection, a combination treatment of behavioral intervention and Botox injections, and sham therapy and Botox is being conducted.

Investigators are actively working to provide locked-in individuals with a direct means of producing speech to allow rapid communication between the individual and care givers as well as control of computers. This will be accomplished through the development of a direct brain-to-speech generator for use in humans which will use an individual's neural signals.

Language research continues to expand the understanding of the role of each hemisphere of the brain in communication and language, of early specialization of the brain, and of the recovery process following brain damage. This research will further our understanding of the neural bases of language and language disorders. Research on acquisition, characterization and utilization of American Sign Language is expanding knowledge of the language used by many people who are deaf.

Language researchers supported by NIDCD are also exploring the genetic bases of child speech and language disorders, as well as characterizing the linguistic and cognitive deficits in children and adults with language disorders. Researchers are developing effective diagnostic and intervention strategies for children who are autistic, or have specific language impairment, as well as adults with aphasia.

This page was last reviewed on January 10, 2006 .

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The NIH Almanac – Organization

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National Institute of Dental and Craniofacial Research

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Until October 21, 1998, the National Institute of Dental Research

Mission

The mission of the National Institute of Dental and Craniofacial Research is to improve oral, dental, and craniofacial health through research, research training, and the dissemination of health information. We accomplish our mission by:

- Performing and supporting basic and clinical research;
- Conducting and funding research training and career development programs to ensure an adequate number of talented, well-prepared and diverse investigators;
- Coordinating and assisting relevant research and research-related activities among all sectors of the research community;
- Promoting the timely transfer of knowledge gained from research and its implications for health to the public, health professionals, researchers, and policy-makers.

Important Events in NIDCR History

1931 – PHS created a Dental Hygiene Unit at NIH and designated Dr. H. Trendley Dean as the first dental research worker. His primary function was to apply principles of epidemiology to a series of community studies on the oral disease known as mottled enamel. His research on fluoride showed not only its relation to mottled enamel, but also its influence on tooth decay.

1945 – Following fluoridation of the water supply in Grand Rapids, Michigan, annual examinations of children were begun to study the effects of fluoride on the development of dental caries.

1948 – On June 24, P.L. 80-755, the National Dental Research Act created NIDR and the National Advisory Dental Research Council. On September 16, the institute was established.

1949 – The first meeting of the National Advisory Dental Research Council was held on January 10. The institute-supported grants program was initiated, and the first grants and fellowships were awarded.

1954 – Results of the first ten years of the Grand Rapids study firmly established water fluoridation as a safe, effective, and economical procedure for the control of dental caries.

On October 30, the first meeting of the Board of Scientific Counselors was held. This board was established to provide advice to NIDR on matters of general policy, particularly from a long-range viewpoint, as they relate to the intramural program.

1958 – The Laboratory of Biochemistry was established to conduct research studies on the chemistry and structure of collagen, elastin, and other proteins. President Eisenhower signed the

appropriations bill, which included provisions to finance the construction of a building for the dental institute.

1960 – On September 21, the cornerstone was laid for the dental institute building (Building 30) at NIH.

1961 – On May 26, DHEW Secretary Abraham A. Ribicoff dedicated the new NIDR building.

1962 – The first grant for a multidisciplinary study of cleft palate was awarded to the University of Pittsburgh Health Center.

1963 – Fifteen years of scientific accomplishment by NIDR were cited by scientists, administrators, and health educators on June 14 in a special anniversary observance.

1966 – A reorganization of the institute's extramural programs was implemented to more adequately plan and support research and training programs designed to attack the major dental diseases and disorders – dental caries, periodontal disease, oral-facial anomalies, and biomaterials.

1967 – An NIDR program of grant support was initiated for the development of several dental research institutes/centers in university environments. This program was designed to utilize all of the appropriate resources of the parent universities to create ideal research and training environments, fostering interdisciplinary approaches to the complex problems of oral diseases and disorders.

1969 – The Laboratory of Histology and Pathology was reorganized and named the Laboratory of Biological Structure. This laboratory conducts basic research on the structural and chemical organization of the hard and soft tissues of the oral cavity.

1971 – The National Caries Program was launched utilizing funds specifically earmarked to accelerate development of preventive methods to reduce tooth decay.

1973 – The Laboratory of Oral Medicine was established to conduct both clinical and laboratory research on the cause, prevention, and treatment of diseases of the soft tissue of the oral cavity.

On June 28-29, a scientific conference commemorating the silver anniversary of NIDR was convened in Washington, D.C.

1974 – To encompass the expanded research studies conducted by the Laboratory of Microbiology, the Laboratory of Microbiology and Immunology was established. Laboratory programs involve the role of host factors in periodontal diseases, autoimmune diseases, and allergic disorders.

To emphasize anesthesia-analgesia dental problems, the NIDR reorganized its intramural program to form a Neurobiology and Anesthesiology Branch composed of the neural mechanism section and the anesthesiology section. The branch collaborates closely with the extramural programs concerned with pain control and behavioral studies.

1975 – Having already established the safety and efficacy of several caries preventive measures, the NIDR initiated selected school demonstration projects through its National Caries Program.

1977 – The institute established its first two specialized clinical research centers in periodontal diseases.

In June, Dr. Marie U. Nysten was named director of intramural research, the first woman to hold such a position at NIH.

1978 – NIDR sponsored its first consensus development conference, *Dental Implants – Benefit and Risk*, to examine available data, suggest future research, and draft guidelines for implant therapy.

1980 – The Diagnostic Systems Branch was created to pursue research and development of noninvasive diagnostic techniques, and analysis of the functional development of the oral and pharyngeal region.

A Clinical Investigations and Patient Care Branch was established to emphasize the intimate association between the institute's patient treatment and clinical dental research programs.

1982 – The Laboratory of Biological Structure and the Laboratory of Biochemistry were replaced by the Laboratory of Oral Biology and Physiology and a Mineralized Tissue Research Branch. The Laboratory of Oral Biology and Physiology conducts research on the cell biology of secretory tissues and the chemical modification of proteins. Skeletal development, regulation, and disorders are under investigation in the Mineralized Tissue Research Branch.

1983 – On March 21, the NIDR opened the first multidisciplinary pain clinic in the U.S. devoted exclusively to research. The clinic provides an opportunity for all NIH researchers and clinicians to pool their knowledge and exchange ideas about the pathophysiology and treatment of pain.

The institute initiated an annual honorary lecture to recognize outstanding scientific accomplishment in basic and clinical research and to honor distinguished scientists who have made important contributions in areas of research directly related to the interests of the dental institute.

1984 – NIDR inaugurated the Dentist Scientist Award Program designed to provide opportunities for dentists to develop into independent biomedical investigators in the oral health research field.

The institute completed its Long-Range Research Plan FY 1985-89 entitled *Challenges for the Eighties*. Under the direction of NIDR director Dr. Harald Løe, a coordinating committee prepared this five-year plan and summary of progress in the oral sciences and in disease prevention, diagnosis, and treatment. The document pinpoints 14 emphasis areas for NIDR's oral health research.

NIDR established three new specialized caries research centers in university environments to continue research investigations into the cause, treatment, and prevention of dental decay.

An NIDR reorganization disbanded the National Caries Program and created the Epidemiology and Oral Disease Prevention Program (EODPP). The EODPP is devoted to research on the etiology, incidence and prevalence of dental caries, periodontal diseases, and other oral diseases and disorders.

Also, a realignment of the administrative offices within the Office of the Director was completed. This realignment established the Office of Planning, Evaluation and Communications (OPEC).

An NIDR annual lecture series was named for a former institute director. Given each September at NIH, it is known as the Seymour J. Kreshover Lecture Award.

1985 – NIDR convened a meeting at NIH of over 160 deans and senior officials from almost every U. S. and Canadian dental school to explore key issues in dental research and education. The conference, first of its kind in NIDR history, was designed to strengthen the relationship between the institute and universities.

1986 – NIDR completed its first nationwide survey on the dental health of American adults – the most comprehensive survey of its kind ever done, and the first to look at the prevalence of root caries and periodontal disease in detail.

1988 – NIDR celebrated its 40th anniversary with a year-long agenda of commemorative activities.

NIDR funded four new oral biology research centers.

The institute released findings of its second National Caries Prevalence Study. Data show half of all American schoolchildren now have no tooth decay.

NIDR held its second consensus development conference on dental implants. According to the summary statement, the use of dental implants has increased four fold from 1983 to 1987.

NIDR and the Fogarty International Center launched an international oral health research study to identify oral health issues that would benefit most from international collaborative research.

The institute launched the "Research and Action Program to Improve the Oral Health of Older Americans and Other Adults at High Risk." The goal is to eliminate toothlessness and prevent further deterioration of oral health in individuals who have compromised dentition.

1990 – The institute completed the *NIDR Long-Range Research Plan for the Nineties: Broadening the Scope*, the blueprint for research in this decade. The plan establishes major initiatives geared to "special care patients" whose oral health is affected by systemic diseases or treatments and to older Americans, with the ultimate goal of eliminating toothlessness among future generations and preventing further deterioration of the oral health of individuals with compromised dentition.

1991 – NIDR hosted a symposium for dental practitioners, "Scientific Frontiers in Clinical Dentistry: An Update at the National Institutes of Health."

The institute sponsored a technology assessment conference on the effects and side effects of dental restorative materials.

The Laboratory of Developmental Biology and Anomalies was renamed the Laboratory of Developmental Biology (LDB). LDB research aims to gain a better understanding of normal human development.

1992 – The Epidemiology and Oral Disease Prevention Program reorganized to expand the scope of EODPP activities. The program now consists of four branches: Molecular Epidemiology and Disease Indicators; Disease Prevention and Health Promotion; Analytical Studies and Decision Systems; and Health Assessment. EODPP is the Federal focus for research in orofacial epidemiology and disease prevention.

A reorganization of the Extramural Program (EP) established the Program Development Branch, consisting of seven categorical programs, and an Office of Policy and Coordination. This office contains manpower development and training activities and the Program Operations Unit, which includes the Scientific Review Office, the Grants Management Office, and the Contracts Management Office. EP provides grant and contract funds for research and research training.

NIDR hosted a second meeting of the leadership from the nation's dental schools, dental professional organizations and industry to explore ways to enhance the research capacity of dental schools.

1993 – The National Oral Health Information Clearinghouse was established as a centralized resource for patients, health professionals, and the public seeking information on the oral health of special care patients.

1994 – The intramural, extramural, and epidemiology organizational components of NIDR were redefined from programs to divisions, establishing the Divisions of: Intramural Research, Extramural

Research, and Epidemiology and Oral Disease Prevention (DEODP).

The DEODP was streamlined from four to three branches: Analytical Studies and Health Assessment; Disease Prevention and Health Promotion; and Molecular Epidemiology and Disease Indicators.

1995 – NIDR sponsored "Partnerships in Communication: A Meeting of Dental Editors," which brought together for the first time at NIH more than 30 editors and executive directors of dental organizations to enhance communication among the group.

The institute met with a diverse group of representatives from pharmaceutical, biotechnology, manufacturing and other industries to develop ways to accelerate the transfer of research findings into application.

NIDR conducted more than 30 focus groups with professional organizations, NIDR staff, specialty groups, and the public toward the development of a new institute strategic plan.

1996 – The first community conference in the institute's history was held in May for employees to review the NIDR strategic planning process to date and to discuss the NIDR mission, vision, situation audit, strategic initiatives, management principles, and plans for the future.

The NIDR sponsored a technology assessment conference on the management of temporomandibular disorders.

The institute's intramural, extramural, and epidemiology organizational components were reorganized into the Division of Intramural Research and the Division of Extramural Research.

NIDR launched its World Wide Web page on the Internet, making all pertinent information available to the public and the research community.

1997 – The NIDR's first strategic plan, *Shaping the Future*, was released in July. Focusing on areas of research opportunities, research capacity, and health promotion, the document serves as a critical structure within which multiple institute initiatives are undertaken.

The institute celebrated its 50th anniversary.

A reorganization within the Office of the Director created the Office of International Health, the Office of Science Policy and Analysis, and the Office of Communications and Health Education. The Office of Planning, Evaluation and Communications was eliminated.

1998 – The institute changed its name to National Institute of Dental and Craniofacial Research to accurately reflect its research base. NIDCR became official on October 21, 1998, with the Omnibus Consolidated and Emergency Supplemental Appropriations Act, H.R. 4328.

1999 – NIDCR introduced its *Strategic Plan to Reduce Racial and Ethnic Health Disparities*. The plan is designed to support research leading to the reduction and prevention of health disparities, including those in the oral cavity, and to provide research opportunities to increase the diversity of the scientific workforce.

The Office of Information Technology was established within the Office of the Director.

2000 – The Institute hosted the first "NIDCR Patient Advocates Forum." The conference, attended by patient advocates from 15 organizations, was designed to enhance communication between patient liaison groups and NIDCR and to bring the patient perspective to Institute planning and research.

NIDCR served as lead agency for the preparation and publication of *Oral Health In America: A Report of the Surgeon General*, released on May 25th. The report, commissioned by DHHS Secretary Donna Shalala and released by Surgeon General David Satcher, is the first of its kind to be dedicated solely to oral health.

The Institute supported the first-ever national, multidisciplinary meeting on children and oral health, "Face of a Child," held June 12-13 in Washington, D.C.

2001 – The Division of Extramural Research was reorganized into three components: Division of Basic and Translational Sciences, Division of Population and Health Promotion Sciences, and Division of Extramural Activities.

NIDCR sponsored a consensus development conference on the Diagnosis and Management of Dental Caries Throughout Life.

The Institute released its strategic plan to eliminate craniofacial, oral, and dental health disparities.

NIDCR funded five new Centers for Research to Reduce Oral Health Disparities.

2003 – NIDCR released its Strategic Plan for FY 2003-2008, which addresses the myriad diseases and conditions that affect the oral cavity and craniofacial structures by outlining a course for the Institute to follow in the areas of research, research training, and communication of research results.

The Institute was a lead agency in preparing *A National Call to Action to Promote Oral Health* released April 29, 2003 by Surgeon General Richard Carmona.

2004 – The Center for Biotechnology and Innovation was created to accelerate development of the next generation of breakthrough biomedical technologies to improve oral health.

2005 – NIDCR awarded three major grants that establish regional “practice-based” research networks to investigate with greater scientific rigor everyday issues in the delivery of oral health care.

Two extramural research programs were reorganized into four centers focusing on craniofacial research, infectious diseases and immunology, clinical research, and health promotion and behavioral research.

NIDCR Legislative Chronology

June 24, 1948 – Public Law 80-755 established NIDR to conduct, support, and foster research investigations on the causes, treatment, and prevention of dental diseases and conditions.

August 1, 1958 – The President signed a DHEW appropriation bill which included provisions to finance construction of laboratory facilities to house NIDR.

October 21, 1998 – The institute's name change to the NIDCR became official when President Clinton signed the Omnibus Consolidated and Emergency Supplemental Appropriations Act, H.R. 4328.

Biographical Sketch of NIDCR Director Lawrence A. Tabak, D.D.S., Ph.D.

Dr. Lawrence A. Tabak was appointed as the seventh director of the NIDCR in September 2000. As Director, he provides leadership for a team of 450 scientists, administrators and support staff with an approximate annual budget of \$393 million.

Prior to joining NIH, Dr. Tabak was the senior associate dean for research and professor of dentistry and biochemistry & biophysics in the School of Medicine and Dentistry at the University of Rochester in New York. He served as director of several multi- and interdisciplinary Institutional programs, including the Medical Scientist Training Program, the Dentist Scientist Training Program, the Summer Program for Underrepresented Dental Students, and the Howard Hughes Medical Institute's Infrastructure Program for Schools of Medicine.

A former NIH MERIT recipient, Dr. Tabak's major research focus has been on the structure, biosynthesis, and function of mucin-glycoproteins. He continues work in this area, maintaining an active research laboratory in addition to his administrative duties.

Dr. Tabak has served actively as co-chair of the Research Teams of the Future component of the NIH Roadmap that emphasizes new ways of doing team science to catalyze additional multi- and interdisciplinary research. He is also a current member of the NIH Steering Committee and co-chairs the Information Technology Working Group of the Steering Committee.

The NIDCR director has received several honors and awards for his work, including being elected a fellow of the AAAS and a member of the Institute of Medicine of the National Academies. A native of Brooklyn, New York, Dr. Tabak received his undergraduate degree from City College of the City University of New York, his D.D.S. from Columbia University, and both a Ph.D. and certificate of proficiency in endodontics from the State University of New York at Buffalo.

NIDCR Directors

Name	In Office From	To
H. Trendley Dean	September 17, 1948	March 31, 1953
Francis A. Arnold, Jr.	April 1, 1953	February 1966
Seymour J. Kreshover	February 1966	June 30, 1975
Clair L. Gardner (Acting)	July 1, 1975	December 31, 1975
David B. Scott	January 1, 1976	December 31, 1981
John F. Goggins (Acting)	January 1, 1982	December 31, 1982
Harald Löe	January 1983	June 1, 1994
Dushanka V. Kleinman (Acting)	June 1994	June 1995
Harold C. Slavkin	July 1995	July 14, 2000
Lawrence A. Tabak	September 2000	Present

Research Programs

NIDCR is the primary sponsor of dental, oral, craniofacial research and research training. Through its five extramural centers, the institute provides funds outside its intramural laboratories and clinics in Bethesda. Funds are made available in the form of grants, cooperative agreements, and contracts, which support scientists working in institutions throughout the U.S. and in foreign countries. These scientists conduct basic, translational, patient-oriented and demonstration research to increase understanding of fundamental processes in health and disease, and to promote timely transfer and community adoption of research findings. The institute also supports research training and career development to ensure an adequate pool of research personnel.

NIDCR supports two Specialized Centers for Oral, Dental and Craniofacial Research. These centers are comprised of individuals with diverse scientific backgrounds who are applying state of the art technologies to highly integrated projects designed to provide new insights into oral and craniofacial diseases and disorders. NIDCR also funds five Centers for Research to Reduce Oral Health Disparities. The centers are focused on identifying factors contributing to oral health disparities and developing and testing strategies for their elimination. Each center also provides training and career

development opportunities for scientists in underrepresented groups and others interested in careers in oral health disparities research.

Center for Infectious Diseases and Immunology

The Center for Infectious Diseases and Immunology supports basic and translational research on the microbial and immunological aspects of oral diseases such as dental caries, periodontal diseases, oral candidiasis, and head and neck cancer. Programs also focus on research to understand the role of oral microbes in health and disease, the association of oral and systemic diseases, and the underlying mechanisms of the oral complications of HIV infection/AIDS. The center has three components: Microbiology Program, Immunology and Immunotherapy Program, and AIDS and Immunosuppression Program.

Center for Integrative Craniofacial Research

The Center for Integrative Craniofacial Research explores the physiology of teeth, bones and cartilage; the onset and progression of head and neck cancers; and the genetic and environmental bases of normal and abnormal development of oral and craniofacial structures. The center also supports research on salivary gland biology and processes involved in orofacial pain, with a focus on temporomandibular joint disorders. The center is comprised of four programs: Mineralized Tissue and Salivary Gland Physiology Program, Molecular and Cellular Neuroscience Program, Epithelial Cell Regulation and Transformation Program, and Developmental Biology and Genetics Program.

Center for Biotechnology and Innovation

The Center for Biotechnology and Innovation (CBI) seeks to develop the next generation of breakthrough biomedical technologies to improve oral health. To accelerate the technology development process, the CBI will rely on interdisciplinary research approaches, with an emphasis on basic and translational studies. The center also will establish strong working relationships with industry, while enhancing communication with other NIH Institutes and Centers, the Food and Drug Administration, and other Federal agencies. The center has three components: the Biotechnology Program, Applied and Translational Research Program, and the Technology Development and Industrial Relations Program.

Center for Clinical Research

The Center for Clinical Research supports and conducts patient-oriented and population-based research, including clinical trials, practice-based networks, epidemiology, and health disparity research in all areas of program interest to NIDCR. Providing statistical support for all Institute centers and divisions, this center also develops and supports programs to foster diversity in the scientific workforce, and clinical research activities focused on the health of vulnerable and special needs populations. The center has four components: Clinical Trials Program, Epidemiology Program, Dental Practice-Based Research Networks, and Health Disparities Research Program.

Center for Health Promotion and Behavioral Research

The Center for Health Promotion and Behavioral Research supports and conducts biobehavioral, social science, health literacy, communication and informatics research, as well as community-based activities in areas of programmatic interest to NIDCR. The center plans and coordinates health data surveys, coordinates and makes available to a wide range of users databases on oral health and related topics, and prepares reports on burden of illness and related health policy research. The center also plans and directs special projects on disease prevention and health promotion to improve the oral health of both individuals and communities. The center's four components include: Health Promotion and Community-Based Research Program, Basic and Applied Behavioral/Social Science Research Program, Health Promotion and Disease Prevention Program, and Health Data and Analysis Program.

Division of Extramural Activities

The Division of Extramural Activities provides leadership and advice in developing, implementing, and coordinating extramural programs and policies. The Division has two components: the Grants Management Branch and the Scientific Review Branch.

Grants Management Branch

The Grants Management Branch is the focal point for all business-related activities associated with the negotiation, award, and administration of grants and cooperative agreements within the NIDCR.

Scientific Review Branch

This branch coordinates the initial scientific peer review of applications for the following mechanisms of support: center research grants, program project grants, small research grants, research conference grants, institutional training grants, short-term training and fellowship grants, Physician Scientist Awards for Dentists, Dentist Scientist Awards, requests for applications issued by NIDCR, certain investigator-initiated clinical trials, cooperative agreements, and all proposals for research and development contracts. The branch also coordinates, conducts, and monitors project site visits, applicant interviews, and all other aspects of NIDCR's peer review process.

Division of Intramural Research

Scientists in the Division of Intramural Research (DIR) conduct basic laboratory and clinical research. Using the latest techniques in biomedical science, such as molecular biology, immunology, cell biology and imaging, researchers investigate the biochemistry, structure, function, and development of bone, teeth, salivary glands and connective tissues; the role of bacteria in oral disease; genetic disorders of the craniofacial region and tumors of the oral cavity; mechanisms of sensory biology and the cause and treatment of acute and chronic pain; and the development of new and improved methods to diagnose oral disease. The division has approximately 300 employees and guest researchers in 31 laboratories and a set of clinical or laboratory core facilities.

The *Gene Therapy and Therapeutics Branch* conducts research related to the diagnosis, prevention and management of salivary gland diseases. Primary efforts are directed at using gene transfer technology and are supported by basic research on virology, salivary secretion and function. Clinical and translational studies focus on Sjögren's syndrome and radiation damage, and on using salivary glands as gene transfer depots to treat systemic single protein deficiency disorders.

The *Craniofacial and Skeletal Diseases Branch* studies development and structure of mineralized tissues (bones, teeth and cartilage). Emphasis is placed on genetic and acquired disorders of the skeleton through research in bone and cartilage cell biology, adult skeletal stem cells, tissue metabolism and extracellular matrix molecules, which are major components of most tissues and critical elements in oral tissue development, function and health.

The *Oral Infection and Immunity Branch* conducts research on the causes, diagnosis, treatment and prevention of infectious and inflammatory diseases. Scientists study bacterial and viral infections at the biochemical, organism, and community levels and analyze the basic mechanisms of immune and inflammatory host responses. Research is also under way to enhance the understanding of signaling mechanisms inside the cell, which prompt host responses to pathogens, and to devise strategies for therapy.

The *Craniofacial Developmental Biology and Regeneration Branch* investigates the roles and gene regulation of the extracellular matrix, a key component of connective tissue, and other cell interaction systems in embryonic development and related processes. Research focuses on such areas as normal and abnormal embryonic development of craniofacial and other tissues, cancer

metastasis, and wound healing.

Research in the *Oral and Pharyngeal Cancer Branch* is directed toward understanding the role of growth and regulatory factors in the development of cancer. Studies focus on molecular mechanisms responsible for conversion of normal cells to cancerous cells.

The *Laboratory of Oral Sensory Biology* investigates basic mechanisms of oral sensation. Established in 2005, this new laboratory is exploring the intricacies of mammalian taste. Scientists are using a combination of molecular, genetic, and physiological approaches to study signal reception, discrimination and coding, as well as information transfer from the mouth to the brain.

The Division also supports research in several units outside of its Branches:

- The *Clinical Pharmacology and Clinical Trials Units* carry out clinical and basic research on pain mechanisms, the development of new methods of assessing pain, and evaluating new approaches to pain control. Collaborative studies, including research on pain associated with cancer and diabetes, have been initiated with other institutes.
- The *Developmental Mechanism Unit* investigates mechanisms of cell fate specification in early embryos, with current emphasis on the gene regulatory network underlying development of primitive neurons.
- The *Human Craniofacial Genetics Section* explores the expression and function of defective genes that are associated with oral health.
- The *Immunopathology Section* studies factors and signal transduction pathways in the modulation of the immune response focusing on human monocytes.

The Division also operates supporting core facilities in clinical research, gene targeting, DNA sequencing, scientific systems, and veterinary resources.

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National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892



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The NIH Almanac – Organization

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National Institute of Diabetes and Digestive and Kidney Diseases

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Until May 19, 1972, the National Institute of Arthritis and Metabolic Diseases; until June 23, 1981, the National Institute of Arthritis, Metabolism, and Digestive Diseases; and until April 8, 1986, the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases.

Mission

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) conducts and supports research on many of the most serious diseases affecting public health. The institute supports much of the clinical research on the diseases of internal medicine and related subspecialty fields as well as many basic science disciplines.

The Institute's Division of Intramural Research encompasses the broad spectrum of metabolic diseases such as diabetes, inborn errors of metabolism, endocrine disorders, mineral metabolism, digestive and liver diseases, nutrition, urology and renal disease, and hematology. Basic research studies include biochemistry, nutrition, pathology, histochemistry, chemistry, physical, chemical, and molecular biology, pharmacology and toxicology.

NIDDK extramural research is organized into four divisions: Diabetes, Endocrinology and Metabolic Diseases; Digestive Diseases and Nutrition; Kidney, Urologic and Hematologic Diseases; and Extramural Activities.

The Institute supports basic and clinical research through investigator-initiated grants, program project and center grants, and career development and training awards. The Institute also supports research and development projects and large-scale clinical trials through contracts.

Important Events in NIDDK History

August 15, 1950 – President Harry S. Truman signed the Omnibus Medical Research Act into law establishing the National Institute of Arthritis and Metabolic Diseases (NIAMD) in PHS. The new institute incorporated the laboratories of the Experimental Biology and Medicine Institute and expanded to include clinical investigation in rheumatic diseases, diabetes, and a number of metabolic, endocrine and gastrointestinal diseases.

November 15, 1950 – The National Advisory Arthritis and Metabolic Diseases Council held its first meeting and recommended approval of NIAMD's first grants.

November 22, 1950 – Surgeon General Scheele established NIAMD.

1959 – Dr. Arthur Kornberg, former chief of the institute's enzyme and metabolism section, won the Nobel Prize for synthesizing nucleic acid.

The institute initiated an intramural research program in gastroenterology and launched an

intramural research program in cystic fibrosis with the establishment of the Pediatric Metabolism Branch.

1961 – Laboratory-equipped, mobile trailer units began an epidemiological study of arthritis among the Blackfeet and Pima Indians in Montana and Arizona, respectively.

October 16, 1969 – The Nobel Prize was awarded to Dr. Marshall W. Nirenberg of the National Heart Institute who reported his celebrated partial cracking of the genetic code while an NIAMD scientist (1957-1962).

November 1970 – The institute celebrated its 20th anniversary. Secretary of Defense Melvin R. Laird addressed leaders in the department, representatives from voluntary health agencies and professional biomedical associations, as well as past and present institute National Advisory Council members.

May 19, 1972 – The institute name was changed to the National Institute of Arthritis, Metabolism, and Digestive Diseases.

October 1972 – Christian B. Anfinsen, chief of the institute's Laboratory of Chemical Biology, shared a Nobel Prize with two other American scientists for his demonstration of one of the most important simplifying concepts of molecular biology, that the three-dimensional conformation of a native protein is determined by the chemistry of its amino acid sequence. A significant part of this research cited by the award was performed while with NIH.

September 1973 – The institute's diabetes centers program was initiated with the establishment of the first Diabetes-Endocrinology Research Centers.

November 1975 – After 9 months of investigation into the epidemiology and nature of diabetes mellitus and public hearings throughout the United States, the National Commission on Diabetes delivered its report, the Long-Range Plan to Combat Diabetes, to Congress. Recommendations encompassed expansion and coordination of diabetes and related research programs; the creation of a diabetes research and training centers program; acceleration of efforts in diabetes health care, education, and control programs; and the establishment of a National Diabetes Advisory Board.

April 1976 – After a year of study and public hearings, the National Commission on Arthritis and Related Musculoskeletal Diseases issued the Arthritis Plan – its report to Congress. The report called for increased arthritis research and training programs; multipurpose arthritis centers; epidemiologic studies and data systems in arthritis; a National Arthritis Information Service and a National Arthritis Advisory Board.

October 1976 – Dr. Baruch Blumberg was awarded the Nobel Prize in Physiology or Medicine for research on the hepatitis B virus protein, the "Australia antigen," which he discovered in 1963 while at the institute. This advance has proven to be a scientific and clinical landmark in detection and control of viral hepatitis and led to the development of preventive measures against hepatitis and liver cancer.

April 19, 1977 – The director, NIH, established a trans-NIH program for diabetes, with lead responsibility in NIAMD.

September 1977 – Over \$5 million in grants was awarded to five institutions to establish Diabetes Research and Training Centers.

October 1977 – In response to the recommendation of the National Commission on Diabetes, the National Diabetes Data Group was established within the institute to collect, analyze, and disseminate data on this disorder to scientific and public health policy and planning associations.

December 1977 – Institute grantees Dr. Roger C.L. Guillemin and Dr. Andrew V. Shally shared the Nobel Prize in Physiology or Medicine with a third scientist, Dr. Rosalyn S. Yalow. Guillemin and Shally's prizes were for discoveries related to the brain's production of peptide hormones.

December 1978 – A study of cystic fibrosis focused on the need for future research activities, including increased support for clinical and basic research, expansion of specialized CF research resources, emphasis on training of scientific personnel, and coordination of public and private cystic fibrosis research activities.

January 1979 – Following 2 years of study and public hearings, the National Commission on Digestive Diseases issued its report, *The National Long-Range Plan to Combat Digestive Diseases*. Recommendations to Congress included the establishment of a National Digestive Diseases Advisory Board, an information clearinghouse, and increased emphasis on educational programs in digestive diseases in medical schools.

December 1979 – A task force completed its study and submitted the report, *An Evaluation of Research Needs in Endocrinology and Metabolic Diseases*.

September 1980 – Dr. Joseph E. Rall, director of NIAMDD intramural research, became the first person at NIH to be named to the distinguished executive rank in the Senior Executive Service. President Carter presented the award in ceremonies at the White House on September 9.

October 15, 1980 – NIAMDD celebrated its 30th anniversary with a symposium, "DNA, the Cell Nucleus, and Genetic Disease," and dinner at the National Naval Medical Center. Dr. Donald W. Seldin, chairman of the department of internal medicine, University of Texas Southwestern Medical School, Dallas, was guest speaker.

June 23, 1981 – The institute was renamed National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases.

April 1982 – HHS Secretary Richard S. Schweiker elevated NIADDK's programs to division status, creating five extramural divisions and the Division of Intramural Research.

November 1982 – Dr. Elizabeth Neufeld received a Lasker Foundation Award. She is cited, along with Dr. Roscoe E. Brady of NINCDS, for "significant and unique contributions to the fundamental understanding and diagnosis of a group of inherited diseases called mucopolysaccharide storage disorders (MPS)."

November 1984 – Grants totaling more than \$4 million were awarded to six institutions to establish Silvio O. Conte Digestive Disease Research Centers. The research centers investigate the underlying causes, diagnoses, treatments, and prevention of digestive diseases.

April 8, 1986 – The institute's Division of Arthritis, Musculoskeletal and Skin Diseases became the core of the new National Institute of Arthritis and Musculoskeletal and Skin Diseases. The NIADDK was renamed the National Institute of Diabetes and Digestive and Kidney Diseases.

June 3, 1986 – The National Kidney and Urologic Diseases Advisory Board was established to formulate the long-range plan to combat kidney and urologic diseases.

August 1, 1987 – Six institutions were funded to establish the George M. O'Brien Kidney and Urological Research Centers.

December 25, 1987 – In response to congressional language on the FY 1988 appropriation for the NIDDK, the institute established a program of cystic fibrosis research centers.

September 16, 1990 – NIDDK celebrated its 40th anniversary. Dr. Daniel E. Koshland, Jr., editor of *Science*, was guest speaker.

June, 1991 – The NIDDK Advisory Council established the National Task Force on the Prevention and Treatment of Obesity to synthesize current science on the prevention and treatment of obesity and to develop statements about topics of clinical importance that are based on critical analyses of the literature.

September 30, 1992 – Three Obesity/Nutrition Research Centers and an animal models core to breed genetically obese rats for obesity and diabetes research were established.

October 12, 1992 – Drs. Edwin G. Krebs and Edmond H. Fischer were awarded the Nobel Prize in Physiology or Medicine for their work on "reversible protein phosphorylation." They have received grant support from NIDDK since 1955 and 1956, respectively.

October 30, 1992 – In response to congressional language on the institute's FY 1993 appropriation, the NIDDK initiated a program to establish gene therapy research centers with emphasis on cystic fibrosis.

November 1, 1993 – The functions of the NIH Division of Nutrition Research Coordination, including those of the NIH Nutrition Coordinating Committee, were transferred to NIDDK.

October 10, 1994 – Dr. Martin Rodbell and Dr. Alfred G. Gilman received the Nobel Prize in Physiology or Medicine for discovering G-proteins, a key component in the signaling system that regulates cellular activity. Dr. Rodbell discovered the signal transmission function of GTP while a researcher in the National Institute of Arthritis and Metabolic Diseases, now NIDDK.

June 22, 1997 – Led by NIDDK, the NIH and the CDC announce the National Diabetes Education Program (NDEP) at the American Diabetes Association annual meeting in Boston. The NDEP's goals are to reduce the rising prevalence of diabetes, the morbidity and mortality of the disease and its complications.

June, 2000 – In an effort to reduce the disproportionate burden of many diseases in minority populations, NIDDK initiates an Office of Minority Health Research Coordination.

November 16, 2000 – NIDDK celebrates its 50th Anniversary. Professional societies in eight U.S. locations and Canada sponsored scientific symposia and hosted an NIDDK exhibit. "A New Century of Science. A New Era of Hope" is published to highlight research supported and conducted by NIDDK and concludes the year with a joint scientific symposium at the Society for Cell Biology's 40th Anniversary meeting in December.

June 13, 2003 – To avoid confusion with the newly-established NIH Obesity Research Task Force, NIDDK changed the name of its National Task Force on Prevention and Treatment of Obesity, established in 1991, to the Clinical Obesity Research Panel (CORP).

June 2003 – The *Report on Progress and Opportunities: Special Statutory Funding for Type 1 Diabetes Research* describes recent achievements and major projects now underway that address unmet research needs in type 1 diabetes. From fiscal year 1998 through fiscal year 2008, the special funding program provides a total of \$1.14 billion in research funds to supplement other funds for type 1 diabetes research provided through the regular appropriations process.

NIDDK Legislative Chronology

December 11, 1947 – Under section 202 of P.L. 78-410 the Experimental Biology and Medicine Institute was established.

August 15, 1950 – Public Law 81-692, the Omnibus Medical Research Act, authorized establishment of NIAMDD to "... conduct researches relating to the cause, prevention, and methods of diagnosis and treatment of arthritis and rheumatism and other metabolic diseases, to assist and foster such researches and other activities by public and private agencies, and promote the coordination of all such researches, and to provide training in matters relating to such diseases...." Section 431 also authorized the Surgeon General to establish a national advisory council.

May 19, 1972 – President Nixon signed P.L. 92-305 to bring renewed emphasis to research in digestive diseases by changing the name of the institute to NIAMDD and by designating a digestive diseases committee within the institute's National Advisory Council.

August 29, 1972 – The National Cooley's Anemia Control Act (PL 92-414) authorized research in the diagnosis, treatment and prevention of this debilitating inherited disease, also known as thalassemia, occurring largely in populations of Mediterranean and Southeastern Asian origin.

July 23, 1974 – Public Law 93-354, the National Diabetes Mellitus Research and Education Act, was signed. The National Commission on Diabetes, called for by this act, was chartered on September 17, 1974, members were appointed by the HEW secretary. The act called for centers for research and training in diabetes and establishment of an intergovernmental diabetes coordinating committee, including NIAMDD and six other NIH institutes.

January 1975 – The National Arthritis Act of 1974 (P.L. 93-640) was signed into law to further research, education and training in the field of the connective tissue diseases. The HEW secretary appointed the mandated National Commission on Arthritis and Related Musculoskeletal Diseases, June 2. The act required centers for research and training in arthritis and rheumatic diseases and the establishment of a data bank, as well as an overall plan to investigate the epidemiology, etiology, control and prevention of these disorders.

October 1976 – P.L. 94-562, the Arthritis, Diabetes, and Digestive Diseases Amendments of 1976, established the National Diabetes Advisory Board charged with advising Congress and the HEW secretary on implementation of the "Long-Range Plan to Combat Diabetes" developed by the National Commission on Diabetes. The law also established the National Commission on Digestive Diseases to deal with many problems, including investigation into the incidence, duration, mortality rates, and social and economic impact of digestive diseases.

The National Arthritis Advisory Board, established by the same law, reviews and evaluates the implementation of the *Arthritis Plan*, formulated by the Arthritis Act of 1974. The board advises Congress, the HHS secretary, and heads of Federal agencies with respect to the plan and other Federal programs relating to arthritis.

December 1980 – Title II of the Health Programs Extension Act of 1980, P.L. 96-538, changed the institute's name to the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. The act also established the National Digestive Diseases Advisory Board. The law authorized the National Diabetes Information Clearinghouse, the Diabetes Data Group, and the National Digestive Diseases Information and Education Clearinghouse. In addition, it reauthorized advisory boards for arthritis and diabetes research.

November 20, 1985 – The Health Research Extension Act of 1985, P.L. 99-158, changed the institute name to the National Institute of Diabetes and Digestive and Kidney Diseases. The act also established the National Kidney and Urologic Diseases Advisory Board. The law gave parallel special authorities to all institute operating divisions, including authorization of the National Kidney and Urologic Diseases Information Clearinghouse; National Kidney, Urologic, and Hematologic Diseases Coordinating Committee; National Kidney and Urologic Diseases Data System; National Digestive Diseases Data System; kidney and urologic diseases research centers; and digestive diseases research centers.

June 10, 1993 – The NIH Revitalization Act of 1993, P.L. 103-43, established NIDDK as the lead institute in nutritional disorders and obesity, including the formation of a research and training centers program on nutritional disorders and obesity.

It also provided for the directors of NIAMS, NIA, NIDR, and the NIDDK to expand and intensify programs with respect to research and related activities concerning osteoporosis, Paget's disease, and related bone disorders.

July 25, 1997 – A House report accompanying H.R. 2264 and Senate report with S. 1061, FY 1998 appropriations bills for Labor/HHS/Education, urged the NIH and NIDDK to establish a diabetes research working group to develop a comprehensive plan for NIH-funded diabetes research that would recommend future initiatives and directions. Dr. C. Ronald Kahn, diabetes research working group chairman, presented "Conquering Diabetes, A Strategic Plan for the 21st Century" to the Congress on March 23, 1999.

August 1997 – The Balanced Budget Act of 1997 (P.L. 105-33) establishes a **Special Statutory Funding Program for Type 1 Diabetes Research**. The program provides \$30 million per year for fiscal years 1998 through 2002. This funding program augments regularly appropriated funds that the Department of Health and Human Services receives for diabetes research through the Labor-HHS-Education Appropriations Committees. The NIDDK, through authority granted by the Secretary of Health and Human Services, has a leadership role in planning, implementing, and evaluating the allocation of these funds.

October 17, 2000 – The "Children's Health Act of 2000" (P.L. 106-310). This law amended the Public Health Service Act with respect to children's health. Title IV, entitled "Reducing Burden of Diabetes Among Children and Youth," section 402, specifies that the National Institutes of Health conduct long-term epidemiology studies, support regional clinical research centers, and provide a national prevention effort relative to type 1 diabetes.

December 2000 – The Fiscal Year 2001 Consolidated Appropriations Act (P.L. 106-554) extends and augments the Special Statutory Funding Program for Type 1 Diabetes Research in amount and time, allocating an additional \$70 million for Fiscal Year 2001 (for a total of \$100 million for Fiscal Year 2001), an additional \$70 million for Fiscal Year 2002 (for a total of \$100 million for Fiscal Year 2002), and \$100 million for Fiscal Year 2003.

October 2002 – The NIH issued a detailed progress report, "Conquering Diabetes: Highlights of Program Efforts, Research Advances, and Opportunities," on NIH-funded diabetes research. The report describes research achievements and initiatives since 1999, when the Diabetes Research Working Group (DRWG), published its 5-year plan. The Congressionally established Group made scientific recommendations in five areas of extraordinary research opportunity: the genetics of diabetes, autoimmunity and the beta cell, cell signaling and cell regulation, obesity, and clinical research and clinical trials. The Group also made recommendations regarding the microvascular and macrovascular complications of diabetes, the special populations most affected by diabetes, and resource and infrastructure needs to further diabetes research.

December 17, 2002 – President Bush signed into law H.R. 5738, a bill that will increase and extend funding for the Special Diabetes Program (formerly P.L. 105-33). The bill provides \$750 million for type 1 diabetes research over a period of five years (FY 04-FY 08).

December 2002 – The Public Health Service Act Amendment for Diabetes (P.L. 107-360) extends and augments the Special Statutory Funding Program for Type 1 Diabetes Research in time and amount, allocating \$150 million per year for fiscal years 2004 through 2008.

December 8, 2003 – The "Medicare Prescription Drug, Improvement, and Modernization Act of 2003" (P.L. 108-173). Title VII, Subtitle D, Section 733 of this law, entitled "Payment for pancreatic islet cell investigational transplants for Medicare beneficiaries in clinical trials," specifies that the

Secretary, acting through the NIDDK, conduct a pancreatic islet transplantation clinical trial that includes Medicare beneficiaries, and that Medicare cover the routine costs, the transplantation, and appropriate related items and services for the Medicare beneficiaries enrolled in the trial.

October 25, 2004 – The “Pancreatic Islet Cell Transplantation Act of 2004” (P.L. 108-362). This law amended the Public Health Service Act for the purposes of increasing the supply of pancreatic islet cells for research, and providing for better coordination of Federal efforts and information on islet cell transplantation. A provision of this law specifies that the annual reports prepared by the Diabetes Mellitus Interagency Coordinating Committee, which is led by the NIDDK, include an assessment of the Federal activities and programs related to pancreatic islet transplantation.

September 2004 – The reports accompanying the FY 2005 Senate and House Labor, HHS, Education appropriations bills (reports 108-345 and 108-636, respectively) called on the NIH and DHHS to establish a national commission on digestive diseases to review the burden of digestive diseases in the United States and develop a long-range research plan to address this burden. The NIH Director subsequently established the National Commission on Digestive Diseases, under NIDDK leadership, in August 2005. Commission activities are expected to include public meetings, review of a report being prepared by the Digestive Diseases Interagency Coordinating Committee on the burden of digestive diseases in the United States, and the development of a Long-Range Plan for Digestive Diseases Research.

Biographical Sketch of NIDDK Director Allen M. Spiegel, M.D.

Appointed director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) in November 1999, Dr. Allen M. Spiegel oversees a staff of 625 full-time employees and a \$1.7 billion budget in Fiscal Year 2005. The Institute conducts research on some of the most serious and chronic diseases affecting the Nation's health at its intramural facilities in Bethesda, Maryland, and Phoenix, Arizona, and it supports the work of about 3,300 investigators in medical centers, universities, and laboratories throughout the United States. "Throughout my career, I've tried to forge strong links between fundamental science and clinical medicine," Spiegel says. "As NIDDK director, I'm committed to continuing our strong support for basic science because it offers the greatest promise for acquiring new knowledge of human disease. At the same time, we vigorously support efforts to apply this new knowledge so that it rapidly reaches patients and measurably improves their lives."

Before becoming director, Spiegel served as NIDDK's scientific director for 9 years, leading one of the largest and most productive intramural research programs at the National Institutes of Health (NIH). In this post, he oversaw 21 laboratories and branches that study diabetes, metabolic disease, sickle cell disease and other red blood cell disorders, endocrinology, hepatitis B and C, genetics, biochemistry and molecular, cellular, developmental, and structural biology. He created a new branch to study the pathogenesis of type 1 diabetes and to test new immunomodulatory treatments aimed at reducing the need for global immunosuppression in patients who undergo kidney and pancreatic islet transplantation.

Spiegel is an internationally recognized researcher and endocrinologist whose work on signal transduction helped to clarify the genetic basis of several endocrine diseases. His research showed that defects in G proteins, the intermediaries between hormone receptors and effectors, could cause inherited disease. Spiegel and colleagues at NIH have identified mutations in G proteins that result in disrupted cell signaling and cause disorders such as pseudohypoparathyroidism type Ia and McCune-Albright syndrome. Spiegel and colleagues also found mutations in G protein-coupled receptors that lead to either hormone resistance in diseases such as nephrogenic diabetes insipidus or excessive hormonal production in diseases such as familial male precocious puberty. His ongoing studies on a G protein-coupled calcium-sensing receptor may help researchers develop treatment for hyperparathyroidism and other disorders involving this receptor.

Spiegel and a team of researchers from NIDDK and the National Human Genome Research Institute (NHGRI) also cloned the multiple endocrine neoplasia type 1 (MEN 1) tumor suppressor gene. A

mutated form of the MEN 1 gene causes this inherited tumor predisposition syndrome, as well as sporadic, noninherited forms of endocrine tumor. As chief of the Molecular Pathophysiology Section, Spiegel continues to collaborate with the NIDDK and NHGRI team, which is studying the structure and function of the MEN 1 gene and its encoded protein, menin.

Spiegel earned his bachelor's degree, summa cum laude, from Columbia University in 1967, and his medical degree, cum laude, from Harvard Medical School in 1971. Spiegel completed an internship and residency in internal medicine at Massachusetts General Hospital in Boston in 1973, and then came to NIDDK's Endocrinology Research Training Program under the mentorship of the late Gerald Aurbach, M.D. He became a senior investigator in the Metabolic Diseases Branch, in 1985 was promoted to chief of the Molecular Pathophysiology Section, and in 1988 to chief of the Metabolic Diseases Branch.

The author of over 350 scientific papers and two books, Spiegel has received many awards recognizing his accomplishments, including the Jacobaeus Prize of the Novo Nordisk Insulin Foundation in 1990, the 1996 Komrower Memorial Lecture Award from the Society for the Study of Inborn Errors in Metabolism, and the 1998 Edwin B. Astwood Lecture Award from the Endocrine Society. He has been elected to membership in the American Society for Clinical Investigation, the Association of American Physicians, and the Institute of Medicine of the National Academies.

NIDDK Directors

Name	In Office From	To
William Henry Sebrell, Jr.	August 15, 1950	October 1, 1950
Russell M. Wilder	March 6, 1951	June 30, 1953
Floyd S. Daft	October 1, 1953	May 3, 1962
G. Donald Whedon	November 23, 1962	September 30, 1981
Lester B. Salans	June 17, 1982	June 30, 1984
Mortimer B. Lipsett	January 7, 1985	September 4, 1986
Phillip Gorden	September 5, 1986	November 14, 1999
Allen M. Spiegel	November 15, 1999	Present

Research Programs

Division of Intramural Research

The Division of Intramural Research conducts research and training within the Institute's laboratories and clinical facilities in Bethesda, Maryland., and at the Phoenix Epidemiology and Clinical Research Branch in Arizona.

The Division has ten Branches and ten Laboratories that cover a wide range of research areas. In addition, there is a section on veterinary sciences and an Administrative Management Branch.

Eight Branches engage in basic and clinical research on diabetes, bone metabolism, endocrinology, obesity, hematology, digestive diseases, kidney diseases and genetics. The Phoenix Branch develops and applies epidemiologic and genetic methods to the study of diabetes and obesity. The tenth branch addresses mathematical modeling of biological problems.

The Laboratories are engaged in fundamental research related to the institute's mission (e.g., molecular biology, structural biology, chemistry, cell biology, pharmacology, chemical physics, biochemistry, neuroscience, and developmental biology). The Laboratory Animal Science section provides research animal support and collaboration for institute research programs.

Office of Obesity Research

The NIDDK Office of Obesity Research (OOR) is responsible for coordination of obesity-related research within NIDDK, and carries out its functions through the NIDDK Obesity Research Working Group. The OOR is located organizationally under the auspices of the Office of the Director, NIDDK, and its co-directors represent the two divisions with primary responsibility for obesity-related extramural research, the Division of Digestive Diseases and Nutrition (DDN) and the Division of Diabetes, Endocrinology, and Metabolic Diseases (DEM). The Obesity Research Working Group consists of representatives of DDN, DEM, the Division of Kidney, Urologic, and Hematologic Diseases (KUH), the NIDDK Review Branch, the Office of Scientific Program and Policy Analysis (OSPAA), and the Division of Nutrition Research Coordination (DNRC). The responsibilities of the NIDDK Obesity Research Working Group are: 1) to provide a forum for sharing and coordination of trans-NIDDK and trans-NIH obesity research activities; 2) to assist the Director, NIDDK in identifying research opportunities, initiatives, and advances; 3) to identify and plan appropriate workshops and conferences; and 4) to assist in the preparation of obesity-related reports and inquiries.

Division of Diabetes, Endocrinology and Metabolic Diseases

The DEMD supports research and research training related to diabetes mellitus, endocrinology, and metabolic diseases including cystic fibrosis. In addition, DEMD leads the administration of the Trans-NIH Diabetes Program and coordinates federally supported diabetes-related activities.

Diabetes Research Programs

The *Adipocyte Biology Research Program* encompasses research that addresses the development and physiology of the adipocyte cell. Specific areas of support include: 1) studies on the properties of transcription factors that regulate adipocyte differentiation; 2) research on the consequences of insulin action on adipocyte physiology; and 3) use of animal and tissue culture models to understand adipocyte biology.

The *Autoimmunity/Viral Etiology of Type 1 Diabetes Research Program* emphasizes support of investigator-initiated basic and clinical research relating to autoimmune endocrine diseases, including type 1 diabetes and autoimmune thyroid disease (AITD). Applications that address the etiology and pathogenesis of type 1 diabetes, immunology, and viral etiology of diabetes are included. Studies utilizing animal models to further our understanding of type 1 diabetes are of continuing interest to this program. Studies, which emphasize autoimmune thyroid disease, including Graves' disease, Hashimoto's thyroiditis, and their complications, are included. Humanized animal models of AITD are also included.

The *Behavioral/Prevention Research Program* encompasses individual, family, and community-based strategies aimed at prevention of diabetes and its complications through lifestyle modifications, education and other behavioral interventions. Particular emphasis is placed on development of culturally sensitive, lifestyle interventions to prevent or treat diabetes in diverse high-risk populations including African Americans, Hispanic Americans, and Native Americans. Specific areas of research include: 1) the link between behavior and physical health as it relates to diabetes and complications; 2) approaches to improving health-related behaviors and to enhancing diabetes self-management; and 3) other aspects of diabetes care.

The *Beta Cell Therapy Research Program* focuses on research to develop alternative cell or tissue sources, as well as an understanding of the basic mechanisms that support regeneration or neogenesis of pancreatic islets. This program supports research in the following areas: 1) Developing methods to expand pancreatic islets or beta cells for transplantation. 2) Optimizing growth conditions for islet cell proliferation and differentiation. 3) Deriving pancreatic islets from stem/precursor cells. 4) Assessing alternative cell or tissue sources by transplantation. 5) Animal models of islet regeneration and neogenesis.

The *Clinical Research in Type 2 Diabetes Program* will focus on patient-oriented research (i.e.,

clinical studies and small clinical trials) related to: pharmacologic interventions and/or lifestyle interventions to prevent or treat type 2 diabetes, including studies relevant to new drug development; development of surrogate markers for use in clinical trials for the prevention or treatment of type 2 diabetes; cellular therapies for the treatment of type 2 diabetes; improving the care of patients with type 2 diabetes.

The *Complications of Diabetes Research Program* encompasses basic and clinical research related to acute (e.g., ketoacidosis and hyperosmolar coma) and chronic complications of type 1 and type 2 diabetes. Chronic complications include the vascular complications of diabetes and the effects of diabetes on any organ system. Clinical studies supported under this program include strategies to prevent or treat the complications of diabetes. Supported basic research examines the molecular and cellular mechanisms by which hyperglycemia mediates its adverse effects and the interrelationships among the mechanisms potentially involved in the pathogenesis of complications, including: increased polyol pathway flux; alterations of intracellular redox state; oxidative stress; glycation of structural and functional proteins; altered expression of growth factors; enhanced activity of PKC; impaired synthesis of nitric oxide and other vasoactive substances; and altered metabolism of fatty acids.

The *Developmental Biology Research Program* supports research related to developmental genetic screens for identifying mutations that effect the formation of tissue such as bone, adipose, endocrine pancreas, or pituitary. Specific areas of support also include: signals, signaling pathway components and transcriptional factors that regulate pattern formation in the embryo, or control the fate, specifications, proliferation and differentiation of cells in the formation of tissues and organs.

The *Diabetes Centers Program* administers two types of center awards, the Diabetes Endocrinology Research Centers (DERC) and the Diabetes Research and Training Centers (DRTC). An existing base of high quality diabetes-related research is a primary requirement for establishment of either type of center. While not directly funding major research projects, both types of center grants provide core resources to integrate, coordinate and foster the interdisciplinary cooperation of a group of established investigators conducting research in diabetes and related areas of endocrinology and metabolism. The two types of centers differ in that the DERC focuses entirely on biomedical research while the DRTC has an added component in training and translation.

The *Diabetes Mellitus Interagency Coordinating Committee (DMICC)*, established in 1974 and chaired by the Director, DDEMD, includes representatives from all Federal departments and agencies whose programs involve health functions and responsibilities relevant to diabetes mellitus and its complications. Functions of the DMICC are 1) coordination of the research activities of the NIH and those activities of other Federal programs that are related to diabetes mellitus and its complications; 2) ensuring the adequacy and soundness of these activities; and 3) providing a forum for communication and exchange of information necessary to maintain coordination of these activities.

The *Endocrine Pancreas Research Program* includes projects to elucidate the basic biology of the endocrine cells of the pancreas, which include alpha, beta, delta, etc., cells within the islet. These include insulin or other hormone synthesis and secretion, coupling of nutrient sensing to insulin secretion, cell interactions, role of incretins, cytokines, other hormones, and innervation, studies of apoptosis and cell turnover in the adult organ, metabolism, basic signal transduction and regulation of gene transcription, especially as these areas relate to beta cell and islet function. This program also contains studies in cell culture to bioengineer glucose-responsive hormone secreting cells or islets for eventual treatment of diabetes.

The *Genetics of Type 1 Diabetes Research Program* seeks to identify the genes that predispose to the development of type 1 diabetes and studies to determine their mechanism. Specific areas of support include: 1) Studies of animal models of type 1 diabetes such as the NOD mouse and the BB rat to identify genes responsible for the development of type 1 diabetes. 2) Studies of the HLA region that contains the major genetic determinant for type 1 diabetes to understand its contribution to the development of diabetes. 3) Studies of immune regulatory regions that may contribute to both type 1

diabetes as well as other autoimmune disorders. 4) Development of genetic resources and patient samples for the studies on type 1 diabetes. 5) Creation of animal models for therapeutic trials.

The *Genetics of Type 2 Diabetes Research Program* seeks to identify genes that contribute to the development of type 2 diabetes mellitus. Specific areas of support include: 1) Studies using animal models to identify diabetes genes. 2) Studies using quantitative statistical methods to identify diabetes genes in human populations. 3) Development of genetic resources, patient samples and methods for studying genetic linkage for diabetes.

The *Glucose Sensors Research Program* will contain projects aimed at developing or implementing glucose sensors that can determine glucose concentration in the plasma, interstitial fluid or other appropriate space in diabetic patients continuously or in repeated samples. This program also includes development of the necessary components of glucose sensors (such as biocompatible materials or fluorescent glucose ligands, new sampling systems, etc.), software, mathematical algorithms and circuitry designed for calibration or insulin pump control, and devices that combine these sensors with insulin delivery systems in a 'closed-loop' artificial pancreas.

The *Glucose Transport Research Program* encompasses all aspects of glucose transport in health and disease, especially as relating to glucose homeostasis in diabetes and obesity. Specific areas of support include: 1) kinetics and regulation of glucose uptake in muscle, liver, heart, gut, pancreas, kidney, etc.; 2) regulation and mechanism of glucose transporter (GLUT) storage, translocation to the membrane, and gene expression by insulin and other hormones, glucose, diet, exercise, and metabolic state (fasting, obesity); 3) structure of glucose transporter; and 4) kinetic and structural studies of the transport proteins and/or membrane channels of other nutrients, such as amino acids, ions and metals.

The *Hypoglycemia in Diabetes Research Program* encompasses clinical and basic studies on the pathogenesis, prevention, treatment and sequelae (including hypoglycemia unawareness) of hypoglycemia in both type 1 and type 2 diabetes. Specific areas of research include studies to: identify the neuronal and hormonal systems involved in recognition and response to hypoglycemia; examine the interplay of counterregulatory endocrine responses; and ascertain the regulatory mechanisms for glucose homeostasis and the cells involved in this regulation.

The *Insulin Receptor/Structure/Function/Action Research Program* encompasses studies of the structure, function and action of the insulin receptor. Specific areas of support include: 1) molecular analysis of ligand binding to receptor; 2) activation of the tyrosine kinase; 3) subsequent insulin receptor function in signal transduction by serving as a platform for the attachment of downstream signaling molecules involved in insulin action; and 4) the Insulin Receptor Signaling proteins (IRS)-1,2,3,4, and other proteins containing Src Homology Domains (e.g., SH2).

The *Islet Transplantation Research Program* encompasses studies of therapeutic or preclinical approaches to treat diabetes. Specific areas include: (1) Transplantation of pancreas, pancreatic endocrine cells (islets or beta cells), beta cells in culture or other insulin producing cells in humans or animal models (including procedures to enhance tolerance, encapsulate/immunoisolate islets or other means to improve transplant survival). (2) Gene therapy or other approaches to manipulate islets to improve viability, durability or other aspects of transplantation.

The *Molecular and Functional Imaging Program* is comprised of projects that employ novel molecular and functional imaging techniques to visualize various aspects of diabetes and obesity, endocrinology, metabolism and metabolic diseases. The emphasis will be on *in vivo* techniques (PET, MRI, Ultrasound, CT, optical tomography, etc.) with applications serving to tag tissues and cells of interest; study biological processes *in vivo*; diagnose disease; or monitor progress during therapy. These will be studies either to monitor physiological or metabolic processes, rate of metabolism, blood flow, sites of hormone action, etc., using imaging and spectroscopic techniques or to identify cell types using molecular imaging probes. Another application might be the technology to develop a probe to identify *in vivo* the sites within the hypothalamus that control satiety.

The *Mouse Metabolic Phenotyping Program* contains a consortium of centers with the purpose of phenotyping mouse models of diabetes and its complications, obesity, or other chronic metabolic diseases. It will include the development of new tests for phenotyping mice, adaptation or miniaturization of existing tests, as well as the performance of these tests to more fully characterize new or existing models of disease. Emphasis is placed on non-invasive or minimally invasive technologies that can be used for longitudinal studies, but this program also includes high-throughput metabolic screens. Examples include glucose and insulin clamps, miniaturized assays for hormones, cytokines, nutrients or intermediary metabolites, kinetic measures of metabolic processes, immunological parameter, measurements of energy balance, body composition and activity, measures for metabolic, behavioral and physiologic abnormalities during disease progression.

The *National Diabetes Data Group (NDDG)* serves as the major Federal focus for the collection, analysis, and dissemination of data on diabetes and its complications. Drawing on the expertise of the research, medical, and lay communities, the NDDG initiates efforts to: 1) define the data needed to address the scientific and public health issues in diabetes; 2) foster and coordinate the collection of these data from multiple sources; 3) identify important data sources on diabetes, and analyze and promulgate the results of these analyses to the scientific and lay public; 4) promote the timely availability of reliable data to scientific, medical, and public organizations and individuals; 5) modify data reporting systems to identify and categorize more appropriately the medical and socioeconomic impact of diabetes; 6) promote the standardization of data collection and terminology in clinical and epidemiologic research; and 7) stimulate development of new investigator-initiated research programs in diabetes epidemiology.

The *National Diabetes Education Program (NDEP)*, co-sponsored by the NIDDK and the Centers for Disease Control and Prevention (CDC), is focused on improving the treatment and outcomes for people with diabetes, promoting early diagnosis, and ultimately preventing the onset of diabetes. The goal of the program is to reduce the morbidity and mortality associated with diabetes through public awareness and education activities targeted to the general public, especially those with at risk for type 2 diabetes, people with diabetes and their families, health care providers, and policy makers and payers. These activities are designed to 1) increase public awareness that diabetes is a serious, common, costly, and controllable disease that has recognizable symptoms and risk factors; 2) encourage people with diabetes, their families, and their social support systems to take diabetes seriously and to improve practice of self-management behaviors; 3) reduce disparities in health care in racial and ethnic populations disproportionately affected by diabetes and 4) alert health care providers to the seriousness of diabetes, effective strategies for its control, and the importance of a team care approach to helping patients manage the disease. Toward these ends, the NDEP is developing partnerships with organizations concerned about diabetes and the health care of its constituents.

The *Prevention of Type 1 Diabetes Research Program* includes studies on drug development, and cellular therapy that are being proposed to prevent type 1 diabetes. Areas of particular interest are: 1) Studies on drug development for type 1 diabetes treatment or prevention. 2) Studies including the creation of animal models for therapy trials or humans to maintain normal blood glucose levels. 3) Tolerance induction for prevention of type 1 diabetes. 4) Immune intervention 5) "Humanized" mouse model (development of transgenic NOD with human HLA molecules on the T cells) for type 1 diabetes 6) Development of therapies for prevention of Impaired Glucose Tolerance (IGT) or interventions to prevent conversion of IGT to type 1 diabetes 7) Drugs designed to enhance peripheral glucose metabolism or reduce hepatic glucose production of type 1 diabetics 8) Therapies designed to increase insulin sensitivity of type 1 diabetics.

The *Regulation of Energy Balance and Body Composition Research Program* encompasses research on regulation of body composition by the hypothalamus and circulating factors. Specific areas of support include: 1) endocrinology of body composition including interactions between nutrition, exercise, and anabolic hormones; 2) neuropeptides and their receptors involved in regulatory pathways controlling feeding behavior, satiety, and energy expenditure; 3) interactions between hypothalamic-pituitary-adrenal axis and peripheral metabolic signals (for example, insulin), leptin, glucocorticoids); 4) hormones and cytokines involved in wasting syndromes (cancer, AIDS);

5) endocrine regulation of energy balance via uncoupling proteins; and 6) hypothalamic integration of peripheral endocrine and metabolic signals.

The *Type 1 Diabetes Clinical Trials Program* supports large, multi-center clinical trials conducted under cooperative agreements or contracts. One primary prevention trial has concluded. The [Diabetes Prevention Trial Type 1 \(DPT-1\) \[http://www.niddk.nih.gov/patient/dpt_1/dpt_1.htm\]](http://www.niddk.nih.gov/patient/dpt_1/dpt_1.htm) was aimed at determining whether it was possible to prevent or delay the onset of type 1 diabetes in individuals determined to be at immunologic, genetic, and/or metabolic risk. It also supported future clinical trials of the Type 1 Diabetes TrialNet which will conduct intervention studies to prevent or slow the progress of type 1 diabetes, and natural history and genetics studies in populations screened for or enrolled in these studies. The program also supports the Epidemiology of Diabetes Interventions and Complications (EDIC) study, an epidemiologic follow-up study of the subjects previously enrolled in the [Diabetes Control and Complications Trial \(DCCT\)](#)

The *Type 2 Diabetes Clinical Trials Program* supports large, multi-center clinical trials conducted under cooperative agreements or contracts. One primary prevention trial is underway. The Diabetes Prevention Program (DPP) is focused on testing lifestyle and pharmacological intervention strategies in individuals at genetic and metabolic risk for developing type 2 diabetes to prevent or delay the onset of this disease.

The *Type 2 Diabetes in the Pediatric Population Research Program* encompasses research on the pathophysiology, prevention, and treatment of type 2 diabetes in children. Specific areas of support include studies: 1) To describe the epidemiology (incidence, prevalence, risk factors) of type 2 diabetes and its complications in children; 2) To develop diagnostic criteria to distinguish type 1 and type 2 diabetes in children; 3) To define the metabolic abnormalities (and the natural history of such abnormalities) in children with type 2 diabetes; 4) To develop practical, effective strategies for the prevention and/or treatment of type 2 diabetes in children; 5) To understand the basis for race/ethnic disparities in the incidence of type 2 diabetes in the pediatric population.

Endocrinology Research Programs

The *Bone and Mineral Metabolism Research Program* encompasses basic and clinical research on the hormonal regulation of bone and mineral metabolism in health and disease. Specific areas of support include: 1) endocrine aspects of disorders affecting bone, including osteoporosis, Paget's disease, renal osteodystrophy, and hypercalcemia of malignancy; 2) pathogenesis, diagnosis and therapy of parathyroid disorders, including primary or secondary hyperparathyroidism; 3) effects of parathyroid hormone (PTH), parathyroid hormone related protein (PTHrP), calcitonin, vitamin D, estrogen, retinoic acid, growth factors (e.g., IGF-I, etc.), glucocorticoids, thyroid hormone and other systemic or local-acting hormones and their receptors on bone metabolism; 4) bone active cytokines (e.g., TGF- β , BMPs, CSF-1); 5) studies of calcium homeostasis, absorption, metabolism, and excretion, including the calcium activated receptor (CaR); 6) basic and clinical studies of vitamin D; and 7) bone morphogenesis, including the roles of developmental factors in bone formation (e.g., hedgehogs, Hox genes).

The *G-Protein Coupled Receptors Program* encompasses studies on the G-protein coupled receptor superfamily. Specific areas of support include: 1) cell surface, or seven transmembrane domain (7-TM), receptors coupled to GTP-binding ("G")- proteins for signal transduction (e.g., beta-adrenergic receptor); 2) receptor structure; 3) receptor down-regulation (homologous desensitization); 4) role(s) of mutated receptors in disease; and 5) coupling of signaling through the receptor to other membrane-bound effectors and or regulators, such as adenylyl cyclase, ion channels, protein phosphatases or kinases, and other receptors. Signal transduction through GPCRs also includes mechanisms of regulation of gene expression through nuclear proteins such as the Cyclic Nucleotide Response Element Binding Protein (CREB) and the CREB binding protein (CBP).

The *Intracellular Signal Transduction Research Program* encompasses research aimed at understanding the structure and function of intracellular signal transducing molecules. Specific areas of support include: 1) intracellular kinases, phosphatases and anchoring proteins; 2) signaling

mechanisms that have altered activity in response to protein phosphorylation, Ca⁺⁺ and cAMP; 3) approaches to solving the three-dimensional structure of signaling proteins including crystallography and NMR; 4) functional analysis of these proteins including comparison of wild-type and naturally occurring or synthetic, mutant proteins or expression of dominant-negative forms of the proteins; 5) microscopic techniques to localize these proteins within cells; 6) the identification of substrates for these signaling proteins; and 7) the analysis of crosstalk among distinct signal transduction pathways.

The *Neuroendocrinology Research Program* encompasses research on neuropeptides of the hypothalamus. Specific areas of research support include: 1) physiological response to stress through the hypothalamic-pituitary-adrenal axis; 2) neuropeptides and neuropeptide receptor signaling pathways; 3) gene regulation in the hypothalamus and pituitary gland; 4) diseases of the pituitary including neoplasia; 5) hypopituitary dwarfism; 6) identification and characterization of novel hypothalamic or pituitary hormones; 7) tissue specific and developmental expression of pituitary and hypothalamic genes; 8) pituitary hormone receptors and actions on target tissues (e.g., GH IGF-1 axis); 9) neuropeptide receptors in diagnosis and treatment of disease; and 10) neuroendocrine-immune interactions.

The *Nuclear Hormone Superfamily Program* encompasses basic and clinical research on members of the steroid hormone superfamily (also known as the nuclear receptor superfamily). The program includes structure/function studies and the role in signal transduction and regulation of gene expression of the steroid hormones (glucocorticoids, mineralocorticoids, progesterone, estrogens, androgens (testosterone), DHEA) and the nuclear receptors including thyroid hormone, vitamin D, retinoids (RAR, RXR, vitamin A), PPARs, and orphan receptors (LXR, Nur77, COUP-TF, and others). Topics covered include receptor structure, interaction with cytoplasmic chaperones (e.g., Hsp90, Hsp70, etc.), interaction with ligand, nuclear translocation, binding to hormone response elements, interaction with nuclear accessory proteins (e.g., SRC-1, N-CoR, CBP, histone acetylase/deacetylase, GRIP1, etc.), and regulation of gene expression.

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The *Nonautoimmune Thyroid Disease Research Program* is focused on normal thyroid physiology and non-autoimmune thyroid disease. Specific areas of research focus on: the physiological regulation of the expression, processing, and secretion of thyroid hormones; dysfunctional regulation of thyroid hormones that results in disease; the etiology, pathogenesis, diagnosis, and therapy of thyroid disorders; the deiodinase enzymes that convert inactive thyroid hormone to active hormone; and neural cells that are targets of regulation by and feedback to the thyroid.

The *Steroid Metabolism Program* includes the biochemistry, molecular biology, intermediary

metabolism, function and structure of steroids and similar molecules derived from cholesterol, including sex steroids and other hormones (glucocorticoids, mineralocorticoids), retinoids, cardiac glycosides, prostaglandins and eicosanoids, and bile acids. Structural and functional studies of the heme proteins, like mitochondrial cytochromes and cytochrome P450 are included in this program. It can also include enzyme structure and biology in activated nitrogen and oxygen species metabolism (nitric oxide, superoxide, hydrogen peroxide, and antioxidant enzymes).

Metabolic Diseases Research Programs

The *Gene Therapy and Cystic Fibrosis Centers Program* supports three types of centers: Gene Therapy Centers (P30), Cystic Fibrosis Research Center (P30), and Specialized Centers for Cystic Fibrosis Research (P50). Gene Therapy Centers provide shared resources to a group of investigators to facilitate development of gene therapy techniques and to foster multidisciplinary collaboration in the development of clinical trials for the treatment of cystic fibrosis and other genetic metabolic diseases. Cystic Fibrosis Research Centers (P30) and Specialized Centers for Cystic Fibrosis Research (P50) provide resources and support research on many aspects of the pathogenesis and treatment of cystic fibrosis.

The *Cystic Fibrosis Research Program* supports investigator-initiated research grants encompassing both fundamental and clinical studies of the etiology, molecular pathogenesis, pathophysiology, diagnosis, and treatment of cystic fibrosis and its complications. Particular areas of emphasis of the program include: 1) characterization of the cystic fibrosis gene, its mutations, and the molecular mechanisms by which mutations cause dysfunction; 2) studies of the cystic fibrosis transmembrane regulator (CFTR) protein encoded by the cystic fibrosis gene, including its processing, trafficking, and folding, and the mechanisms by which mutations alter CFTR trafficking and structure/function; 3) elucidation of the pathways of electrolyte transport in affected epithelia and the relationship between CFTR and other epithelial ion channels; 4) elucidation of the potential roles of CFTR in transport of molecules other than chloride, posttranslational processing of mucins and other proteins, exocytosis and recycling of cell membranes, subcellular organelle function, and other cellular processes; 5) studies of the relationship between genotype and phenotype in cystic fibrosis and identification of genetic or environmental factors which explain the variable clinical presentations and severity of disease; 6) delineation of the mechanisms underlying the inflammation and infection characteristic of cystic fibrosis and how mutations in the cystic fibrosis gene and alterations in CFTR function result in inflammation and infection; 7) research on other clinical manifestations of cystic fibrosis, including the pathophysiologic mechanisms underlying malnutrition and growth failure, impaired fertility, liver disease, and overall physical and psychosocial development, and approaches to ameliorate the complications of cystic fibrosis; 8) development of potential therapeutic approaches to modulating the transport defect in cystic fibrosis and to stabilize mutant CFTR and enhance its targeting and integration into the cell membrane; 9) development of safe and effective methods for gene therapy; 10) development of animal or cell models useful for study of cystic fibrosis and its therapy; and 11) evaluation of therapeutic interventions in cystic fibrosis in clinical studies or animal models.

The *Gene Therapy Research Program* encompasses research aimed at developing basic and applied gene therapy for genetic metabolic diseases. Specific areas of support include: 1) pilot and feasibility studies (R21) to improve gene delivery systems; 2) studies of the basic science of AAV, adenovirus, retrovirus and lentivirus vectors; 3) studies of non-viral methods of gene transfer such as liposomes or DNA-conjugates; 4) studies to target gene delivery to specific cell types; and 5) gene therapy of stem cells to treat a genetic metabolic disease.

The *Inborn Errors of Metabolism Research Program* encompasses research in the pathophysiology and treatment of genetic metabolic diseases. Specific areas of support include: 1) studies of etiology, pathogenesis, prevention, diagnosis, pathophysiology, and treatment of these diseases; 2) characterization of the genes, gene defects and regulatory alterations that are the underlying causes of these diseases; 3) studies of the mutant enzyme and its effect on the structure and function of the protein 4) the development of animal models for genetic disease; 5) development and testing of dietary, pharmacologic and enzyme replacement therapies; and 6) development of stem cell transplantation both prenatally and postnatally as a treatment for metabolic diseases.

The *Metabolic Complications of HIV Research Program* encompasses research on the endocrine and body composition abnormalities associated with HIV infection and its treatment. Specific areas of support are: 1) Studies of hormones and cytokines involved in wasting syndrome. 2) Studies of changes in body composition in HIV patients. 3) Studies of abnormalities of insulin sensitivity (and other components of the "Metabolic Syndrome" or "Syndrome X") in patients with HIV.

The *Metabolism and Insulin Resistance Program* is comprised of grants that study intermediary metabolism and physiology on the whole body, organ, and cell level. These studies can be done *in vivo*, in isolated tissues or in cell culture. They have as a focus flux and regulation of either a single metabolic pathway, interacting pathways in a cell or organ, or interactions between organs in the whole body. Especially important are *in vivo* measurements of whole body flux, such as glucose production or turnover, or blood flow. Examples of important goals for these studies include an understanding of insulin resistance, regulation of gluconeogenesis and glucose disposal, protein turnover rate and regulation, cellular and whole body lipid fluxes, interaction between carbohydrate and lipid metabolism, rate of tricarboxylic acid cycle flux and energy production in the cell, transcriptional regulation of important flux regulating enzymes or transporters for a given pathway, etc.

The *Protein Trafficking/Secretion/Processing Research Program* encompasses research aimed at understanding the mechanisms that account for the fate of proteins after their initial translation. Specific areas of support include: 1) protein folding; 2) post-translational modifications and the enzymes that catalyze them; 3) the movement of proteins in vesicles from the endoplasmic reticulum (ER) through the golgi and endosomes and their ultimate secretion; 4) mechanisms that account for vesicle formation (pinching off) and vesicle fusion which are paramount to understanding trafficking; 5) the movement of proteins in the direction opposite of secretion, including endocytosis and retrograde transport; 6) proteins and small molecules that regulate protein trafficking; and 7) proteasomes, ubiquitin conjugation, and the N-end rule.

The *Proteomics in Diabetes, Endocrinology and Metabolic Diseases Program* is comprised of grants that study the structure, mechanism, kinetics, and regulation of isolated purified proteins. This would include x-ray crystallography, mass spectroscopic, electron microscopic, nuclear magnetic resonance, and mutational studies of structure. It would include studies of subunit interactions and interactions with small regulatory ligands, substrates, intermediates, and products. Of special interest are new technologies for structure determination (especially membrane proteins), crystallization, identification of interacting molecules and proteins, and assignment of function to unknown gene products of interest to the fields of diabetes, endocrinology and metabolic diseases. High throughput methods are highlighted. All informatics associated with the field of proteomics are included.

Division of Digestive Diseases and Nutrition

This division supports research related to liver and biliary diseases, pancreatic diseases, gastrointestinal diseases, including neuroendocrinology, motility, immunology, and digestion in the GI tract, nutrient metabolism, obesity, eating disorders, and energy regulation. The division provides leadership in coordinating activities related to digestive diseases and nutrition throughout the NIH and with various other Federal agencies.

Digestive Diseases Programs

The *Acquired Immunodeficiency Syndrome Program* encourages research into the characterization of intestinal injury, mechanism of maldigestion, and intestinal mucosal functions, as well as hepatic and biliary dysfunction in AIDS. In addition, studies are supported on mechanisms of nutrient dysfunction, deficiencies of various micronutrients nutritional management of the wasting syndrome and other aspects of malnutrition related to AIDS.

The *Clinical Trials in Digestive Diseases Program* supports patient-oriented clinical research

focusing on digestive diseases. Small clinical studies (pilot), planning grants or phase III clinical trials may be appropriate to this program. The small clinical studies should focus on research that is innovative and/or potentially of high impact. They should lead to full scale clinical trials. Please see the current program announcement for [small grants for clinical trials](#). Phase III clinical trials usually are multi-center and involve several hundred human subjects that are randomized to two or more treatments, one of which is usually a placebo. The aim of the trial is to provide evidence for support of, or a change in, health policy or standard of care. The interventions/treatments may include pharmacologic, nonpharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Areas of emphasis include: *Helicobacter pylori*; inflammatory bowel disease; functional bowel syndrome and constipation; non-ulcer dyspepsia; celiac disease; intestinal failure, short gut syndrome and small bowel transplantation.

The *Digestive Diseases Research Core Centers Program (DDRCCs)* provides a mechanism for funding shared resources (core facilities) that serve to integrate, coordinate, and foster interdisciplinary cooperation between groups of established investigators who conduct programs of high quality research that are related to a common theme in digestive disease research. An existing base of high quality digestive disease-related research is a prerequisite for the establishment of a center.

The research emphases of centers in this program presently focus on liver diseases, gastrointestinal motility, absorption and secretion processes, inflammatory bowel disease, structure/function relationships in the gastrointestinal tract, neuropeptides and gut hormones, and gastrointestinal membrane receptors. Due to a restriction on the number of core center grants that can be supported, new center grant proposals will be accepted only in response to a Request for Applications (RFA) announced in the NIH Guide for Grants and Contracts.

The *Pancreas Program* encourages research into the structure, function, and diseases (excluding cancer and cystic fibrosis) of the exocrine pancreas. Research efforts focus on: Neurohormonal factors involved in the regulation of pancreatic exocrine function in response to pathophysiological stimuli; Studies on receptor and function of intra-cellular signal transducing molecules, coupling to downstream effectors; Compartmentalization of enzymes, substrates, and their effectors; Understanding post-translational mechanisms that account for the fate of proteins, including folding, trafficking and secretion. Understanding the properties and functions of intracellular and extracellular filamentous suprastructures that are involved in hormone signaling and exocrine pancreatic function.

Studies on the biochemistry, etiology, pathogenesis, genetics, epidemiology, diagnosis, treatment and prevention of disorders of the exocrine pancreas; Development of experimental models; Studies relating to development of the exocrine pancreas including the growth and differentiation factors involved in this process and the characterization, isolation, production and uses of pancreatic stem cells; Studies on organ collection, preservation and transplantation.

The *Genetics and Genomics of Digestive Diseases* supports research on identification of genes influencing predisposition to diseases of the gut, liver, and exocrine pancreas, as well as studies of control of gene expression during normal development and disease states of these organs.

Liver Disease Research Programs

The *Liver and Biliary Program* supports basic and clinical research on both the normal function and the diseases of the liver and biliary tract. Areas of basic research include hepatic regeneration, gene therapy, and liver cell injury, fibrosis, and apoptosis; basic and applied studies on liver transplantation, including techniques of preservation and storage; metabolism of bile acids and bilirubin; physiology of bile formation; control of cholesterol levels in bile; and gallbladder and bile duct function. Areas of disease-oriented research include cholesterol and pigment gallstones; inborn errors in bile acid metabolism; chronic hepatitis that evolves from autoimmune, viral, or alcoholic liver disease; and various liver ailments such as Wilson's disease, primary biliary cirrhosis, primary sclerosing cholangitis, portal hypertension, hepatic encephalopathy, and Crigler-Najjar syndrome.

The *Clinical Trials in Liver Disease Program* supports patient-oriented clinical research in liver diseases to evaluate one or more experimental intervention(s) in comparison with a standard treatment and/or placebo control among comparable groups of patients. Experimental interventions may include pharmacologic, nonpharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Areas of program emphasis in liver disease include non-alcoholic steatohepatitis (NASH); chronic hepatitis C; primary biliary cirrhosis; primary sclerosing cholangitis; prevention, management, and treatment of portal hypertension; and recurrent liver disease after transplantation. Either pilot studies or phase III trials may be appropriate. A phase III clinical trial usually involves several hundred or more comparable human subjects, the aim of the trial being to provide evidence for support of, or a change in, health policy or standard of care.

The NIDDK's **HALT-C (Hepatitis C Antiviral Long-Term Treatment against Cirrhosis) Trial** is a multi-center, randomized controlled study, designed to determine if long-term treatment with peginterferon in previous non-responders with advanced hepatic fibrosis can prevent cirrhosis and reduce the risk of developing end-stage liver disease and hepatocellular carcinoma. Antiviral therapy with peginterferon and ribavirin leads to a sustained virological response in approximately half of patients with chronic hepatitis C. Patients who achieve a sustained loss of hepatitis C virus (HCV) usually have marked improvements in liver histology. Lesser but important degrees of improvement in liver histology also occur in interferon-treated patients who fail to achieve a virological response. Furthermore, data from a recent controlled study suggest that continuing interferon in non-responder patients can maintain the histological improvements. Interferon therapy may also reduce the incidence of hepatocellular carcinoma and improve survival in patients with cirrhosis.

In this trial, non-responders to previous treatment with interferon, interferon and ribavirin, or peginterferon were retreated initially with peginterferon alfa-2a (Pegasys, Roche Pharmaceuticals) in a dose of 180 mcg/week and ribavirin in a dose of 1,000 to 1,200 mg/day for 24 weeks (the lead-in phase). Those who became HCV RNA negative were continued on treatment for 48 weeks, whereas those who remained HCV RNA positive entered the formal protocol and were randomly assigned either to continue treatment with peginterferon alfa-2a alone (90 mcg/week) for an additional 42 months or be followed without treatment. Patients are followed with outpatient visits and blood tests every three months. Liver biopsies are performed at baseline and after 2 and 4 years of treatment.

The study goal to randomize 900 patients into the controlled phase was achieved in June 2003. This sample size will provide 90% power to detect a decrease in the annual rate of development of cirrhosis or its complications from 6% per year among controls to 3% per year in those treated.

Primary outcome variables to be assessed in the two groups of patients include:

1. Progression to cirrhosis on liver biopsy
2. Development of hepatic decompensation
3. Development of hepatocellular carcinoma
4. Death

Secondary outcomes include quality of life and serious adverse events.

The study is being conducted at 10 clinical centers in the United States, with the support of a virology laboratory and a data-coordinating center. The study is also supported by a clinical research and development agreement with Roche Pharmaceuticals and is cosponsored by the National Cancer Institute, the National Institute of Allergy and Infectious Diseases, and the National Center on Minority Health and Health Disparities.

[Virahep-C](#) - Recent large randomized controlled trials of therapies for chronic hepatitis C have reported sustained eradication of hepatitis C virus (HCV) and remission in disease in over half of treated patients. In two separate studies, enrolling more than 1000 patients each, the combination of peginterferon and ribavirin was found to be superior to standard interferon and ribavirin and to achieve sustained virological response rates of 54% and 56%. These excellent response rates

provide justification for treating patients with hepatitis C who have histological and/or clinical evidence of progressive disease.

Unfortunately, therapies that are proven to be safe and effective in well designed, multicenter randomized trials may not prove to be as safe or as effective when applied in clinical practice. Perhaps the major reason for this discrepancy is that the average patient enrolled in a clinical trial that satisfies all inclusion and exclusion criteria may not be representative of the average patient with hepatitis C in practice. Several groups of patients with hepatitis C are underrepresented in the registration trials of new therapies for this disease, some intentionally and some by chance. Such understudied groups include children, the elderly, minority individuals, patients with comorbidities of human immunodeficiency virus infection, neuropsychiatric or renal disease, persons in institutions or who are incarcerated, patients with advanced hepatitis C, and patients who have had a solid organ transplant.

Quite striking in many of the initial large randomized controlled trials of interferon-based therapy of hepatitis C has been the underrepresentation of African-Americans. In a combined analysis of studies of standard interferon monotherapy and combination therapy, less than 5% of patients enrolled were black, despite the fact that African-Americans have a higher rate of hepatitis C than non-Hispanic white Americans and probably account for more than 20% of cases of chronic hepatitis C in the United States. Also, striking has been a lower response rate to interferon-based therapies among African-Americans compared to Caucasians. In several studies, the sustained response rate among African-Americans was one-third to one-half of that in whites. In the recent multi-national studies of peginterferon and ribavirin, blacks represented less than 5% of patients enrolled and had response rates that were less than half of the average, even after controlling for genotype. The numbers of African Americans in these studies, however, were not adequate to provide an accurate estimate of response rate.

For these reasons, the Division of Digestive Diseases and Nutrition is funding a multicenter clinical trial of peginterferon and ribavirin therapy in a cohort of patients that would include an adequate number of African-Americans to establish an accurate estimation of the response rate in this group and to initiate basic research studies of the reasons for non-response and antiviral resistance. The "Study of Viral Resistance to Antiviral Therapy of Chronic Hepatitis C (Virahep-C)" is being conducted at eight clinical centers in the United States, and is supervised by a data coordinating center. Four ancillary studies are supported which focus on analyses of the basis for antiviral resistance. Full enrollment is expected by the end of 2003.

The elucidation of the nature and determinants of a response to antiviral therapy and a more clear delineation of the efficacy of combination therapy in all groups of patients with hepatitis C are areas of high priority for the NIH in the long-term initiative on prevention and control of hepatitis C.

NASH Clinical Research Network - Nonalcoholic fatty liver disease is one of the most common causes of liver disease in the United States, and its prevalence appears to be increasing. In surveillance studies of chronic liver disease, nonalcoholic fatty liver disease is the third most common diagnosis, accounting for 10% of new cases. The spectrum of nonalcoholic fatty liver disease includes simple steatosis, steatosis with inflammation, and what is currently referred to as nonalcoholic steatohepatitis (NASH). The differentiation of simple steatosis from NASH requires liver biopsy as there are no laboratory tests for this distinction. The diagnosis of NASH requires the presence of fat, inflammation, and centrilobular (zone 3) ballooning degeneration with either pericellular fibrosis or Mallory bodies. This distinction is important because NASH is believed to be a progressive liver disease which can lead to cirrhosis and even hepatocellular carcinoma, whereas simple steatosis or fatty liver is usually non-progressive and benign. In some cases, however, patients with steatosis alone are later found to develop full-blown NASH. Clinical features, serum aminotransferase elevations, and hepatic imaging studies showing changes suggestive of fatty liver not adequate alone or in combination to distinguish simple steatosis from NASH. These considerations make it difficult to evaluate the natural history and course of nonalcoholic fatty liver disease or better define its need for therapy or intervention. The causes of NASH are not well defined, but it typically occurs in association with obesity, insulin resistance or type II diabetes, and

hyperlipidemia, suggesting that fatty liver and NASH are hepatic manifestations of the dysmetabolic syndrome, and might better be referred to as metabolic steatohepatitis (MESH). The lack of clear understanding of the pathogenesis of NASH, its natural history, prognostic features, and treatment all underscore the need for clinical and basic research into this important liver disease.

In response to these needs, the NIDDK initiated a request for applications (RFA) to create a multicenter study on the natural history, pathogenesis and therapy of NASH. The RFA was published in February 2001, and eight clinical centers and a data coordinating center were awarded in September 2002. Cofunding to allow for expansion of the pediatric component was provided by the National Institute of Child Health and Development (NICHD). The NASH Network will create both a prospective and retrospective database of adult and pediatric cases of nonalcoholic fatty liver disease that will be evaluated and followed prospectively in a standardized fashion. A pathology committee has proposed a standardized system for histological grading and staging and has initiated studies of its reliability and reproducibility. The Network has also developed plans to conduct randomized controlled trials of promising therapies of NASH, both in children and in adults. These studies will focus initially on use of insulin-sensitizing agents and vitamin E. Endpoints of therapy will be based upon histological improvements using the standardized grading and staging systems that are currently being refined. An important component of the NASH Clinical Research Network is to develop a cohort of patients and a collaborative group of clinical and basic researchers to generate hypotheses and develop ancillary studies using the resources of the database. These ancillary studies may be in the area of laboratory research or clinical investigation and will focus on pathogenesis and determinants of progression and severity.

Biliary Atresia Clinical Research Consortium - Neonatal liver disease affects 1 in 2,500 liver births and its major cause is biliary atresia. At present, biliary atresia is the single most common reason for liver transplantation in children and is a major challenge for early detection, diagnosis, and management. At the same time, the underlying cause of biliary atresia is unclear. The disease is congenital but does not appear to be familial or inherited. Various hypotheses have been advanced to explain the occurrence of biliary atresia, but none have proven to be true or to lead to a practical means of early detection, diagnosis, treatment or prevention. Because biliary atresia and other forms of neonatal liver disease are rare, no single referral center in North America cares for enough new patients each year to allow for intensive analysis of etiology and risk factors or to critically assess novel means of diagnosis or treatment. For these reasons, the NIDDK established a Biliary Atresia Clinical Research Network (BARC). The consortium is charged with establishing and maintaining the infrastructure for accruing sufficient numbers of biliary atresia and neonatal hepatitis patients to perform adequately powered clinical studies. The overall goal of this consortium is to gather clinical and biochemical data and adequate numbers of serum, tissue, and DNA samples in a prospective manner to facilitate research and generate new hypotheses and test existing hypotheses on the pathogenesis and optimal diagnostic and treatment modalities of these disorders. It is also hoped that the establishment of this consortium and the serum and tissue bank will stimulate other scientists to develop an interest in investigating the etiology and pathogenesis of these disorders and collaborate with the consortium, with serum and tissue being made available for appropriate studies. The study is funded by the NIDDK and the Office of Rare Disorders. At present BARC consists of nine pediatric liver disease Clinical Centers and a Data Coordinating Center.

Adult-to-Adult Living Donor Liver Transplantation Cohort Study - Liver transplantation is now the standard of care for patients with end-stage liver disease. At present, more than 4,500 liver transplants are done yearly. Unfortunately, more than 18,000 patients await liver transplantation, and in recent years, the waiting list has continued to grow. As a consequence, the numbers of patients dying on the liver transplant waiting list has grown. The introduction of the MELD system was designed to assign livers to the patients in most critical need for transplantation and, thereby, decrease the waiting list mortality. While this approach may have been partially successful, the continued shortage of cadaveric livers and continued growth of demand for liver transplantation will mean that the mortality rate on the waiting list will continue to be high.

Among possible remedies to the shortage of cadaveric livers for transplantation, living donor liver transplantation is perhaps the most practicable, but also the most controversial. Living donor liver

transplantation has become widely accepted for pediatric patients. For children, the left lobe of an adult liver is adequate for transplantation, and left-lobe living donor liver transplantations (particularly from parent to child) have been done successfully for more than a decade. For adults, transplantation of a left lobe of the liver (approximately 20-30% of the liver mass) is usually inadequate to support life, particularly in a patient already suffering from end-stage liver disease. Transplantation of the right lobe (50-60% of the liver mass) can be successful in adults, but the donor operation is accordingly more extensive and more life-threatening. Adult-to-adult living donor liver transplantation was first accomplished in the late 1990s and was introduced into the United States in 1997 and now accounts for approximately 5% of all liver transplants done in the United States. Nevertheless, the donor operation in adult-to-adult liver transplantation is challenging and potentially dangerous.

To address the issues of proper use, relative risks, and potential benefits of adult-to-adult living donor liver transplantation, the NIDDK established a multicenter clinical cohort study. The "Adult-to-Adult Living Donor Liver Transplantation Cohort Study" (A2ALL) consists of nine liver transplant centers experienced in performing living donor liver transplantation and a data coordinating center responsible for directing and maintaining an infrastructure of a clinical database on patients. The primary goal of A2ALL will be to provide valuable information on the outcomes of living donor liver transplantation. The cohort study will follow both donors and recipients before and after the liver transplant operation assessing clinical outcomes and quality of life. This information is needed to aid decisions made by physicians, patients, and potential donors.

Hepatotoxicity Network - Liver injury due to medications is one of the most common causes of acute liver disease and jaundice. Importantly, the mortality rate of hepatic idiosyncratic drug reactions is quite high, and over half of cases of acute liver failure in the United States are due to medications. Elucidation of the mechanisms of hepatic drug injury, however, is often difficult. Drug-induced liver disease is typically unpredictable, idiosyncratic and rare. Most of the medications that cause acute liver injury in humans do not produce injury in experimental animals. Attribution of acute liver injury to a medication is frequently difficult: the patient with hepatotoxicity often has multiple other risk factors for liver disease, may be on many potentially hepatotoxic drugs, and may not present until the injury resolved. Drug-induced liver injury is also quite variable in clinical expression. Patterns of injury mimic virtually all other forms of liver disease, including acute viral hepatitis, autoimmune liver disease, bland cholestasis, mixed cholestatic-hepatic syndromes, acute cholangitis, microvesicular steatosis with lactic acidosis, alcohol-like steatohepatitis, and venoocclusive disease. Finally, drugs that cause hepatotoxicity are usually withdrawn from use, and are no longer available for study.

Despite the clinical significance of drug-induced liver injury, this form of liver disease is a relatively unstudied area of research. Part of the difficulty in studying drug-induced liver disease is the absence of a sufficient cohort of well-characterized patients in whom to carry out clinical, genetic, immunological and biochemical investigation. To help develop a prospective database on drug-related hepatotoxicity, the NIDDK has established a Hepatotoxicity Clinical Research Network. The Network consists of five interactive clinical centers and a data coordinating center. The objective of the Network is to develop standardized definitions and instruments to identify and characterize bona fide cases of drug-induced liver injury. Researchers could then analyze the epidemiology and clinical spectrum of hepatotoxicity and identify cases of medication-induced liver disease prospectively. They could also collect biological samples to study the pathogenesis of hepatotoxicity using biochemical, serological and genetic techniques. The Network will be expected to collaborate with other investigators in the areas of hepatocyte biology and cell injury as well as pharmacokinetics and pharmacogenetics. A repository will be established for storage of serum, tissue and DNA samples. The Network will be funded as a pilot phase (3 years) which, if successful, will be extended by future RFAs.

Obesity Research Programs

The *Bariatric Surgery Clinical Research Consortium (BSCRC)* will provide infrastructure for and facilitate coordinated clinical, epidemiological, and behavioral research in the field of bariatric surgery through the cooperative development of common clinical protocols and a bariatric surgery

database. The Consortium will also provide the preliminary data and background for further investigator-initiated research. Goals of the BSCRC include a greater understanding of the risks and benefits of bariatric surgery as a treatment; the standardization of definitions and data collection instruments to enhance the ability to provide meaningful evidence-based recommendations for patient evaluation, selection, and follow-up care; basic and clinical studies to explore the mechanisms by which surgery affects obesity-related co-morbid conditions, energy expenditure, nutrient partitioning, appetitive behaviors, and psychosocial factors. Four to six clinical centers and a data coordinating center were funded in September, 2003.

The Program on *Genetics and Genomics of Obesity* supports research directed at identification of genes influencing obesity and related anatomical, physiological, and behavioral traits such as body fat composition and distribution, metabolic rate, energy balance, food consumption and preference, and physical activity levels, as well as research on patterns of gene expression associated with these traits, and mechanisms of regulation of these patterns. The Program supports research on humans as well as model organisms, encouraging both genome-wide and candidate-gene based approaches exploiting naturally occurring genetic variation as well as artificially induced mutations. Typical approaches include genetic linkage, association, and linkage-disequilibrium studies, QTL mapping, phenotype- and gene-driven mutagenesis screens, and macro- and microarray-based surveys of gene expression.

The *Obesity and Eating Disorders Program* emphasizes support of investigator-initiated basic and clinical research relating to biomedical and behavioral aspects of obesity and eating disorders, particularly binge eating disorder and its relationship to obesity. Areas of research interest include investigations of factors that affect food choices, food intake, eating behavior, appetite, satiety, body composition, nutrient partitioning, physical activity and energy regulation. The roles of neural and hormonal factors from the molecular to the whole animal/human level are encompassed within this program if the primary goal of the investigations is to examine their role in the development or maintenance of obesity. The physiological and metabolic consequences of weight loss or weight gain, the effects of exercise and diet composition on appetite and weight control, and the individual variability in energy utilization and thermogenesis are contained within the specific research interests of this program. Investigations incorporating improved methods for assessment of body composition, examination of health risk factors with specific degrees of obesity or body composition, and determination of the effect of exercise on body composition also are supported.

The *Obesity Prevention and Treatment Program* supports research that focuses on the prevention and treatment of overweight and obesity in humans. Prevention includes primary and secondary approaches to prevent the initial development of overweight/obesity through control of inappropriate weight gain and increases in body fat; weight maintenance among those at risk of becoming overweight, and prevention of weight regain once weight loss has been achieved. Treatment includes clinical trials evaluating approaches to lose weight or maintain weight loss, including, but not limited to, behavioral, pharmacologic, and surgical approaches. This program also includes environmental, policy-based, and population-based approaches to the prevention and/or treatment of obesity.

Look AHEAD: Action for Health in Diabetes is a clinical trial recruiting 5000 obese individuals with type 2 diabetes into an 11.5 year study that will investigate the long term health consequences of interventions designed to achieve and sustain weight loss. The primary outcome of the trial is cardiovascular events: heart attack, stroke and cardiovascular death. The study also will examine impact of the interventions on cardiovascular risk factors, diabetes control, cost effectiveness, quality of life, and a number of additional measures. The Obesity Special Projects program also administers ancillary studies to Look AHEAD. Recruitment for Look AHEAD is expected to end at most centers by the end of 2003.

As a means of encouraging a multidisciplinary approach to obesity and nutrition research, the Division supports *Obesity/Nutrition Research Centers (ONRC)*. The goal of an ONRC is to help coordinate and strengthen support for research activities primarily by providing funds for core facilities and associated staff that serve the various projects on a shared basis. This approach

ensures that an ONRC has multiple sponsors, both Federal and non-Federal, and thereby reduces the likelihood that the ONRC will become unduly dependent on any one source of funds for its continued operation. The specific objectives of an ONRC include efforts to create or strengthen a focus in biomedical research institutions for multidisciplinary research in obesity and nutrition; to develop new knowledge concerning the development, treatment, and prevention of obesity and eating disorders; to understand control and modulation of energy metabolism; to understand and treat disorders associated with abnormalities of energy balance and weight management such as in anorexia nervosa, AIDS, and cancer; and to strengthen training environments to improve the education of medical students, house staff, practicing physicians, and allied health personnel about these conditions. To accomplish the overall goal of these centers, the applicant's institution must have an on-going program of excellence in biomedical research related to the study of obesity and associated disorders. Due to a restriction in the number of core center grants that can be supported, new center grant proposals will be accepted only in response to a Request for Applications (RFA) announced in the NIH Guide for Grants and Contracts.

Epidemiology

The *Epidemiology and Data Systems Program* serves as a focus for the collection, analysis, and dissemination of data on digestive diseases and their complications. The program (1) identifies the data needed to address the scientific and public health issues in digestive diseases and nutrition; (2) addresses the epidemiology of digestive diseases and nutritional disorders of public health significance, with particular emphasis on national surveys and their follow-up; (3) promotes the timely availability of reliable data to pertinent scientific, medical, and public organizations; (4) promotes the standardization of data collection and terminology in clinical and epidemiological research; and (5) works closely with members of the scientific community to develop investigator-initiated research in digestive diseases and nutrition epidemiology.

The program encourages research that addresses risk factors for disease occurrence and disease prognosis or natural history. The program also supports databases and biological repositories that support clinical and epidemiological studies in digestive diseases and nutrition.

Nutrition Sciences Programs

The *Nutrient Metabolism Program* supports basic and clinical studies related to the requirement, bioavailability, and metabolism of nutrients and other dietary components at the organ, cellular, and subcellular levels in normal and diseased states. Specific areas of research interest include the understanding of the physiologic function and mechanism of action/interaction of nutrients within the body; nutrient influence on gene regulation and expression; metabolism and function of nutrient antioxidants; the effects of environment, heredity, stress, drug use, toxicants, and physical activity on problems of nutrient imbalance and nutrient requirements in health and disease; and specific metabolic considerations relating to alternative forms of nutrient delivery and use, such as total parenteral nutrition. The program also supports research to improve methods of assessing nutritional status in health and disease.

The *Clinical Trials in Nutrition Program* supports clinical research on nutrition and eating disorders, focusing on metabolic and/or physiologic mechanisms. Small clinical studies (pilot), planning grants or phase III clinical trials may be appropriate to this program. The small clinical studies should focus on research that is innovative and/or potentially of high impact. They should lead to full scale clinical trials. Please see the current program announcement [http://grants1.nih.gov/grants/guide/pa-files/ PAR-01-056.html](http://grants1.nih.gov/grants/guide/pa-files/PAR-01-056.html) for small grants for clinical trials. Phase III clinical trials usually are multi-center and involve several hundred human subjects that are randomized to two or more treatments, one of which is a placebo. The aim of the trial is to provide evidence for support of, or a change in, health policy or standard of care.

A *Clinical Nutrition Research Unit (CNRU)* is an integrated array of research, educational, and service activities focused on human nutrition in health and disease. It serves as the focal point for an interdisciplinary approach to clinical nutrition research and for the stimulation of research in areas

such as improved nutritional support of acutely and chronically ill persons, assessment of nutritional status, effects of disease states on nutrient needs, and effects of changes in nutritional status on disease. Funding for the CNRU program, which began in 1979, is provided through the core center grant mechanism. Due to a restriction in the number of core center grants that can be supported, new center grant proposals will be accepted only in response to a Request for Applications (RFA) announced in the NIH Guide for Grants and Contracts.

Other Programs

- [Conferences](#)
- [Small Business Innovation Research \(SBIR\)](#)
- [Small Business Technology Transfer \(STTR\)](#)
- [Training](#)
- Career Development

Division of Kidney, Urologic and Hematologic Diseases

The division supports research on diseases of the kidney, genitourinary tract, and blood and blood-forming organs, and on the fundamental biology relevant to these organ systems. It funds training and professional development of investigators in disciplines critical for research in these areas.

Kidney Research

The *Basic Renal Biology Program* supports research on normal development, structure and function of the kidney. Areas of emphasis include glomerular function and cell biology, transport physiology and structure-function analysis of transport proteins, and integrated regulation of solute and water excretion. The program supports investigation of adverse effects of nephrotoxic drugs and environmental toxins and mechanisms of hypoxic renal cell injury.

A major area of strength is studies examining intracellular signal transduction for renal hormones and growth factors. In addition to study on mammalian systems, investigation is supported on transport function and development and genomic analysis of membrane transport proteins using simple systems such as bacteria *C. elegans* and zebrafish.

The *Chronic Renal Diseases Program* supports basic and clinical studies on the etiology, prevention, diagnosis and treatment of chronic renal diseases. Disease categories receiving particular emphasis include analgesic nephropathy, polycystic kidney disease, diabetic nephropathy, glomerulonephritis and other immune disorders of the kidney, hypertensive nephrosclerosis and HIV nephropathy. A major interest in this program is renal diseases that affect children and the effects of chronic renal insufficiency on growth and development of children.

The *End-Stage Renal Disease Program* supports investigation on the pathogenesis of the uremic state, on end-stage renal disease treatment by peritoneal and hemodialysis, and on nutrition in renal disease. Investigation on renal transplantation is supported with particular emphasis on nonimmunological renal injury and on methods of increasing organ availability, particularly in minority populations.

The *Diabetic Nephropathy Program* supports investigation into the pathogenesis, prevention and treatment of the kidney disease associated with diabetes mellitus. One major area of emphasis is the identification of genes associated responsible for the familial clustering of diabetic kidney disease, through sponsorship of the FIND consortium.

The *Pediatric Nephrology Program* supports basic and clinical research on the causes, treatments, and prevention of kidney diseases of children. Research efforts focus on inherited and congenital renal diseases; kidney disease of diabetes mellitus; IgA nephropathy; and kidney disease and hypertension, which starts in early childhood.

The *Renal Epidemiology Program* – Investigation into the incidence and prevalence of renal diseases, the factors associated with increased mortality and co-morbidity and cost-benefit assessment of prevention and treatment strategies are areas supported through the renal epidemiology program.

The *U.S. Renal Data System (USRDS)*, an information resource for the epidemiology of end-stage renal disease, is supported through this program. USRDS investigation of cost factors in dialysis care is co-funded with the Centers for Medicare and Medicaid Services, formerly known as the Health Care Financing Administration.

Urology Research

The *Basic Urology Program* supports basic research on the normal and abnormal development, structure and function of the genitourinary tract. A major area of interest is investigation of the biology of bladder cells, including studies on transport properties, effects of obstruction on patterns of protein expression and examination of interactions between urinary pathogens and cells of the urinary tract. The program on prostate biology has particular strengths in investigation of prostate cell growth and mechanisms of growth factor signal transduction.

The *Clinical Urology Program* – The mission of this program is research that will increase the knowledge of etiology, diagnosis, pathophysiology, therapy and prevention of major pediatric and adult urological disorders. Non-malignant disorders of the bladder and prostate, including benign prostatic hyperplasia, interstitial cystitis, urinary tract infections, urinary incontinence and urolithiasis are areas of emphasis, as are the effects of systemic diseases such as diabetes mellitus, spinal cord injury, and multiple sclerosis on these organs. In addition, the program supports studies of diagnostic and therapeutic modalities such as 1) shock-wave and laser lithotripsy, 2) urolithiasis inhibitors, 3) bladder substitution procedures and devices, and 4) prostate growth inhibitor and reduction therapies.

The *Urologic Diseases Epidemiology Program* – The major emphasis of this program is to develop a source of epidemiological information that may further understanding of natural history, risk factors and health resource utilization for urologic conditions. Plans are to collect and analyze new and existing data on incidence, prevalence, morbidity, mortality and health resource utilization associated with various urologic conditions of high public health importance. The information will be presented in a planned publication tentatively titled "Urologic Diseases in America."

Hematology Research

The *Hematology Program* supports research into the fundamental processes underlying the normal and pathologic function of blood cells and the reticuloendothelial system. Major areas of interest include the genetic regulation of hemoglobin and other proteins of the blood; acquired and inherited anemias; cell membrane composition and regulatory processes; iron metabolism, storage, and transport; hematopoiesis and its regulation by growth factors, including erythropoietin; transcription and signaling factors such as the JAK/STAT pathway involved in hematopoietic cell differentiation; immunohematology; hematopoiesis, hematopoietic stem cell biology, and the expression of differentiation potential of hematopoietic stem cells; stem cell plasticity and the cellular, molecular, and genetic mechanisms that allow cells to express plasticity. Emphasis is on the application of fundamental knowledge to current issues such as gene transfer therapy and bone marrow transplantation, and disorders such as sickle cell anemia, thalassemia, hemochromatosis, iron deficiency anemia, thrombocytopenia and hemolytic anemia.

The *Chelator Therapy Program* – Research is supported on the development of new iron chelating drugs for the treatment of transfusion iron overload, such as in Cooley's anemia, sickle cell disease, and other instances of iron overload. A safe and inexpensive orally active iron chelator that effectively promotes iron excretion is needed urgently, since the only currently available drug,

desferrioxamine B, is expensive and is painful and cumbersome to administer, leading to widespread non-compliance among the young adult patient population. Pre-clinical toxicity studies of potential iron chelating drugs are performed under the contract mechanism. Grant support is offered for basic research on the kinetics of iron chelation, the identity of the iron pools addressed, and ways to enhance the chelating activity and reduce the toxicity of known iron chelators.

The *Hematopoietic Lineage Genomics Anatomy Program* – This program has been initiated to merge the fields of hematopoietic cell biology, including erythroid cell physiology, with bioinformatics. The combination of these two fields will: 1) advance the ability to catalog and monitor genes that are expressed during normal and variant hematopoietic cell differentiation, 2) facilitate a more comprehensive understanding of the dynamics of molecular events that occur during differentiation, and most importantly, 3) develop a quantitative model that incorporates known gene expression data into a description of a red blood cell. This model could then be used to test novel expression patterns as they are discovered and also be used as a scaffold from which to devise models for other tissue and organ development.

Genomics Research

The *Genomics Research Program* encompasses research on genomics and related technologies in the study of kidney, genitourinary tract, and blood and blood-forming organs. This program also supports model organism genomics research, including the development of genetic tools for high-throughput functional genomics studies. One major programmatic area is the leadership of a major trans-NIH initiative to develop genomics of zebrafish, *Danio rerio*.

Office of the Director

Office of Minority Health Research Coordination. To address the burden of diseases and disorders that disproportionately impact the health of minority populations, the Director of the NIDDK created the NIDDK Office of Minority Health Research Coordination (OMHRC). The OMHRC will help implement the Institute's strategic plan for health disparities and build on the strong partnership with the National Center on Minority Health and Health Disparities at NIH. For more information, please contact: Office of Minority Health Research Coordination, 6707 Democracy Boulevard, Suite 901/933, Bethesda, Maryland 20892, phone: (301) 435-2988.

Advisory Council

Under the auspices of the NIDDK Advisory Council, the *National Task Force on Prevention and Treatment of Obesity* was established in June 1991 to synthesize current scientifically based information on the prevention and treatment of obesity and to develop statements about topics of clinical importance that are based on critical analyses of the literature. It is composed of leading obesity researchers and clinicians who advise the institute on research needs and sponsor workshops on topics related to the prevention and treatment of obesity. In June 2003, the name was changed to the Clinical Obesity Research Panel (CORP).

Health Information and Education Services

National Diabetes Information Clearinghouse (NDIC)

National Digestive Diseases Information Clearinghouse (NDDIC)

National Kidney and Urologic Diseases Information Clearinghouse (NKUDIC)

The three clearinghouses serve as information resources for patients, the public, and health professionals concerned with diabetes, digestive diseases, and kidney and urologic diseases. Each was authorized by Congress to increase knowledge and understanding about these areas through the effective dissemination of information. The NDIC was authorized by Congress in 1976, the NDDIC in 1980, and the NKUDIC in 1987.

The clearinghouses answer inquiries; develop, print and distribute publications; and work closely with professional and patient-advocacy organizations and U.S. Government agencies to coordinate informational resources about diabetes, digestive diseases, and kidney and urologic diseases.

The clearinghouses also develop and maintain relevant sections of the Combined Health Information Database – a free, online bibliographic database of references to books, journal articles, audiovisuals, directories, bibliographies, manuals, product descriptions, brochures and pamphlets, computer programs, monographs, newsletters, and other educational materials (<http://chid.nih.gov>).

Addresses are:

- NDIC, 1 Information Way, Bethesda, Maryland 20892-3560, phone: 1-800-860-8747;
- NDDIC, 2 Information Way, Bethesda, Maryland 20892-3570, phone: 1-800-891-5389;
- NKUDIC, 2 Information Way, Bethesda, Maryland 20892-3580, phone: 1-800-891-5390.

National Diabetes Education Program (NDEP)

The *NDEP*, co-sponsored by the NIDDK and the Centers for Disease Control and Prevention (CDC), is focused on improving the treatment and outcomes for people with diabetes, promoting early diagnosis, and ultimately preventing the onset of diabetes. The goal of the program is to reduce the morbidity and mortality associated with diabetes through public awareness and education activities targeted to the general public, especially those with at risk for type 2 diabetes, people with diabetes and their families, health care providers, and policy makers and payers. These activities are designed to 1) increase public awareness that diabetes is a serious, common, costly, and controllable disease that has recognizable symptoms and risk factors; 2) encourage people with diabetes, their families, and their social support systems to take diabetes seriously and to improve practice of self-management behaviors; 3) reduce disparities in health in racial and ethnic populations disproportionately affected by diabetes and 4) alert health care providers to the seriousness of diabetes, effective strategies for its prevention and control, and the importance of a team care approach to helping patients manage the disease. Toward these ends, the NDEP develops partnerships with organizations concerned about diabetes and the health care of its constituents.

NDEP publications are available through the NDEP home page at <http://ndep.nih.gov>. The mailing address is 1 Diabetes Way, Bethesda, Maryland 20892-3600, phone 800-438-5383.

National Kidney Disease Education Program (NKDEP)

The *NKDEP* addresses the growing problem of kidney disease in this country and to reduce the morbidity and mortality caused by kidney disease and its complications. The program will raise awareness about the seriousness of kidney disease, the importance of prevention, early diagnosis and appropriate management of kidney disease, and the prevention and management of complications.

Weight-control Information Network (WIN)

The *WIN* is a national information service of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH). WIN was established in 1994 to provide health professionals and consumers with science-based information on obesity, weight control, and nutrition. WIN has also developed the *Sisters Together: Move More, Eat Better* Media program that encourages Black women 18 and over to maintain a healthy weight by becoming more physically active and eating healthier foods. For more information, write, or call: The Weight-control Information Network, 1 WIN Way, Bethesda, Maryland 20892-3665, phone 1-877-946-4627.

This page was last reviewed on February 2, 2006 .

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National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892



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The NIH Almanac – Organization

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National Institute on Drug Abuse

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Mission

The National Institute on Drug Abuse (NIDA) provides national leadership for research on drug abuse and addiction. Through its extramural research program and its Intramural Research Program in Baltimore, NIDA supports a comprehensive research portfolio that focuses on the biological, social, behavioral and neuro-scientific bases of drug abuse as well as its causes, prevention, and treatment. NIDA also supports research training, career development, public education and research dissemination efforts. Through grants and contracts to investigators at research institutions around the country and overseas, NIDA supports research and research training on:

- the neurobiological, behavioral, and social mechanisms underlying drug abuse and addiction;
- specific biomedical and behavioral effects of drugs of abuse, including nicotine, marijuana, heroin, and cocaine, on the body and brain;
- effective prevention and treatment approaches, including a broad research program designed to develop new treatment medications and behavioral therapies for drug addiction;
- the causes and consequences of drug abuse, including impact on society and morbidity and mortality in selected populations, e.g., ethnic minorities, youth, women;
- the relationship of drug use to problem behaviors and psychosocial outcomes such as mental illness, unemployment, low socioeconomic status, violence;
- biomedical, behavioral, genetic, and social factors associated with vulnerability to drug abuse and addiction;
- the relationship of drug abuse to the acquisition, transmission, and clinical course of HIV/AIDS, tuberculosis, and other diseases and the development of effective prevention/intervention strategies;
- the relationship of drug abuse to cultural and ethical issues such as health disparities;
- the mechanisms of pain and the search for non-addictive analgesics; and
- tobacco and nicotine addiction.

Important Events in NIDA History

1935 – A research facility is established in Lexington, KY, as part of a USPHS hospital. It became

the Addiction Research Center in 1948.

1972 – Drug Abuse Warning Network and National Household Survey on Drug Abuse were initiated under the Special Action Office for Drug Abuse Prevention.

1974 – NIDA is established as the Federal focal point for research, treatment, prevention and training services, and data collection on the nature and extent of drug abuse.

National Drug and Alcohol Treatment Unit Survey begins to identify the location, scope, and characteristics of public and private drug prevention and treatment programs.

1975 – The Monitoring the Future Survey, also known as the High School Senior Survey, was initiated to measure prevalence and trends of non-medical drug use and related attitudes of high school seniors and young adults.

NIDA began its "Research Monograph Series," which is one of its primary vehicles for disseminating the newest scientific information in the drug abuse field. Each monograph contains scientific papers that discuss a variety of subjects including drug abuse treatment and prevention research.

1976 – NIDA begins the Community Epidemiology Work Group, made up of state and local representatives meeting semiannually with NIDA staff to assess recent drug abuse trends and to identify populations at risk.

1979 – The clinical research program moves from Lexington, KY, to the campus of the Francis Scott Key Medical Center (later Johns Hopkins Bayview Medical Center) in Baltimore, MD. The basic science program follows in 1985.

NIDA sponsors the Treatment Outcome Prospective Study (TOPS), which continued through 1987 to evaluate the overall effectiveness of treatment and to identify certain factors as important determinants of drug abuse treatment success, such as length of time in treatment.

1985 – NIDA publishes the first issue of its bimonthly newsletter, *NIDA Notes*.

1986 – The dual epidemics of drug abuse and HIV/AIDS are recognized by Congress and the Administration in a quadrupling of NIDA funding for research on both major diseases.

1987 – NIDA initiates the National AIDS Demonstration Research projects to study and change the high-risk behaviors of injection drug users not enrolled in drug treatment and their sex partners.

1990 – NIDA established the Medications Development Program, focusing on developing new medications for treating addiction.

1991 – The Monitoring the Future Survey is expanded to include 8th and 10th graders.

NIDA begins data collection for the Drug Abuse Treatment Outcome Study (the successor to TOPS) to assess the effectiveness of treatment in reducing drug abuse and to identify predictors of drug abuse treatment success.

NIDA holds its first research technology transfer conference in Washington, D.C.: "National Conference on Drug Abuse Research and Practice: An Alliance for the 21st Century."

1992 – NIDA joins the National Institutes of Health (NIH).

1993 – The institute obtained FDA approval for LAAM, the first medication approved in a decade for

the treatment of opioid addiction.

1995 – NIDA researchers cloned the dopamine transporter, cocaine's primary site of action in the brain.

The Institute held the first "National Conference on Marijuana Use: Prevention, Treatment, and Research" in Arlington, VA.

1996 – NIDA dedicated the Regional Brain Imaging Center located at the institute's intramural research center in Baltimore.

1997 – NIDA released *Preventing Drug Use Among Children and Adolescents: A Research-based Guide*, which described the most successful concepts for treating young people with drug abuse and addiction problems.

The Institute sponsored "Heroin Use and Addiction: A National Conference on Prevention, Treatment and Research," in Washington, D.C.

1998 – NIDA establishes a new Center for AIDS and Other Medical Consequences of Drug Abuse, to coordinate a comprehensive, multidisciplinary research program aimed at improving the knowledge base on drug abuse and HIV/AIDS and other short and long-term health consequences associated with drug abuse and addiction.

1999 – In collaborations with the National Cancer Institute (NCI) and the Robert Wood Johnson Foundations, NIDA creates the Transdisciplinary Tobacco Use Research Centers for studying tobacco use and new ways to combat it and its consequences.

1999 – NIDA launches its National Drug Abuse Treatment Clinical Trials Network, to rapidly and efficiently test the effectiveness of behavioral and pharmacological treatments in real life settings.

1999 – NIDA releases "Principles of Drug Addiction Treatment: A Research-Based Guide" developed for use in local communities that describes the most successful concepts for treating people with drug abuse and addiction problems.

2000 – NIDA distributes its "Clinical Toolbox", a collection of the latest comprehensive science-based publications on drug addiction and its treatment.

2001 – The Institute launches the National Prevention Research Initiative to stimulate research that will fill critical gaps in the knowledge and use of science-based drug abuse prevention strategies in communities across the country.

2002 – The Institute launches the new peer-reviewed journal "Science and Practice Perspectives" to encourage more collaboration between researchers and practitioners.

2002 – The FDA approves buprenorphine for the treatment of opioid dependence. NIDA supported the development of this medication. It is the first form of opioid treatment to be given in a physician's office.

2002 – In September 2002, with support from eight partner agencies in the U.S Departments of Health and Human Services and Justice, NIDA launched the major research initiative called the Criminal Justice Drug Abuse Treatment Studies (CJ-DATS). The goal of CJ-DATS is to establish and utilize a research infrastructure to develop and test models for an integrated approach to the treatment of incarcerated individuals with drug abuse or addictive disorders.

2003 – NIDA releases its newly updated publication, *"Preventing Drug Use among Children and*

Adolescents: A Research-Based Guide for Parents, Educators, and Community Leaders, Second Edition " that reflects NIDA's expanded research program and knowledge base in the area of drug abuse prevention.

2003 – NIDA launches its “NIDA Goes Back to School” campaign and “NIDA for Teens” website in an effort to keep parents, teachers, and teenagers informed on the science behind drug abuse.

2004 – NIDA continues to address the gap that exists in the drug abuse treatment field between clinical practice and basic scientific investigation through its “Blending” series of meetings. This year’s meeting was titled “Blending Clinical Practice and Research: Forging Partnerships in the Great Lakes States To Enhance Drug Addiction Treatment.”

2004 – NIDA collaborates with the Drug Enforcement Administration and other federal agencies to design a traveling museum exhibit, which debuted in New York City. This exhibit draws attention to the social, economic, and medical consequences associated with drug abuse.

NIDA Legislative Chronology

1966 – P.L. 89-793, the Narcotic Addict Rehabilitation Act, provided for increased Federal efforts in the rehabilitation and treatment of narcotic addicts (limited to opiate abusers).

1970 – P.L. 91-513, the Comprehensive Drug Abuse Prevention and Control Act, replaced the PHS Act's definition of "narcotic addict" with a definition of "drug dependent person" to authorize treatment for both narcotic addicts and other persons with drug abuse problems.

1972 – P.L. 92-255, the Drug Abuse Office and Treatment Act, created a Special Action Office for Drug Abuse Prevention (SAODAP) in the Executive Office of the President, and authorized the establishment of NIDA within the Department to become operational in 1974. In cooperation with other Federal agencies, especially NIMH's Division of Narcotic Addiction and Drug Abuse (DNADA), SAODAP established a national network of multi-modality drug abuse treatment programs.

1974 – P.L. 93-282, The Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act Amendments, created ADAMHA which was charged with supervising and coordinating the functions of NIMH, NIDA, and NIAAA.

Programs and responsibilities of DNADA and SAODAP were moved to NIDA.

1979 – P.L. 96-181, the Drug Abuse Prevention, Rehabilitation, and Treatment Act, mandated that at least 7 percent in FY 1980 and 10 percent in FY 1981 of NIDA's Community Programs budget be spent on prevention.

1981 – P.L. 97-35, the Omnibus Budget Reconciliation Act, repealed NIDA's formula grants and Community Programs project grants and contracts authorities, and established the ADMS Block Grant program giving more control of treatment and prevention services to the states.

1986 – P.L. 99-570, the Anti-Drug Abuse Act of 1986, increased the Block Grant and created a substance abuse treatment enhancement; and provided increased funds for all NIDA research, particularly AIDS research. Executive Order 12564 mandated a drug-free federal workplace program. NIDA became the lead agency, creating its Office of Workplace Initiatives.

1987 – P.L. 100-71, Supplemental Appropriations Act of 1987, required DHHS (NIDA) to publish guidelines in the *Federal Register* for Federal drug testing.

1988 – P.L. 100-690, the Anti-Drug Abuse Act of 1988, established the Office of National Drug Control Policy (ONDCP) in the Executive Office of the President; and authorized funds for Federal,

state and local law enforcement, school-based drug prevention efforts and drug abuse treatment with special emphasis on injection drug abusers at high risk for AIDS.

1989 and 1990 – P.L. 101-166 and P.L. 101-517, the Departments of Labor, HHS, and Education Appropriations Acts for FY 1990 and 1991, contained identical prohibitions precluding the use of funds provided under these enactments to carry out any program of distributing sterile needles.

1992 – P.L. 102-321, the ADAMHA Reorganization Act, transferred NIDA to NIH; earmarked 15 percent of the Institute's research appropriation for health services research; established a Medication Development Program within NIDA; provided authority to designate Drug Abuse Research Centers for interdisciplinary research on drug abuse and related biomedical, behavioral, and social issues; and created an Office on AIDS at NIDA. P.L. 102-394, the Departments of Labor, HHS, and Education FY 1993 Appropriations Act, provided that up to \$2 million of NIDA research funds be available to carry out section 706 of P.L. 102-321, which required the DHHS Secretary, acting through NIDA, to request an NAS study of U.S. programs that provide both sterile hypodermic needles and bleach.

1993 – P.L. 103-112, the Department of Labor, HHS and Education FY 1994 Appropriations Act, prohibited the use of funds under the Act for (1) any further implementation of section 706 of P.L. 102-321 (see above); and (2) any program for distributing sterile needles.

1994 and 1996 – P.L. 103-333, the Departments of Labor, HHS and Education Appropriations Act for FY 1995; P.L. 104-134, the Omnibus Consolidated Rescissions and Appropriations Act for FY 1996; and P.L. 104-208, the Omnibus Consolidated Appropriations Act for FY 1997 – each prohibited use of any funds provided in the enactments to carry out any program of distributing sterile needles.

1997 – P.L. 105-78, the Departments of Labor, HHS, and Education Appropriation Act for FY 1998, continued prior restrictions on needle-exchange programs through 3/31/98, permitting funding thereafter of those programs meeting certain statutory requirements including criteria of the DHHS Secretary.

1998 – P.L. 105-277, the Omnibus Consolidated and Emergency Supplemental Appropriations Act-1999, restored the general prohibition on funds for needle exchange programs; statutorily reestablished ONDCP in the Executive Office of the President with significantly expanded authority over drug control agencies; and required ONDCP to conduct a four-year (FYs 1999-2002) national anti-drug media campaign aimed at youth.

1999 – P.L. 106-113, the Consolidated Appropriations Act-2000, continued the ban on funding of sterile needle and syringe exchange programs; prohibited use of appropriated funds for promotion of legalization of any Schedule I controlled substance; and postponed termination of NIDA's triennial report until 5/15/2000.

2000 – P.L. 106-554, the Consolidated Appropriations Act-2001, authorized the Director of NIH to negotiate a long-term lease for research facilities at Baltimore's Bayview Campus, and continued prior prohibitions on funding of sterile needle/syringe exchange programs and on promotion of legalization of Schedule I controlled substances. P.L. 106-310, the Children's Health Act of 2000, repealed the Narcotic Addict Rehabilitation Act of 1966 [P.L. 89-793]; waived certain requirements of the Controlled Substances Act to permit qualified physicians to engage in office-based treatment of opiate dependence; and authorized expansion of NIDA research on methamphetamine and increased emphasis on Ecstasy research.

2001 – P.L. 107-116, the Departments of Labor, HHS and Education FY 2002 Appropriations Act, continued prior prohibitions on funding of sterile needle and syringe exchange programs and on legalization of Schedule I controlled substances.

2002 – Title II of P.L. 107-273 - (HR2215), the Drug Abuse Education, Prevention, and Treatment Act of 2002, authorized NIDA expansion of interdisciplinary research and clinical trials with treatment centers of the National Drug Abuse Treatment Clinical Trials Network; and requires a NIDA study on development of medications for amphetamine/methamphetamine addiction.

2003 – Division G of P.L. 108-7, the Departments of Labor, HHS and Education FY 2003 Appropriations Act, continued prior prohibitions on funding of sterile needle and syringe exchange programs and on legalization of Schedule I controlled substances.

2004 – P.L. 108-358, The Anabolic Steroids Control Act of 2004 significantly expands the list of anabolic steroids classified as controlled substances; requires a review of federal sentencing guidelines; and authorizes \$15 million, for each of the next fiscal years through 2009, for educational programs in schools to highlight the dangers of steroids, with preference given to programs deemed effective by NIDA.

Biographical Sketch of NIDA Director, Nora D. Volkow, M.D.

Dr. Volkow became Director of the National Institute on Drug Abuse (NIDA) in May 2003. A leader in drug addiction research, she is the first woman to serve as NIDA's director since the founding of the Institute. Dr. Volkow came to NIDA from Brookhaven National Laboratory (BNL), where she held concurrent positions including associate director for life sciences, director of nuclear medicine, and director of the NIDA-Department of Energy Regional Neuroimaging Center. In addition, Dr. Volkow was a professor in the department of psychiatry and associate dean of the medical school at the State University of New York (SUNY)-Stony Brook.

Dr. Volkow brings to NIDA a long record of accomplishment in drug addiction research. She is a recognized expert on the brain's dopamine system with her research focusing on the brains of addicted, obese, and aging individuals. Her studies have documented changes in the dopamine system affecting the actions of frontal brain regions involved with motivation, drive, and pleasure and the decline of brain dopamine function with age. Her work includes more than 275 peer-reviewed publications, three edited books, and more than 50 book chapters and non-peer reviewed manuscripts. The recipient of multiple awards, she was elected to membership in the Institute of Medicine in the National Academies and was named "Innovator of the Year" in 2000 by U.S. News and World Report.

Dr. Volkow received her B.A. from Modern American School, Mexico City, Mexico, her M.D. from the National University of Mexico, Mexico City, and her postdoctoral training in psychiatry at New York University. In addition to BNL and SUNY-Stony Brook, Dr. Volkow has worked at the University of Texas Medical School and Sainte Anne Psychiatric Hospital in Paris, France.

NIDA Directors

Name	In Office From	To
Robert L. DuPont	September 1973	July 1978
William Pollin	1979	1985
Charles R. Schuster	1986	1992
Richard A. Millstein (Acting)	January 1992	1994
Alan I. Leshner	1994	November 2001
Glen R. Hanson (Acting)	December 2001	April 2003
Nora D. Volkow	May 2003	Present

Research Programs

Division of Epidemiology, Services, and Prevention Research

The Division of Epidemiology, Services and Prevention Research (DESPR); (1) plans, stimulates, develops and supports a broad extramural research program to study: (a) prevention of drug use and addiction and services research including the prevention of medical/social/ psychological sequelae of drug use; (b) innovative sampling, data collection and analytic methodologies designed to support epidemiologic and prevention and early intervention and services research; (c) the nature, patterns and consequences of drug use among general, special, community-based, and subpopulations; (d) behavioral and social science research in the context of communities and defined populations, including the consequences of drug use such as delinquency and violence; (e) services research on the impact of the organization, financing and management of treatment programs and services systems on quality, cost, access, and outcomes of care; and (f) economic modeling and configuration of the treatment system; and DESPR also (2) supports research training programs to ensure the quality and quantity of investigators in the areas of drug use/addiction prevention, epidemiology, and services research.

Division of Basic Neuroscience and Behavior Research

The primary goal of the Division of Basic Neuroscience and Behavioral Research (DBNBR) is to support basic biomedical and behavioral science research that relates to the public health problem of drug abuse and addiction. DBNBR accomplishes this goal through developing and supporting an extramural program of research in the basic biomedical and behavioral sciences. The supported research provides an understanding of the neurobiological, and behavioral effects of drugs of abuse. Research focuses on the molecular, neurobiological and genetic mechanisms of addiction, drug craving, effects of drugs on behavior and cognition, long-term chronic effects of drugs, and drug metabolism. Basic research concerned with understanding the complex interrelationship between HIV/AIDS progression and transmission and drug abuse is also supported. DBNBR supports research training to increase the skills, quantity and quality and utilization of research investigators in biomedical and behavioral disciplines in the drug abuse field. The research supported by DBNBR provides important fundamental information to for developing prevention and treatment interventions for drug abuse and addiction.

Division of Clinical Neuroscience, Development, and Behavioral Treatment

The Division of Clinical Neuroscience, Development, and Behavioral Treatment (DCNDBT) supports a broad range of research focused on translating addiction science related to brain, behavior, and health through an integrated research program in clinical neuroscience, development, and behavioral treatment, including HIV/AIDS-related factors. This division has three research branches that develop and administer national research and research training programs, the Clinical Neuroscience Branch (CNB), the Behavioral and Brain Development Branch (BBDB), and the Behavioral and Integrative Treatment Branch (BITB). The CNB advances broad translational research and research training program directed toward understanding the neurobiological substrates of drug abuse and addiction processes, including pain processes related to the pharmacology of abused drugs, and in characterizing how abused drugs affect the structure and function of the human central nervous system. Another major emphasis of this branch is on biological etiology; studies that seek to define the individual differences in neurobiological, genetic, and neurobehavioral factors that confer increased vulnerability and/or resilience to drug abuse, the transitions from use to abuse to addiction, and drug-related disorders. The BBDB supports a spectrum of research and research training programs, including research using translational approaches, directed toward understanding how developmental processes and developmental outcomes are affected by drug exposure and factors related to drug abuse. The primary focus is on behavioral and neurobiological development and includes an active research program that seeks to understand normal brain and behavioral development. Another major program within this branch is research designed to ameliorate or prevent the negative developmental outcomes that result from drug exposure and factors associated with drug use and abuse. The BITB advances broad translational research and research training programs directed toward the development, refinement, and testing of behavioral/psychosocial treatments and complementary/alternative interventions for drug abuse, alone and in combination with medications for drug addiction. This branch also supports the development and testing of interventions to promote adherence to treatment, as well

as to HIV prevention interventions for use in drug abuse treatment populations. An overall focus of this program is on strategies to attract drug abusers to treatment, retain them in treatment, and help them avoid relapse.

Center for the Clinical Trials Network

The Center for Clinical Trials Network (CCTN) supports and leads a network of 17 Regional Research Training Centers (RRTCs) and 120 Community Treatment Programs (CTPs) in a bi-directional effort to bridge the gap between the science of drug treatment and its practice through the study of scientifically based treatments in real world settings. This Clinical Trials Network (CTN) serves as a resource and forum for a) multi-site efficacy and effectiveness trials of promising medications and behavioral interventions; (b) researchers who use the CTN as a platform for studies supported outside of the CCTN; c) NIDA supported training using pre- and postdoctoral and career awards mechanisms; d) secondary analyses of its rich data base ; e) rapidly addressing emerging public health needs; and, e) the systematic transfer of research findings, both positive and negative, to treatment programs, clinicians and patients.

Division of Pharmacotherapies and Medical Consequences of Drug Abuse

The Division of Pharmacotherapies and Medical Consequences of Drug Abuse (DPMCDA) plans and directs studies necessary to identify, evaluate, develop and obtain FDA marketing approval for new medications for the treatment of drug dependence and addiction and other brain and behavioral disorders. DPMCDA develops and administers a national program of (a) basic and clinical pharmaceutical research to develop innovative pharmacological treatment approaches, DPMCDA supports research training in the fundamental and clinical sciences. DPMCDA also collaborates with: (a) the pharmaceutical and chemical industry in the United States and other Nations; and (b) the Federal medications development programs and works closely with FDA in assuring that research designed to show the clinical efficacy of new compounds is evaluated and approved in the most expeditious manner possible. DPMCDA also coordinates and provides leadership with respect to HIV/AIDS research activities, and other medical/psychiatric consequences of drug use (including such areas as prevention of HIV transmission, HIV treatment, and/or treatment and prevention of other medical/psychiatric conditions associated with drug use).

Office of Extramural Affairs

NIDA's Office of Extramural Affairs (1) provides advice and guidance to the Director regarding the Institute's peer and objective review process; (2) provides scientific analyses of the Institute's extramural research program, assessing the breadth and scope of the Institute's research activities; (3) administers the peer and objective review of all extramural grant applications; (4) administers the concept and peer review of all contract proposals; (5) administers the National Advisory Council on Drug Abuse second level review of extramural support mechanisms and advises on overall NIDA program and policy matters; (6) coordinates and assures the development of program policies and rules relating the Institute's extramural activities, including Institute responsibility for inquiries and investigations into misconduct in science; (7) coordinates Institute activities under the Privacy Act, including supervision of issuance of Confidentiality Certificates; and (8) administers the Institute's committee management function under the National Advisory Council Act.

Office of Planning and Resources Management

The Office of Planning and Resources Management (1) provides all administrative and management support services to the Institute in such areas as: financial planning, analysis, and management; administrative services; personnel management; information resources management; grants and contract management; administrative management policies, procedures, and guidelines; (2) develops and monitors the implementation of program policies and plans; and evaluates progress in meeting established Institute objectives; (3) develops data requirements pertinent to short- and long-range program planning and develops the Institute's program evaluation policy; (4) administers the Institute's program evaluation system for all Institute employees; and (5) maintains

responsibility for all management and administrative policy studies, reports, analyses, and program objectives.

Office of Science Policy and Communications

The Office of Science Policy and Communications (1) provides leadership and direction in planning, coordinating, analyzing, and evaluating the Institute's scientific research and research training programs; (2) represents the Institute's research and research training programs to other government agencies, the Congress, scientific and professional organizations, and the public; (3) evaluates, analyzes, and develops policy options in regard to the Institute's scientific research and research training activities; (4) prepares briefing materials and testimony for congressional hearings and serves as liaison with the Congress, the White House, and other significant Federal and governmental agencies; (5) prepares reports, develops responses, and provides information on legislative efforts, responds to congressional inquiries and analyzes legislative proposals for the Director; (6) advises the Director on national drug abuse policy issues; (7) conducts relevant public affairs activities and collaborates with a variety of public and private entities to enhance knowledge and awareness of NIDA's program and findings; (8) provides liaison with scientific and professional groups and private organizations; (9) develops and disseminates publications designed to communicate the current science regarding drug abuse and (10) plans, coordinates, analyzes, and evaluates the Institute's international program.

Intramural Research Program

NIDA's Intramural Research Program (IRP) is located in Baltimore, MD. Originally known as the Addiction Research Center, IRP conducts multidisciplinary research on basic biological and behavioral mechanisms that underlie drug abuse and addiction, including its causes and adverse consequences. Research is also supported on treatments for drug addiction and HIV transmission of injection drug users. Studies range from molecular to laboratory research with animals to clinical studies with human volunteers. The program employs the latest technology – including positron emission tomography – to study the action of drugs in the human brain and transgenic species to better understand the role genes in drug abuse. The intramural program also serves as a national and international training center for young investigators in the drug abuse field.

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National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892



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The NIH Almanac – Organization

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National Institute of Environmental Health Sciences Research Triangle Park, N.C.

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Mission

Asthma, bronchitis, cancer, dermatitis, and on through the alphabet to zinc deficiencies - these diseases generally result from interactions of environmental exposures, individual susceptibilities, and time, or age. The National Institute of Environmental Health Sciences (NIEHS) works to reduce environment-related illnesses and dysfunctions by understanding each element in their development and how they interrelate. The research of NIEHS, with the National Toxicology Program (NTP) headquartered at the Institute, has helped eliminate, reduce or control many hazards: lead, mercury, asbestos and many industrial chemicals, food dyes and agricultural chemicals. NIEHS research has also begun to unravel the causes of disease at a cellular level.

In fact, scientists believe a time is coming when they will be able to pinpoint the exact molecular step when environmental exposures tip a normal cell's balance toward rampant growth or other changes that lead to cell death or disease. The institute, through its emphasis on toxicogenomics, is a leader in the effort to locate these disease points - and to thus enable medicine to prevent or correct disease states. As part of this effort, the institute studies individual susceptibility to environmental and other factors through the Environmental Genome Project.

NIEHS supports training in environmental toxicology, pathology, mutagenesis, epidemiology and biostatistics, with emphasis on attracting women and minorities. The institute also funds basic and applied research on the health effects of human exposure to potentially toxic or harmful environmental agents. Its communication strategies include training, education, technology transfer, community outreach, and news and information for the general public.

NIEHS and NTP also support efforts to develop, test, and validate alternative, biological and gene-based assay systems that can augment or substitute for rodent testing in predicting the toxic effects of substances in humans. NIEHS/NTP testing helps the public and private agencies and organizations that develop regulations, policies, and procedures to prevent or reduce environmentally induced diseases.

Important Events in NIEHS History

June 7, 1960 – A study group on the Public Health Service mission and organization states that environmental health problems require increased public and private effort, and predicts that a central laboratory facility would be needed.

November 1, 1961 – The Committee on Environmental Health Problems recommends to PHS that a national center be established to undertake integrated research and other activities related to environmental health.

September 1964 – In the wake of the best-selling book by Rachel Carson, *Silent Spring* – which

forecast the deaths of birds and possibly people from the use of persistent chemicals – Congress authorizes funds to plan a central environmental health research facility.

January 7, 1965 – The U.S. Surgeon General announces the establishment of the Division of Environmental Health Sciences as a part of the National Institutes of Health.

September 26, 1967 – A deed for 509.25 acres within Research Triangle Park, N.C., is presented to the Surgeon General for a permanent site for the Division of Environmental Health Sciences.

January 12, 1969 – The Secretary of the then-Department of Health, Education and Welfare elevates the division to institute status - as the National Institute of Environmental Health Sciences.

April 1972 – The first edition of *Environmental Health Perspectives*, an NIEHS scientific journal, is issued.

April 1977 – Construction begins on NIEHS' \$65.7 million facility.

November 15, 1978 – HEW Secretary Califano announces the establishment of the National Toxicology Program.

July 14, 1981 – HHS Secretary Schweiker approves the reorganization of NIEHS, transferring the National Cancer Institute's Division of Cancer Cause and Prevention bioassay program to NIEHS.

October 5, 1981 – The National Toxicology Program is made a permanent activity of HHS.

November 20, 1985 – NIEHS is established in law by the Health Research Extension Act of 1985 (Public Law 99-158).

October 10, 1994 – Martin Rodbell, NIEHS scientist emeritus and former scientific director, is named co-recipient of the 1994 Nobel Prize in Physiology or Medicine for his work in discovering G-proteins, which transmit signals between cells.

September 14, 1994 – NIEHS and collaborators at the University of Utah announce identification of the first breast cancer gene, BRCA1.

May 12, 1995 – NIEHS announces isolation and cloning of a gene that suppresses the spread of prostate cancer.

December 6, 1995 – Experiments conducted by NIEHS researchers show that phenolphthalein, a widely used laxative, causes ovarian and other cancers in laboratory rats and mice.

February 6, 1996 – NIEHS scientists report that people who are missing the gene GST11 are more likely to get myelodysplastic syndrome, or MDS - a serious, often fatal, bone marrow disease.

July 2, 1996 – NIEHS researchers find that women who douche more than once a week are about 30 percent less likely to conceive in a given month than those who do not.

October 29, 1996 – The newly completed four-story laboratory "F Module" is dedicated on the celebration of NIEHS' 30th anniversary.

October 17-18, 1997 – NIEHS' Environmental Genome Project is announced to an international audience of scientists. The project is described as one to explore the gene variations (called "polymorphisms," which means "many forms") that influence people's susceptibility to environmental exposures that cause disease in some people, none in others.

1998 – NIEHS' Marine and Freshwater Research Centers and the U.S. Navy sponsor the ocean-theme United States Pavilion, complete with an iceberg, at the World Expo in Lisbon, Portugal.

August 10, 1998 – NIEHS and the Environmental Protection Agency jointly fund the creation of eight Children's Environmental Health Research Centers.

June 22, 1999 – The new Interagency Coordinating Committee on the Validation of Alternative Methods – a group formed by NIEHS, the National Toxicology Program (which is headquartered at NIEHS) and other health and regulatory agencies - for the first time concludes that, in many chemical tests, a non-animal test can replace the use of laboratory animals in a key test of whether a chemical is likely to burn or corrode human skin. Acceptance of this alternative test is followed on **December 28, 1999** by acceptance by regulatory agencies of the Murine Local Lymph Node Assay for products causing allergic contact dermatitis, a change likely to reduce, by thousands, the number of guinea pigs used in testing.

May 9, 2000 – The First National Allergen Survey, led by NIEHS scientists in collaboration with the Department of Housing and Urban Development, finds more than 45 percent of U.S. housing stock has bedding with dust mite allergen concentrations that exceed 2 micrograms per gram of dust, a level associated with the development of allergies.

December 14, 2000 – NIEHS-supported researchers at The Johns Hopkins University School of Public Health publish research findings showing a strong correlation between exposure to particulate matter air pollution and death from all causes including cardiovascular and respiratory illnesses. These analyses provide evidence that particulate matter pollution continues to cause adverse health outcomes and strengthens the argument for maintaining air quality standards for this pollutant.

January 2001 – Grantees from the University of Southern California publish reports showing modest increases in ambient ozone concentration are associated with increases in school absenteeism.

September 2001 – NIEHS-supported grantees in and around New York City joined forces to monitor exposures and advise clean-up crews and residents exposed to hazardous working and living conditions resulting from the terrorists attacks on the World Trade Center. Air monitoring stations were established, and many research studies were begun to determine possible adverse health effects. Grantees from the NIEHS Worker Safety and Education Program were on-site immediately following the collapse of the buildings to provide advice and assistance for protecting the health of the clean-up crews.

November 5, 2001 – NIEHS awards \$37 million to five academic research organizations to form a Toxicogenomics Research Consortium with the Institute's own National Toxicogenomics Center. Building a library of known toxins and the genes they turn "on" or "off," the Center seeks to use an array of cloned genes to review chemicals for toxicity. Further down the road, the technology may be used on individual patients to tailor preventive, diagnostic and treatment methods.

July 3, 2002 – An NIEHS analysis of data from seven European cities suggests that healthy young couples need not jump into expensive reproductive assistance too soon. The study showed that better than 90 percent of the couples who failed to achieve a pregnancy in their first year of unprotected intercourse achieved conception before a second year was out – without medical assistance.

August 29, 2002 – NIEHS-supported researchers at the University of California at San Diego discover that *B. anthracis* evades the host immune system, using a toxin called lethal factor (LF) to destroy macrophages and spread throughout the body. These results may explain why anthrax infections proceed nearly undetected until the patient is very sick and near death.

April 17, 2003 – NIEHS grantees at the Cincinnati-Children's Hospital Medical Center and the

University of Rochester Medical Center found that IQ scores for children with blood lead levels at 10 micrograms/dl were 7.4 points lower than for children at 1 microgram/dl. Surprisingly, the study also concluded that as blood lead increased from 10 to 30 micrograms/dl, there was a more modest decline in IQ scores indicating that more damage occurs at lower levels for any given exposure. These results emphasize the importance of prevention and add further evidence that there is indeed no safe level of lead exposure.

Biographical Sketch of NIEHS Director David A. Schwartz, MD., M.P.H.

Dr. David A. Schwartz became the fourth Director of the National Institute of Environmental Health Sciences (NIEHS) in May, 2005. Dr. Schwartz oversees the Institute's comprehensive research portfolio of basic and applied research to reduce the burden of human diseases that are triggered by the environment. Dr. Schwartz also serves as the Director of the National Toxicology Program, an interagency program established in 1978 by the Secretary of the U.S. Department of Health and Human Services to test chemicals and other agents of public health concern.

Prior to accepting the role of NIEHS Director, Dr. Schwartz, a nationally recognized researcher and practicing physician specializing in environmental lung disease, served at Duke University, where he held concurrent positions at the Medical Center including Vice Chair for Research and Director of Pulmonary and Critical Care Medicine. Additionally, Dr. Schwartz was Professor in the Department of Medicine, Genetics, and Environmental Sciences at the University since 2000. While at Duke, Dr. Schwartz played a pivotal role in establishing three interdisciplinary Centers in Environmental Health Sciences, Environmental Genomics, and Environmental Asthma, illustrating his commitment to bring together an array of scientific expertise with state-of-the-art technology to tackle critical public and individual health issues.

Throughout his career as a physician-scientist, Dr. Schwartz has made numerous contributions toward understanding the role that biological and genetic determinants play in the onset of diseases like asthma and other chronic pulmonary diseases that are influenced by environmental exposures. His research identified endotoxins or lipopolysaccharide (LPS) as an important cause of airway disease among those exposed to agricultural dusts. He is recognized for his role in identifying that a specific genetic variation in the Toll-4 gene is associated with a diminished airway response to inhaled LPS in humans, and that this same variation places individuals at higher risk of sepsis. Dr. Schwartz' interest in environmental and occupational lung disease has provided new insights into many other areas including; the pathophysiology and biology of asbestos induced lung disease, interstitial lung disease or lung scarring, environmental airway diseases, and innate immunity, or an organism's natural ability to resist diseases.

Dr. Schwartz has authored more than 150 peer-reviewed research papers, 38 book chapters, and a textbook. He has served on numerous editorial boards and scientific review committees including, most recently, the NIH/National Heart Lung and Blood Institute's Innovative Grant Program Review Committee and the VA Merit Review Board. He is a member of the American Society for Clinical Investigation and the Association of American Physicians. The recipient of many awards, the American Thoracic Society presented Dr. Schwartz with a Scientific Accomplishment Award in 2003.

A native of New York, Dr. Schwartz earned his BA in biology from the University of Rochester in 1975. He received his medical degree from the University of California, San Diego, in 1979. After completing a residency and chief residency in Internal Medicine at Boston City Hospital, he completed a fellowship in Occupational Medicine at Harvard School of Public Health, where he received his MPH in 1985. While at the University of Washington, Dr. Schwartz completed a research fellowship in the prestigious Robert Wood Johnson Clinical Scholars Program, then served as a Pulmonary and Critical Care Fellow. In 1988 he joined the faculty at the University of Iowa, where he rose through the ranks becoming Director of Occupational Medicine in the Department of Internal Medicine, until he joined Duke University in 2000. Dr. Schwartz is married to Dr. Louise Sparks and they have three children.

NIEHS Directors

Name	In Office From	To
Paul Kotin	November 1, 1966	February 28, 1971
David P. Rall	March 1, 1971	October 1, 1990
David G. Hoel (Acting)	October 1990	June 1991
Kenneth Olden	June 18, 1991	May 21, 2005
David A. Schwartz	May 22, 2005	Present

Major Programs

Through its research programs, NIEHS is providing a science base for protecting the health of Americans by preventing environmentally related diseases.

The growth of population and technology can increase environmental contamination problems, as can new forms of energy production, expanded uses of plastics and aerosols, and greater development of the chemical industry. Recent experiences with asbestos, mercury, vinyl chloride, bischloromethyl ether, methyl butyl ketone, sulfuric acid mist, polychlorinated and polybrominated biphenyls, kepone, dioxins, methylisocyanate, and chlorophenol indicate these compounds are not theoretical threats but real causes of illness and death.

NIEHS' *Division of Extramural Research and Training* supports investigators at colleges, universities, and research foundations through individual research grants, program project grants and other support mechanisms. These research activities provide information essential to an understanding of the way in which human health is adversely affected by chemical, physical and other environmental factors. The breadth of the institute's mission dictates a multidisciplinary approach to problem solving which involves major biological, chemical, and physical science disciplines.

Through this division, the institute supports basic and applied research on the consequences of the exposure of humans to potentially toxic or harmful agents in the environment.

Environmental Health Sciences Centers. These centers, at universities throughout the country, support multidisciplinary research in environmental health problems. They fill critical needs in the national environmental health program that cannot be met by individual research grants or program project grants. Each center has a different thrust and problem orientation. Overall, they serve as national focal points and resources for research and manpower development in health problems related to air, water and food pollution occupational and industrial health and safety heavy metal toxicity agricultural chemical hazards and the relationships of environment to cancer, birth defects, behavioral anomalies, respiratory and cardiovascular diseases, and diseases of other organs.

Much of the research conducted by the centers, in addition to substantive contributions to preventive medicine, has served to clarify the scope of environmental health problems and future needs in this field.

Marine and Freshwater Biomedical Sciences Centers foster multidisciplinary research on marine and freshwater organisms in the study of mechanisms of toxicity of environmental agents, as models for human diseases and disorders resulting from exposure to environmental toxicants.

Research Manpower Development Programs support pre- and postdoctoral training in toxicology, pathology, mutagenesis, and epidemiology and biostatistics as they pertain to the environment. Three mechanisms are used to fund training: 1) institutional awards for pre- and postdoctoral trainees (training programs); 2) individual awards for postdoctoral fellows only (fellowship awards); and 3) senior fellowship awards to support training for new research oriented physician-researchers to enhance the teaching of environmental and occupational medicine. The division uses the environmental/occupational medicine academic award for curriculum and institutional resource

development.

The *Superfund Basic Research Program* is university-based basic research supported by NIEHS under the 1986 Superfund Amendments and Reauthorization Act. The program combines basic research in ecology, engineering, and hydrogeology into a core program of biomedical research to provide a broader and more detailed body of scientific information to be used in decisionmaking related to the management of hazardous substances.

The *Division of Intramural Research* conducts basic, applied, and clinical research directed toward increasing fundamental knowledge of environmentally related diseases and disorders. Broad approaches are used, including basic mechanistic studies at the cellular and molecular level, applied toxicology testing, and clinical and epidemiology studies. Intramural scientists address such complex research issues as genetic susceptibility, receptor mediated pathobiology, differentiation and development, signal transduction, environmental regulation of cell proliferation and cell death, environmental carcinogenesis and mutagenesis, and environmental epidemiology.

These research endeavors, in turn, support such biomedical and clinical program interests as the environmental contributions to aging and age-related diseases and conditions (e.g., neurodegenerative diseases like Alzheimer's and Parkinson's, osteoporosis, cancer of the breast, prostate, endometrium and lung), environmental factors and respiratory disease (e.g., asthma and respiratory fibrosis), environmental contribution to reproductive and developmental disorders (e.g., infertility, abnormal growth and development, reproductive senescence), and how environmental factors interact with proteins and other cellular responses (e.g., abnormal hormonal influences and structures of critical cellular molecules that are targets of environmental factors).

DIR pursues its scientific goals principally through its laboratories and branches in three scientific programs: the Environmental Biology and Medicine Program, the Environmental Carcinogenesis Program, and the Environmental Toxicology Program.

Division of Research Coordination, Planning, and Translation (DRCPT)

Division of Research Coordination, Planning, and Translation was established in 2003 by Dr. Kenneth Olden, Director of the National Institute of Environmental Health Sciences (NIEHS). The goal of the division is to improve public health by facilitating collaboration and communication in order to achieve efficient translation of NIEHS programs into public health and the practice of medicine. This goal is achieved by planning and evaluating NIEHS research and training programs related to environmental exposures and their impact on human health; coordinating intramural, extramural, and interagency activities to achieve optimal research productivity; publishing the journal *Environmental Health Perspectives (EHP)*, which consists of news and research on all areas of environmental health sciences; providing access to information about the NIEHS and its research for the American public; managing strategic information services and resources that advance environmental health research; and facilitating cooperation among NIEHS scientists, commercial biotechnology and pharmaceutical industries, and academic institutions to make publicly funded biomedical research data available for human health. Overall, DRCPT is aimed at ensuring that NIEHS research reaches the public and those professionals who can apply it to medical care and public health. The Division's mission is accomplished through its branches and offices: Office of Policy, Planning, and Evaluation; Office of Communications and Public Liaison; Environmental Health Perspectives Branch; Library and Information Services Branch; and Office of Technology Transfer.

Office of Policy, Planning, and Evaluation (OPPE)

Office of Policy, Planning, and Evaluation is responsible for strategic and other research planning activities; program evaluation and institutional review; research information collection and information management; program analysis and program development; development of Institute budget-related justifications and other budgetary and appropriations support materials; interagency liaison; legislative analysis and impact review; legislative affairs; planning and coordination of NIEHS

town meetings; and external affairs related to Institute research activities and Institute policies. OPPE staff collect information and write reports in response to a variety of queries from NIH, HHS, the White House, Congress, the Office of Management and Budget, the Government Accounting Office, the Institute of Medicine, public advocacy groups, and others. OPPE staff author journal articles, policy papers, briefing papers, impact papers, and speeches. OPPE staff represent the Institute on many interagency committees and activities, several in a leadership role.

Office of Communications and Public Liaison (OCPL)

Office of Communications and Public Liaison conveys information about the Institute and its research and training to the general public through the news media, by the distribution of news releases and by working with media representatives in accessing experts on subjects of interest. The office designs, develops and maintains the Institute's external web site; scripts and produces orientation videos and public service announcements; handles public inquiries submitted by phone, correspondence, email; and designs and staffs exhibits at a number of major scientific meetings each year. The office conducts a program of internal Institute communications to keep employees updated on Institute research and programs. Freedom of Information and Privacy Act requests are handled by this office. Also, the OCPL is a conduit for public concerns to be relayed to senior staff. The overall mission of the office is to provide access to information about the Institute and its research for the American public.

Environmental Health Perspectives Branch (EHPB)

Environmental Health Perspectives Branch serves as the Institute's focal point for global dissemination of information to those who work in the field of environmental health sciences and publishes the journal *Environmental Health Perspectives (EHP)*, which consists of news and research on all areas of environmental health sciences. *EHP* publishes 17 issues annually that include: a monthly children's environmental health section, a monthly environmental medicine section, a quarterly Toxicogenomics section, and occasional mini-monographs.

Library and Information Services Branch (LISB)

Library and Information Services Branch manages strategic information services and resources that advance environmental health research. LISB actively partners with researchers by providing them with the decision-making information most appropriate for their needs as quickly as possible. LISB also collaborates with policy analysts to convey analytical and quantitative information about research programs at NIEHS. LISB develops policies, databases, and other resources that help communicate environmental health information to the public. LISB uses state-of-the-art technology to provide organization-wide access to online journals and databases in the biomedical sciences; training to use those resources; books, photocopies, and digital copies through an international interlibrary loan system; in-depth reference assistance and literature searching; and collaboration on developing innovative means of information delivery.

Office of Technology Transfer

The Office of Technology Transfer facilitates cooperation among NIEHS, NIH scientists, commercial biotechnology and pharmaceutical industries, and academic institutions to make publicly funded biomedical research data available for human health. This office reviews and approves Material Transfer Agreements (MTAs), Cooperative Research and Development Agreements (CRADAs), Employee Invention Reports (EIRs), and biologic license applications within NIH established policies so that NIEHS can conduct and share research data with the private sector. Technology Transfer serves as the focal point for bringing together shared research objectives among scientists in the United States, Europe, and Asia and advises NIEHS scientists about NIH policies and procedures. This office coordinates these technology transfer functions with the NIH Office of Technology Transfer, Bethesda, Deans and/or Research Provosts in academia, and Directors of Research/Medical Affairs in commercial organizations.

This page was last reviewed on August 18, 2005 .

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National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892



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National Institute of General Medical Sciences

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Mission

The National Institute of General Medical Sciences (NIGMS) primarily supports basic biomedical research that lays the foundation for advances in disease diagnosis, treatment, and prevention. The Institute's training programs help provide the most critical element of good research: well-prepared scientists.

NIGMS is one of the National Institutes of Health (NIH), the principal biomedical research agency of the Federal Government. NIH is a component of the U.S. Department of Health and Human Services.

Each year, NIGMS-supported scientists make major advances in understanding fundamental life processes. In the course of answering basic research questions, these investigators also increase our knowledge about the mechanisms and pathways involved in certain diseases. Other grantees develop important new tools and techniques, many of which have medical applications. In recognition of the significance of their work, a number of NIGMS grantees have received the Nobel Prize and other high scientific honors.

NIGMS is organized into divisions and a center that support research and research training in basic biomedical science fields. One division has the specific mission of increasing the number of underrepresented minority biomedical and behavioral scientists.

NIGMS was established in 1962. In fiscal year 2005, its budget was \$1.9 billion. The vast majority of this money funds grants to scientists at universities, medical schools, hospitals, and research institutions throughout the country. At any given time, NIGMS supports over 4,500 research grants — about 10 percent of the grants funded by NIH as a whole. NIGMS also supports approximately 26 percent of the trainees who receive assistance from NIH.

The institute places great emphasis on the support of individual, investigator-initiated research grants. It funds a limited number of research center grants in selected fields, including structural genomics, trauma and burn research, and the pharmacological sciences. In addition, NIGMS funds several important resources for basic scientists.

In recent years, NIGMS has launched initiatives in such cutting-edge areas as structural genomics (the Protein Structure Initiative), pharmacogenetics, collaborative research initiatives (which includes "glue grants"), and systems biology. NIGMS is also participating in the NIH Roadmap for Medical Research, a series of far-reaching initiatives that seek to transform the nation's biomedical research capabilities and speed the movement of research discoveries from the bench to the bedside.

NIGMS research training programs recognize the interdisciplinary nature of biomedical research today and stress approaches to biological problems that cut across disciplinary and departmental lines. Such experience prepares trainees to pursue creative research careers in a wide variety of

areas.

Certain NIGMS training programs address areas in which there is a particularly serious need for well-prepared scientists. One of these, the Medical Scientist Training Program, provides investigators who can bridge the gap between basic and clinical research by supporting research training leading to the combined M.D.-Ph.D. degree. Other programs train scientists to conduct research in the rapidly growing field of biotechnology and at the interface between the fields of chemistry and biology.

NIGMS also has a Pharmacology Research Associate Program, in which postdoctoral scientists receive training in NIH or FDA laboratories and clinics.

Important Events in NIGMS History

July 16, 1958 – The Secretary, DHEW, approved establishment of the Division of General Medical Sciences.

October 17, 1962 – Congress authorized establishment of the National Institute of General Medical Sciences.

January 30, 1963 – The DHEW Secretary approved establishment of NIGMS.

October 8, 1963 – The National Advisory General Medical Sciences Council held its first meeting.

October 13, 1982 – NIGMS celebrated its 20th anniversary by establishing the DeWitt Stetten, Jr., Lecture. Dr. David S. Hogness, Stanford University, gave the first lecture.

October 1, 1989 – Administration of the Minority Biomedical Research Support Program was transferred to NIGMS from the NIH Division of Research Resources.

May 14, 2001 – NIGMS created the Center for Bioinformatics and Computational Biology.

NIGMS Legislative Chronology

October 17, 1962 – Public Law 87-838 authorized the Surgeon General to establish an institute to conduct and support research and research training in the general or basic medical sciences and in related natural or behavioral sciences that have significance for two or more other institutes of NIH, or that lie outside the general areas of responsibility of any other institute.

Biographical Sketch of NIGMS Director Jeremy M. Berg, Ph.D.

Dr. Berg became the NIGMS director in November 2003. Prior to his appointment, he directed the Institute for Basic Biomedical Sciences at The Johns Hopkins University School of Medicine in Baltimore, Maryland, where he also served as a professor and director of the Department of Biophysics and Biophysical Chemistry. In addition, he directed the Markey Center for Macromolecular Structure and Function and co-directed the W.M. Keck Center for the Rational Design of Biologically Active Molecules at the university.

Dr. Berg's research focuses on the structural and functional roles that metal ions, especially zinc, have in proteins. He has made major contributions to understanding how zinc-containing proteins bind to the genetic material DNA or RNA and regulate gene activity. His work, and that of others in the field, has led to the design of metal-containing proteins that control the activity of specific genes. These tailored proteins are valuable tools for basic research on gene function, and such proteins could one day have medical applications in regulating genes involved in diseases, as well. Dr. Berg has also made contributions to our understanding of systems that target proteins to specific

compartments within cells and to the use of sequence databases for predicting aspects of protein structure and function.

Dr. Berg served on the faculty at Johns Hopkins from 1986-2003. Immediately before his faculty appointment, he was a postdoctoral fellow in biophysics at the university. He is the recipient of numerous awards, including a Presidential Young Investigator Award (1988-1993), the American Chemical Society Award in Pure Chemistry (1993), the Eli Lilly Award for Fundamental Research in Biology Chemistry (1995), and the Maryland Outstanding Young Scientist of the Year (1995). He also received teaching awards from both medical students and graduate students and served as an advisor to the Johns Hopkins Postdoctoral Association since its founding.

Dr. Berg received B.S. and M.S. degrees in chemistry from Stanford University in 1980 and a Ph.D. in chemistry from Harvard University in 1985. He is the coauthor of more than 120 research papers and 3 textbooks, *Principles of Bioinorganic Chemistry*, *Biochemistry (5th Edition)*, and *A Clinical Companion to Accompany Biochemistry*.

NIGMS Directors

Name	In Office From	To
Clinton C. Powell	July 1962	July 1964
Frederick L. Stone	August 1964	April 1970
DeWitt Stetten, Jr.	October 1970	August 1974
Ruth L. Kirschstein	September 1974	July 1993
Marvin Cassman (Acting)	July 1993	August 1996
Marvin Cassman	August 1996	May 2002
Judith H. Greenberg (Acting)	May 2002	November 2003
Jeremy M. Berg	November 2003	Present

Major Programs

Division of Cell Biology and Biophysics

The Division of Cell Biology and Biophysics seeks greater understanding of the structure and function of cells, cellular components, and the biological macromolecules that make up these components. The research it supports ranges from studies of single molecules to work in structural genomics and proteomics. The long-term goal of the division is to find ways to prevent, treat, and cure diseases that result from disturbed or abnormal cellular activity.

The division has three components: the Biophysics Branch, the Cell Biology Branch, and the Structural Genomics and Proteomics Technology Branch.

Biophysics Branch

This branch supports studies in the areas of biophysics, a discipline that uses techniques derived from the physical sciences to examine the structures and properties of biological substances.

Areas of emphasis in biophysical research include the determination of the structures of proteins and nucleic acids; studies of the structural features that determine macromolecular conformation; the structural analysis of macromolecular interactions and of ligand-macromolecular interactions; bioinformatics as it relates to protein and nucleic acid structure; the development of physical methodology for the analysis of molecular structure; and the development and use of theoretical methods to investigate biological systems.

Other research interests include the development and refinement of instruments needed to conduct research in the areas described above. These include nuclear magnetic resonance spectroscopy, X-ray crystallography and other scattering techniques; optical spectroscopy and other forms of microscopy. This branch also supports the development of new bioanalytical methods and biomaterials.

Cell Biology Branch

This branch supports general studies on the molecular and biochemical activities of cells and subcellular components, as well as on the role of cellular dysfunction in disease. Emphasis is placed on research with applications to more than one cell type, model system, or disease state, as well as research that does not fall within the disease-oriented mission of another NIH component.

Representative studies include those on plasma and intracellular membranes, receptors, and signal transduction mechanisms; the structure and function of the cytoskeleton; cell motility; the regulation of protein and membrane synthesis and activation of cell growth; subcellular organelles; cell division; and lipid biochemistry.

Structural Genomics and Proteomics Technology Branch

This branch supports studies that take a genomics or computational approach to determining protein structures and functions. Such research includes the development of high-throughput methods for protein structure determination, bioinformatics as it relates to the analysis of protein structures *en masse*, and the development of mass spectroscopy and other tools for the rapid analysis of biological molecules.

The branch is responsible for monitoring the research centers and research grants associated with the NIGMS Protein Structure Initiative (PSI). This responsibility also includes developing a database of model structures and a repository for the distribution of materials resulting from the PSI.

Division of Genetics and Developmental Biology

The Division of Genetics and Developmental Biology supports studies directed toward gaining a better understanding of the fundamental mechanisms of inheritance and development. These studies underlie the more targeted research projects supported by other NIH components. Most of the projects supported by the division make use of non-human model systems. It is expected that the results of these studies will lead to the eventual diagnosis, prevention, therapy, and cure of human genetic and developmental disorders.

Among areas under active investigation are cell growth and differentiation; chromosome organization and mechanics; control of gene expression; developmental genetics; extrachromosomal inheritance; mechanisms of mutagenesis; neurogenetics and the genetics of behavior; population genetics, evolution, and the genetics of complex traits; protein synthesis, the replication, recombination, and repair of genes; and RNA processing and transcription.

Along with its research and research training activities, the division supports the Human Genetic Cell Repository, in which cell lines and DNA samples from people with genetic disorders and their family members, as well as somatic cell hybrids, are stored and made available for studies by scientists.

Division of Minority Opportunities in Research

The Division of Minority Opportunities in Research administers research and research training programs aimed at increasing the number of minority biomedical scientists. Support is available at the undergraduate, graduate, postdoctoral, and faculty levels, as well as for education and research infrastructure improvements.

The division has three components: the Minority Access to Research Careers (MARC) Branch, Minority Biomedical Research Support (MBRS) Branch, and Special Initiatives.

MARC Branch

The MARC Branch offers special research training support to four-year colleges, universities, and health professional schools with substantial enrollments of such minorities as African Americans, Hispanic Americans, Native Americans (including Alaska Natives), and natives of the U.S. Pacific Islands. The branch's goals are to increase the number and competitiveness of underrepresented minorities engaged in biomedical research by strengthening the science curricula at minority-serving institutions and increasing the research training opportunities for students and faculty at these institutions.

MBRS Branch

To increase the number of researchers who are members of minority groups underrepresented in the biomedical sciences, the MBRS Branch awards grants to two- or four-year colleges, universities, and health professional schools with substantial enrollments of minorities. These grants support research by faculty members, strengthen the institutions' biomedical research capabilities, and provide opportunities for students to work as part of a research team.

Special Initiatives

The division develops and launches new research and research training programs and other initiatives for minority scientists. These include the Bridges to the Future Programs (Bridges to the Baccalaureate and Bridges to the Doctorate), that are co-sponsored by the NIH National Center on Minority Health and Health Disparities.

The division is also responsible for organizing meetings and other activities that build networks among individuals and educational institutions to promote minority participation in sponsored research.

Division of Pharmacology, Physiology, and Biological Chemistry

The Division of Pharmacology, Physiology, and Biological Chemistry supports a broad spectrum of research and research training aimed at improving the molecular-level understanding of fundamental biological processes and discovering approaches to their control. Research supported by the division takes a multifaceted approach to problems in pharmacology, physiology, biochemistry, and biorelated chemistry that are either very basic in nature or that have implications for more than one disease area.

The goals of supported research include an improved understanding of drug action and mechanisms of anesthesia; pharmacogenetics and mechanisms underlying individual responses to drugs; new methods and targets for drug discovery; advances in natural products synthesis; an enhanced understanding of biological catalysis; a greater knowledge of metabolic regulation and fundamental physiological processes; and the integration and application of basic physiological, pharmacological, and biochemical research to clinical issues in anesthesia, clinical pharmacology, and trauma and burn injury. The division also supports quantitative studies of complex systems involving areas within its scope.

Biochemistry and Biorelated Chemistry Branch

This branch supports basic research in areas of biochemistry, such as enzyme catalysis and regulation, bioenergetics and redox biochemistry, and glycoconjugates. It also supports research in areas of biorelated chemistry, such as organic synthesis and methodology, as well as bioinorganic and medicinal chemistry.

Examples of biochemical investigations include studies of the chemical basis of the regulation and catalytic properties of enzymes, intermediary metabolism, the chemical and physical properties of the cellular systems for electron transport and energy transduction, and the biosynthesis and structure of carbohydrate-containing macromolecules.

Chemical investigation examples include the development of strategies for natural products synthesis, studies of the structure and function of small molecules, the chemistry of metal ions in biological systems, the development of novel medicinal agents or mimics of macromolecular function, and the creation of new synthetic methodologies.

The branch also supports studies in biotechnology. This work focuses on the development of biological catalysts, including living organisms, for the production of useful chemical compounds, medicinal or diagnostic agents, or probes of biological phenomena.

Pharmacological and Physiological Sciences Branch

This branch supports research in pharmacology, anesthesiology, and the physiological sciences. Studies range from the molecular to the organismal level, and can be clinical in nature.

In the pharmacological sciences and anesthesiology, important areas being studied are the effects of drugs on the body and the body's effects on drugs, as well as how these effects vary from individual to individual. This includes traditional investigations of the absorption, transport, distribution, metabolism, biotransformation, and excretion of drugs, as well as drug delivery strategies and determinants of bioavailability. It also includes a newer focus on pharmacogenetics, linking phenotype to genotype in drug action.

Understanding the mechanisms of drug interactions with receptors and signal transduction mechanisms is another major focus of this section. This includes studies of soluble and membrane-bound receptors and channels, secondary and tertiary messenger systems, mediator molecules, and their regulation and pharmacological manipulation.

Examples of studies in the physiological sciences include basic and clinical investigations directed toward improving understanding of the total body response to injury, including the biochemical and physiological changes induced by trauma. Research supported in this section includes studies on the etiology of post-traumatic sepsis and the mechanisms of immunosuppression, wound healing, and hypermetabolism following injury. This section also supports research in basic molecular immunobiology which focuses on using cells of the immune system to study fundamental cellular and molecular mechanisms.

Division of Extramural Activities

The Division of Extramural Activities is responsible for the grant-related activities of the institute, including the receipt, referral, and advisory council review of applications as well as grant funding and management. It maintains an overview of the institute's scientific and financial status and advises the NIGMS director and other key staff on policy matters and on the planning, development, and scientific administration of institute research and training programs. The division recommends budget allocations for the various NIGMS programs. It also acts as a liaison with other NIH components for activities relating to grant application assignments and foreign grants.

Center for Bioinformatics and Computational Biology

The Center for Bioinformatics and Computational Biology supports research and research training in areas that join biology with the computer sciences, engineering, mathematics, and physics. Toward this end, the center develops and manages programs in computational biology, such as the generation of mathematical models of biological networks, the development of modeling and

simulation tools, the conduct of basic theoretical studies related to network organization and dynamic processes, and the development of methods for the analysis and dissemination of computational models. The center also defines the institute's needs for database development and applications, and it collaborates with other NIH components and Federal agencies in developing policies in this area. Other center activities include the support of multidisciplinary collaborations and of workshops, courses, and specialized meetings.

The center oversees NIH's Biomedical Information Science and Technology Initiative (BISTI) through its management of the BISTI Consortium (BISTIC). The goal of this initiative is to make optimal use of computer science and technology to address problems in biology and medicine. BISTIC is composed of senior-level representatives from the NIH institutes and centers and representatives of other Federal agencies concerned with bioinformatics and computer-based applications.

This page was last reviewed on January 11, 2006 .

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National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892



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National Institute of Mental Health

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Mission

The mission of the National Institute of Mental Health (NIMH) is to reduce the burden of mental illness and behavioral disorders through research on mind, brain, and behavior.

In the United States, mental disorders collectively account for more than 15 percent of the overall "burden of disease" – a term that encompasses both premature death and disability associated with mental illness. Mental disorders occur across the life span, from very young childhood into old age.

Investments made over the past 50 years in basic brain and behavioral science have positioned NIMH to exploit recent advances in neuroscience, molecular genetics, behavioral science and brain imaging; to translate new knowledge about fundamental processes into researchable clinical questions; and to initiate innovative clinical trials of new pharmacological and psychosocial interventions, with emphasis on testing their effectiveness in the diagnostically complex, diverse group of patients typically encountered in front-line service delivery systems. NIMH-funded investigators also seek new ways to translate results from basic behavioral science into research relevant to public health, including the epidemiology of mental disorders, prevention and early intervention research, and mental health service research.

Diverse scientific disciplines contribute to the design and evaluation of treatments and treatment delivery strategies that are relevant and responsive to the needs of persons with and at risk for mental illness. A thrust of this research is to eliminate the effects of disparities in the availability of and access to high quality mental health services. These disparities, which impinge on the mental health status of all Americans, are felt in particular by many members of ethnic/cultural, minority groups, and by women, children, and elderly people.

In this era of opportunity, NIMH is strongly committed to scientific programs to educate and train future mental health researchers, including scientists trained in molecular science, cognitive and affective neuroscience, and other disciplines urgently needed in studies of mental illness and the brain.

Mechanisms of Support. The NIMH provides leadership at a national level for research on brain, behavior, and mental illness.

Under a rigorous and highly competitive process, the institute funds research project and research center grant awards and contracts to individual investigators in fields related to its areas of interest and to public and private institutions. NIMH also maintains and conducts a diversified program of intramural and collaborative research in its own laboratories and clinical research units at the National Institutes of Health.

NIMH's informational and educational activities include the dissemination of information and

education materials on mental illness to health professionals and the public; professional associations; international, national, state, and local officials; and voluntary organizations working in the areas of mental health and mental illness.

Important Events in NIMH History

1946 – On July 3 President Truman signs the National Mental Health Act, which called for the establishment of a National Institute of Mental Health. The first meeting of the National Advisory Mental Health Council (NAMHC) was held on August 15. Because no federal funds had yet been appropriated for the new institute, the Greentree Foundation financed the meeting.

1947 – On July 1 the PHS Division of Mental Hygiene awarded the first mental health research grant (MH-1) entitled "Basic Nature of the Learning Process" to Dr. Winthrop N. Kellogg of Indiana University.

1949 – On April 15 the NIMH was formally established; it was one of the first four NIH institutes.

1955 – The Mental Health Study Act of 1955 (P.L. 84-182) called for "an objective, thorough, nationwide analysis and reevaluation of the human and economic problems of mental health." The resulting Joint Commission on Mental Illness and Health issued a report, *Action for Mental Health* that was researched and published under the sponsorship of 36 organizations making up the Commission.

1961 – *Action for Mental Health*, a 10-volume series, assessed mental health conditions and resources throughout the United States "to arrive at a national program that would approach adequacy in meeting the individual needs of the mentally ill people of America." Transmitted to Congress on December 31, 1960, the report commanded the attention of President John F. Kennedy, who established a cabinet level interagency committee to examine the recommendations and determine an appropriate federal response.

1963 – President Kennedy submitted a special message to Congress – the first Presidential message to Congress on mental health issues. Energized by the President's focus, Congress quickly passed the Mental Retardation Facilities and Community Mental Health Centers Construction Act (P.L. 88-164), beginning a new era in Federal support for mental health services. NIMH assumed responsibility for monitoring the Nation's community mental health centers (CMHC) programs.

1965 – During the mid-1960s, NIMH launched an extensive attack on special mental health problems. Part of this was a response to President Johnson's pledge to apply scientific research to social problems. The Institute established centers for research on schizophrenia, child and family mental health, suicide, as well as crime and delinquency, minority group mental health problems, urban problems, and later, rape, aging, and technical assistance to victims of natural disasters. A provision in the Social Security Amendments of 1965 (P.L. 89-97) provided funds and a framework for a new Joint Commission on the Mental Health of Children to recommend national action for child mental health.

Also in this year, staffing amendments to the CMHC act authorized grants to help pay the salaries of professional and technical personnel in federally funded Community Mental Health Centers.

Alcohol abuse and alcoholism did not receive full recognition as a major public health problem until the mid-1960s, when the National Center for Prevention and Control of Alcoholism was established as part of NIMH; a research program on drug abuse was inaugurated within NIMH with the establishment of the Center for Studies of Narcotic and Drug Abuse.

1967 – NIMH separated from NIH and was given Bureau status within PHS by reorganization effective January 1. However, NIMH's intramural research program, which conducted studies in the

NIH Clinical Center and other NIH facilities, remained at NIH under an agreement for joint administration between NIH and NIMH.

On August 13 DHEW Secretary John W. Gardner transferred St. Elizabeth's Hospital, the Federal Government's only civilian psychiatric hospital, to NIMH.

1968 – NIMH became a component of PHS's Health Services and Mental Health Administration (HSMHA).

1970 – Dr. Julius Axelrod, an NIMH researcher, won the Nobel Prize in Physiology or Medicine for research into the chemistry of nerve transmission for "discoveries concerning the humoral transmitters in the nerve terminals and the mechanisms for their storage, release and inactivation." He found an enzyme that terminated the action of the nerve transmitter, noradrenaline in the synapse and which also served as a critical target of many antidepressant drugs.

In a major development that reaped untold benefits for people suffering from manic-depressive illness (bipolar disorder), the FDA approved the use of lithium as a treatment for mania, based upon NIMH research. The treatment led to sharp drops in inpatient days and suicides among people with this serious mental illness and to immense savings in the economic costs associated with bipolar disorder.

Also during this year, the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act (P.L. 91-616) established the National Institute of Alcohol Abuse and Alcoholism within NIMH.

1972 – The Drug Abuse Office and Treatment Act established a National Institute on Drug Abuse within NIMH.

1973 – NIMH went through a series of organizational moves. The Institute temporarily rejoined NIH on July 1 with the abolishment of HSMHA. Then, the DHEW secretary administratively established the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) – composed of the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and NIMH – as the successor organization to HSMHA.

1974 – ADAMHA was officially established on May 4 when President Nixon signed P.L. 93-282.

1975 – The community mental health centers program was given added impetus with the passage of the CMHC amendments of 1975.

1977 – President Carter established the President's Commission on Mental Health on February 17 by Executive Order No. 11973. The commission was charged to review the mental health needs of the Nation, and to make recommendations to the President as to how best meet these needs. First Lady Rosalyn Carter served as the Honorary Chair of the commission.

1978 – The 4-volume Report to the President from the President's Commission on Mental Health was submitted.

1980 – The Epidemiologic Catchment Area (ECA) study, an unprecedented research effort that entailed interviews with a nationally representative sample of 20,000 Americans was launched. The field interviews and first wave analyses were completed in 1985. Data from the ECA provided an accurate picture of rates of mental and addictive disorders and services usage.

The Mental Health Systems Act – based on recommendations of the President's Commission on Mental Health and designed to provide improved services for persons with mental disorders – was passed. NIMH also participated in development of the National Plan for the Chronically Mentally Ill,

a sweeping effort to improve services and fine-tune various Federal entitlement programs for those with severe, persistent mental disorders.

1981 – President Ronald Reagan signed the Omnibus Budget Reconciliation Act of 1981. This act repealed the Mental Health Systems Act and consolidated ADAMHA's treatment and rehabilitation service programs into a single block grant that enabled each State to administer its allocated funds. With the repeal of the community mental health legislation and the establishment of block grants, the Federal role in services to the mentally ill became one of providing technical assistance to increase the capacity of State and local providers of mental health services.

Dr. Louis Sokoloff, an intramural NIMH researcher, received the Albert Lasker Award in Clinical Medical Research for developing a new method of measuring brain function that contributed to basic understanding and diagnosis of brain diseases. His technique, which measures the brain's utilization of glucose, made possible exciting new applications positron emission tomography, or PET scanning, the first imaging technology that permitted scientists to "observe" and obtain visual images of the living, functioning brain.

Dr. Roger Sperry, a longtime NIMH research grantee, received the Nobel Prize in Medicine or Physiology for discoveries regarding the functional specialization of the cerebral hemispheres, or the "left" and "right" brain.

1983 – NIMH-funded investigator Fernando Nottebohm discovered the formation of new neurons in brains of adult song-birds; this evidence of "neurogenesis" opened an exciting and clinically promising new line of research in brain science; it was 15 years, however, before investigators reported finding evidence for continued neurogenesis in the brains of adult human subjects.

1987 – Administrative control of St. Elizabeth's Hospital is transferred from the NIMH to the District of Columbia. NIMH retained research facilities on the grounds of the hospital.

1989 – Congress passed a resolution, subsequently signed as a proclamation by President George Bush, designating the 1990s as the "Decade of the Brain."

The NIMH Neuroscience Center and the NIMH Neuropsychiatric Research Hospital, located on the grounds of St. Elizabeth's Hospital, were dedicated on September 25.

1992 – Congress passed the ADAMHA Reorganization Act (P.L. 102-321), abolishing ADAMHA. The research components of NIAAA, NIDA and NIMH rejoined NIH, while the services components of each institute became part of a new PHS agency, the Substance Abuse and Mental Health Services Administration (SAMHSA). The return to NIH and the loss of services functions to SAMHSA necessitated a realignment of the NIMH extramural program administrative organization. New offices are created for research on Prevention, Special Populations, Rural Mental Health and AIDS.

1993 – NIMH established the Silvio O. Conte Centers program to provide a unifying research framework for collaborations to pursue newly formed hypotheses of brain-behavior relationships in mental illness through innovative research designs and state-of-the-art technologies.

NIMH established the Human Brain Project to develop, through cutting-edge imaging, computer, and network technologies, a comprehensive neuroscience database accessible via an international computer network.

1994 – Intramural Research Program Revitalization – The House Appropriations Committee mandated that the director of NIH conduct a review of the role, size, and cost of all NIH intramural research programs (IRP). NIMH and the NAMHC initiated a major study of the NIMH Intramural Research Program. The planning committee recommended continued investment in the IRP and recommended specific administrative changes; many of these were implemented upon release of

the committee's final report; other changes – for example, the establishment of a major new program on Mood and Anxiety Disorders – have been introduced in the years since.

1996 – NIMH, with the NAMHC, initiated systematic reviews of a number of areas of its research portfolio, including the genetics of mental disorders; epidemiology and services for child and adolescent populations; prevention research; clinical treatment and services research. At the request of the NIMH director, the NAMH Council established programmatic groups in each of these areas. NIMH continued to implement recommendations issued by these Workgroups.

Childhood Mental Disorders Research Prioritization – NIMH increased the priority placed on research on childhood mental disorders and clinical neuroscience and initiated efforts to expand research in these areas.

Implementation of Human Subjects Protection in Clinical Research – NIMH expanded its efforts to safeguard and improve the protections of human subjects who participate in clinical mental health research.

1996-1998 – Peer Review Integration in Neuroscience, Behavioral Science, and AIDS – NIMH initiated planning for integration of the Institute's peer review system for neuroscience, behavioral and social science and AIDS research applications into the overall NIH peer review system.

1997 – Extramural Program Reorganization – NIMH realigned its extramural organizational structure to capitalize on new technologies and approaches to both basic and clinical science, as well as immense changes that have occurred in health care delivery systems, while retaining the Institute's focus on mental illness. The new extramural organization resulted in three research divisions: Basic and Clinical Neuroscience Research; Services and Intervention Research; and Mental Disorders, Behavioral Research and AIDS.

1997-1999 – NIMH refocused career development resources on early careers and added new mechanisms for clinical research.

1999 – The NIMH Neuroscience Center/Neuropsychiatric Research Hospital was relocated from St. Elizabeth's Hospital in Washington, D.C. to the NIH Campus in Bethesda, MD, in response to the recommendations of the 1996 review of the NIMH Intramural Research Program by the IRP Planning Committee.

The first White House Conference on Mental Health, held June 7, in Washington, DC, brought together national leaders, mental health scientific and clinical personnel, patients, and consumers to discuss needs and opportunities. NIMH developed materials and helped organize the conference.

NIMH convened its fourth rural mental health research conference in August. "Mental Health at the Frontier: Alaska," was held in Anchorage, with visits by researchers and program representatives to several towns and villages. The aim was to solicit assistance in the development of a research agenda focusing on mental health issues for people who live in rural or frontier areas, with a focus on the needs of Alaska Natives.

NIMH hosted "Dialogue: Texas," which was the first in a series of mental health forums to solicit input from the public on the direction of future research at NIMH and to highlight current research. Held in San Antonio, the forum provided Texas consumers, researchers, care providers, and policymakers the opportunity to discuss mental health issues of greatest concern. The meeting focused on Latino and Hispanic populations.

U.S. Surgeon General David Satcher released *The Surgeon General's Call To Action To Prevent Suicide*, in July, and the first Surgeon General's Report on Mental Health, in December. NIMH, along with other Federal agencies, collaborated in the preparation of both of these landmark reports.

In the late 1990s, NIMH began to strengthen its efforts to include the public in its priority setting and strategic planning processes, instituting a variety of approaches in which to insure increased public participation.

The NIMH expanded and revitalized its public education and prevention information dissemination programs, including information on suicide, eating disorders, and panic disorder, in addition to the ongoing Institute educational program, Depression: Awareness, Recognition, and Treatment (D/ART).

NIMH also launched an initiative to educate people about anxiety disorders, to decrease stigma and trivialization of these disorders, and to encourage people to seek treatment promptly.

NIMH included members of the public on its scientific review committees reviewing grant applications in the clinical and services research areas.

2000 – NIMH created the Council Work Group on Training for Diversity in February 2000 to ensure adequate opportunities for minorities to pursue research careers, and to track the success of related Institute programs.

NIMH launched a 5-year communications initiative in March 2000 called the Constituency Outreach and Education Program, enlisting nationwide partnerships with state organizations to disseminate science-based mental health information to the public and health professionals, and increase access to effective treatments.

NIMH co-hosted two town meetings in Chicago on the mental health needs of minority youth and related research. The first meeting, held in April 2000, focused on behavioral, emotional, and cognitive disorders; the impact of violence; the criminalization of youth with treatment needs; service system issues; barriers to treatment; and barriers to research. The July 2000 meeting addressed the prevention of sexually transmitted diseases, such as HIV, and the role of the family and society in stemming the spread of HIV, as well as the increase in violence. Members of the general public, parents, teachers, school officials, guidance counselors, and professionals in the health, family assistance, social services, and juvenile justice fields attended the meetings.

NIMH assisted First Lady Hillary Rodham Clinton conduct a meeting on the Safe Use of Medication To Treat Young Children, in March.

NIMH organized the "14th International Conference on Challenges for the 21st Century: Mental Health Services Research," held in Washington, D.C., July 2000, to address how to meet mental health service needs nationwide most effectively, reduce health disparities, and provide equitable treatments in an era of managed care.

Dr. Eric Kandel and Dr. Paul Greengard, each of whom have received NIMH support for more than three decades, shared the Nobel Prize in Physiology or Medicine with Sweden's Dr. Arvid Carlsson. Dr. Kandel received the prize for his elucidating research on the functional modification of synapses in the brain. Initially using the sea slug as an experimental model but later working with mice, he established that the formation of memories is a consequence of short and long-term changes in the biochemistry of nerve cells. Further, he and his colleagues showed that these changes occur at the level of synapses, individual contacts between nerve cells. Dr. Greengard was recognized for his discovery that dopamine and a number of other transmitters can alter the functional state of neuronal proteins. These findings made it clear that signaling between neurons could alter their function not only in the short term but also in the long term. Also, he learned, such changes could be reversed by subsequent environmental signals.

Nancy Andreasen, M.D., Ph.D., a psychiatrist and long-time NIMH grantee, wins National Medal of Science for her groundbreaking work in schizophrenia and for joining behavioral science with neuroscience and neuroimaging. The Presidential Award is one of the nation's highest awards in

science.

2001 – NIMH convened in Pittsburgh more than 150 clinical and basic scientists with expertise relevant to the study of mood disorders to help develop a Research Strategic Plan for Mood Disorders. A public forum held in conjunction with the meeting focused on the frequent co-occurrence of depression with general medical illnesses.

NIMH launched several long-term, large-scale, multi-site, community based clinical studies to determine the effectiveness of treatment for bipolar disorder (also called manic-depressive illness); depression in adolescents; antipsychotic medications in the treatment of schizophrenia, and management of psychotic symptoms and behavioral problems associated with Alzheimer's disease; and subsequent treatment alternatives to relieve depression.

The Surgeon General released a Report on Children's Mental Health indicating that the nation is facing a public crisis in the mental health of children and adolescents. The National Action Agenda outlines goals and strategies to improve services for children and adolescents with mental and emotional disorders. NIMH along with other Federal agencies collaborated in the preparation of this report.

2002 – NIMH published a national conference report entitled "Mental Health and Mass Violence: Evidence-Based Early Psychological Intervention for Victims/Survivors of Mass Violence: A Workshop to Reach Consensus on Best Practices." While most people recover from a traumatic event in a resilient fashion, the report indicates that early psychological intervention guided by qualified mental health caregivers can reduce the harmful psychological and emotional effects of exposure to mass violence in survivors. NIMH and the Department of Defense, along with other Federal Agencies and the Red Cross collaborated in the preparation of this report.

Mental Health and Mass Violence: Evidence-Based Early Psychological Intervention for Victims/Survivors of Mass Violence Report released. Workshop co-sponsored by the Departments of Health and Human Services, Defense, Veterans Affairs, Justice and the American Red Cross.

2003 – Real Men. Real Depression campaign launched to raise awareness about depression in men and create an understanding of the signs, symptoms and treatment options available. The campaign is designed to inspire other men to seek help after hearing from real men talking about their experiences with depression, treatment and recovery.

NIMH Legislative Chronology

1929 – P.L. 70-672 established two Federal "narcotics farms" and authorized a Narcotics Division within PHS.

1930 – P.L. 71-357 redesignated the PHS Narcotics Division to the Division of Mental Hygiene.

1939 – P.L. 76-19 transferred PHS from the Treasury Department to the Federal Security Agency.

1946 – P.L. 79-487, the National Mental Health Act, authorized the Surgeon General to improve the mental health of U.S. citizens through research into the causes, diagnosis, and treatment of psychiatric disorders.

1949 – NIMH was established April 15.

1953 – Reorganization plan #1 assigned PHS to the newly created Department of Health, Education and Welfare.

1955 – P.L. 84-182, the Mental Health Study Act, authorized NIMH to study and make recommendations on mental health and mental illness in the U.S. The act also authorized the

creation of the Joint Commission on Mental Illness and Health.

1956 – P.L. 84-830, the Alaska Mental Health Enabling Act, provided for territorial treatment facilities for mentally ill individuals in Alaska.

1963 – P.L. 88-164, the Mental Retardation Facilities and Community Mental Health Centers Construction Act, provided for grants for assistance in the construction of community mental health centers nationwide.

1965 – P.L. 89-105, amendments to P.L. 88-164, provided for grants for the staffing of community mental health centers.

1966 – P.L. 89-793, Narcotic Addict Rehabilitation Act of 1966, launched a national program for long-term treatment and rehabilitation of narcotic addicts.

1967 – P.L. 90-31, Mental Health Amendments of 1967 separated NIMH from NIH and raised it to bureau status in PHS.

1968 – NIMH became a component of the newly created Health Services and Mental Health Administration.

P.L. 90-574, Alcoholic and Narcotic Addict Rehabilitation Amendments of 1968, authorized funds for the construction and staffing of new facilities for the prevention of alcoholism and the treatment and rehabilitation of alcoholics.

1970 – P.L. 92-211, Community Mental Health Centers Amendments of 1970, authorized construction and staffing of centers for 3 more years, with priority on poverty areas.

P.L. 91-513, Comprehensive Drug Abuse Prevention and Control Act of 1970, expanded the national drug abuse program by extending the services of federally funded community treatment centers to non-narcotic drug abusers as well as addicts.

P.L. 91-616, Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act, provided the resources needed to launch a comprehensive, all-out attack. Authorized the establishment of a National Institute on Alcohol Abuse and Alcoholism within NIMH.

1972 – P.L. 92-255, Drug Abuse Office and Treatment Act of 1972, provided that a National Institute on Drug Abuse be established within NIMH.

1973 – NIMH rejoined the NIH.

NIMH later became a component of the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA).

1974 – P.L. 93-282, authorized the establishment of ADAMHA.

1978 – P.L. 95-622, the Community Mental Health Centers Extension Act of 1978.

1979 – P.L. 96-88, the Department of Education Organization Act, created the Department of Education and renamed DHEW the Department of Health and Human Services (DHHS).

1980 – P.L. 96-398, the Mental Health Systems Act, reauthorized the community mental health centers program.

1981 – P.L. 97-35, the Omnibus Reconciliation Act, repealed P.L. 96-398 and consolidated ADAMHA's treatment and rehabilitation programs into a single block grant that enabled each State to administer allocated funds.

1983 – P.L. 98-24, Alcohol Abuse Amendments of 1983, consolidated the current authorization for ADAMHA and the institutes into a new title V of the PHS act.

1984 – P.L. 98-509, Alcohol Abuse, Drug Abuse, and Mental Health Amendments, authorized funding for block grants for fiscal years 1985 through 1987, as well as extending the authorizations for Federal activities in the areas of alcohol and drug abuse research, information dissemination, and development of new treatment methods.

1991 – P.L. 99-550, PHS act, contained the requirement for State Comprehensive Mental Health Services Plan.

1992 – P.L. 102-321, the ADAMHA Reorganization Act, abolished ADAMHA, created the Substance Abuse and Mental Health Services Administration, and transferred NIMH research activities to NIH.

2000 – P.L. 106-310, The Children's Health Act of 2000, Title I Autism, instructed the Director of NIH to carry out this section through the Director of NIMH and in collaboration with other agencies that the Director determined appropriate. The Act expands, intensifies, and coordinates activities of the NIH with respect to research on autism, including the establishment of not less than 5 centers of excellence that conduct basic and clinical research into autism. The Act also mandated that the Secretary, DHHS establish an Interagency Autism Coordinating Committee (IACC) to coordinate autism research and other efforts within the Department. Authority to establish the IACC was delegated to the NIH. The NIMH was designated the NIH lead for this activity.

NIMH Directors

Name	In Office From	To
Robert H. Felix	1949	1964
Stanley F. Yolles	1964	1970
Bertram S. Brown	1970	1977
Herbert Pardes	1977	1984
Shervert H. Frazier	1984	1986
Lewis L. Judd	1988	1992
Frederick K. Goodwin	1992	1994
Rex William Cowdry (Acting)	1994	1996
Steven E. Hyman	1996	2001
Richard K. Nakamura (Acting)	2001	2002
Thomas R. Insel	2002	Present

NIMH Programs

<http://www.nimh.nih.gov/researchfunding/reorganization.cfm>

In 2004, NIMH reorganized the extramural research program structure into five divisions (from the previous three), enabling the Institute to fully exploit recent scientific breakthroughs, increase cross-disciplinary collaboration, and facilitate translation of basic science discoveries into new interventions.

Office of the Director

<http://www.nimh.nih.gov/about/nimhoffices.cfm>

Office on AIDS

This office coordinates all NIMH research and activities working towards a better understanding of the causes, diagnosis, treatment, and prevention of HIV/AIDS. The office also cooperates with voluntary and professional health organizations, other NIH components, and Federal agencies, to identify national research needs and opportunities directed towards meeting AIDS-related public health goals.

Office of Communications

This office disseminates research findings and communicates information aimed at improving the diagnosis, treatment, and prevention of mental and brain disorders. By providing information to a variety of audiences, including the media, health care professionals, and the public, the office demonstrates that such illnesses are real, common, and treatable; helps reduce the stigma attached to these conditions; and encourages people who suffer from mental and brain disorders to seek needed treatment.

Office of Constituency Relations and Public Liaison

This office oversees the NIMH's public liaison and outreach efforts, including requesting and receiving public input on the Institute's activities, as well as promoting and coordinating Institute interactions with patient advocacy, professional, scientific, and community-based organizations with specific interests in NIMH's mission and/or programs. The office also monitors mental health-related legislation and issues, and reviews all mental health-related reports to the Congress and/or other Federal agencies. On request, the office develops analyses and serves as a principal point of contact for interactions with NIH and Departmental staff, as well as with senior staff of the Office of the President and other Federal agencies.

Office of Diversity and Employee Advocacy Programs

This office reviews and analyzes information, programs, policies, and issues related to affirmative action, equal employment opportunity, compliance with the Americans with Disabilities Act, workforce diversity, quality of worklife, and community outreach activities. In addition, the office develops and monitors plans to improve diversity and employee advocacy, advises the NIMH Director and senior staff regarding new initiatives, and provides recommendations for addressing problems and implementing changes.

Office of Global Mental Health

This office coordinates, participates in, and reports on international activities with respect to mental health research, such as tracking international grants, identifying opportunities and establishing partnership/collaborative agreements with other domestic and international organizations and government agencies, and working with NIMH extramural and intramural program staff to develop global projects and provide technical consultation to the international mental health community.

Office of Neuroinformatics

This office supports research on and development of cutting-edge, computer-based tools and approaches to acquire, store, manipulate, analyze, integrate, synthesize, disseminate, and utilize information about the brain and behavior. The office also coordinates and provides leadership to the interagency Human Brain Project.

Office of Prevention

This office promotes NIMH research programs concerning the prevention of mental disorders and

the promotion of mental health by developing, planning, executing, and assessing national programs, including the coordination of cross-Institute prevention research and representing the Institute in NIH, Departmental, cross-agency, private, and international prevention efforts.

Office of Resource Management

This office directs the Institute's resource allocation and management improvement processes by overseeing program planning and financial management, acquisition management, information resource management, management policy and procedure development, interpretation and implementation, the provision of general administrative services throughout the Institute, and personnel operations.

Office of Rural Mental Health

This office supports research activities and provides information on conditions unique to people living in rural areas, including research on the delivery of mental health services to such areas. Also, the office coordinates related Departmental research and activities with public and nonprofit entities.

Office of Science Policy and Program Planning

This office provides advice and guidance to the NIMH Director and senior Institute staff concerning science policy; strategic planning; program planning and evaluation; technology and information transfer; as well as the status, scope, and direction of the mental health field and in the articulation of national mental health policy. The office develops long-term planning activities and directs a process to develop recommendations for achieving national mental health policy objectives, such as designing studies on issues of major significance to mental health research; coordinating evaluation research to examine and improve program performance; and maintaining communicating with NIMH divisions and relevant components of NIH, PHS, and DHHS regarding mental health policy issues.

Office for Special Populations

This office develops research policies and programs to assure increased emphasis on the mental health needs of women, minorities, and other special populations. The office supports programs of basic and applied social and behavioral research on the mental health problems of special populations; studies the effects of discrimination on institutions and individuals, including majority institutions and individuals; supports and develops research designed to eliminate institutional discrimination; and provides increased emphasis on the concerns of special populations in the Institute's training, service delivery, and research programs.

Division of Neuroscience and Basic Behavioral Science (DNBBS)

<http://www.nimh.nih.gov/dnbbs/dnbbs.cfm>

The DNBBS provides support for research programs in the areas of basic neuroscience, genetics, basic behavioral science, research training, resource development, technology development, drug discovery, and research dissemination. In cooperation with other components of the Institute and the research community, the division has the responsibility of ensuring that relevant basic science knowledge is generated and then harvested to create improved diagnosis, treatment, and prevention of mental and behavioral disorders.

Office of Interdisciplinary Research and Science Technology

This office supports interdisciplinary research centers that span and integrate different aspects of basic brain research fundamental to the mission of the NIMH. The office also supports the development of scientific technologies related to brain and behavioral research, including software (such as informatics tools and resources), hardware (such as devices and instrumentation), and wetware (such as novel genetic methods or bioactive and molecular imaging agents). The office

comprises the following programs:

- Basic Neuroscience Centers
- Neurotechnology
- Small Business Innovative Research (SBIR) – Small Business Technology Transfer (STTR)

Office of Research Training and Career Development

This office supports research training at the predoctoral, postdoctoral, and early investigator level of career development in basic neuroscience, basic behavioral science, and other areas relevant to the focus of the DNBBS. The office's primary goal is to ensure that sufficient, highly trained research investigators will be available to address basic and clinical research questions pertinent to mental health and mental illness and thereby to reduce the burden of mental and behavioral disorders.

Office of Human Genetics and Genomic Resources

This office supports research on the identification, localization, function, and expression patterns of genes that produce susceptibility to mental disorders. Research projects supported by the office use a number of tools, technologies, and methods, including DNA and cDNA arrays, protein chips, functional genomics, positional cloning, single nucleotide polymorphisms (SNPs), fine mapping, gene therapy, candidate gene approaches, haplotype analysis, and direct and indirect association analysis. The office also supports research that generates genomic resources for use in human and animal studies, including genome-wide projects that generate structural genetic data (such as ESTs, SNPs), cDNA clones, mutant mice, and gene expression maps.

Molecular, Cellular, and Genomic Neuroscience Research Branch

This branch plans and administers research programs that elucidate the genetic, molecular, and cellular mechanisms underlying brain development, neuronal signaling, synaptic plasticity, circadian rhythmicity, and the influence of hormones and immune molecules on brain function. Other supported activities include drug discovery, identification of novel drug targets, development of functional imaging ligands, development of imaging probes as potential biomarkers, testing of models for assessing novel therapeutics, and studies of mechanisms of action of therapeutics in animals and humans.

Behavioral Science and Integrative Neuroscience Research Branch

This branch supports innovative research – including empirical, theoretical and modeling approaches – on cognitive, affective, social, motivational, and regulatory systems and their development across the lifespan in humans, in non-human primates, and in other animals. Relevant reduced and model systems approaches are also supported. Basic research in these areas provides a foundation for new insights into the nature and origins of mental and behavioral disorders and for the development of improved treatment and prevention interventions.

Division of Adult Translational Research and Treatment Development (DATR) _

<http://www.nimh.nih.gov/datr/datr.cfm>

The DATR supports programs aimed at understanding the pathophysiology of adult and late life mental illness and hastening the translation of behavioral science and neuroscience advances into innovations in clinical care. The division supports a broad research portfolio, which includes studies of the phenotypic characterization and risk factors for major psychiatric disorders; clinical neuroscience to elucidate etiology and pathophysiology of these disorders; and psychosocial, psychopharmacologic, and somatic treatment development. The division includes the following programs and branches:

Small Business Innovation Research (SBIR) Program and the Small Business Technology Transfer

(STTR) Program

The SBIR program supports research and development by small businesses of innovative technologies that have the potential to succeed commercially or to provide significant societal benefits; the STTR program has the same objectives but requires academic research involvement. In the DATR, the SBIR and STTR programs support research aimed at facilitating the validation and commercialization of new methods of assessing psychopathology, measuring treatment response to therapeutic agents or approaches, and the clinical development of novel psychopharmacological or psychosocial approaches to the treatment of adult and late life mental illness.

Research Training and Career Development Program

This program supports research training at the pre-doctoral, post-doctoral, and early investigator levels of career development in areas relevant to the DATR. These areas include adult psychopathology and psychosocial interventions, clinical neuroscience, geriatrics, translational research focusing on adults, and experimental therapeutics and treatment mechanisms related to mental illness. The program's primary goal is to ensure that sufficient numbers of highly trained, independent investigators will be available to address the complexities of adult psychopathology and translational research.

Traumatic Stress Research Program

This program is the DATR/NIMH point of contact for disaster/terrorism/biodefense-related research, supporting studies on biopsychosocial risk/protective factors for psychopathology after traumatic events and on interventions for post-traumatic stress disorder (PTSD) in adults. The program also oversees research spanning and integrating basic science, clinical practice, and health care system factors, including interventions and service delivery, regarding the effects of mass trauma and violence (e.g. war, terrorism, natural and technological disaster) on children, adolescents, and adults.

Adult Psychopathology and Psychosocial Intervention Research Branch

This branch promotes translational research that is directed toward an understanding of how the development, onset, and course of adult psychopathology may be studied in terms of dysfunction in fundamental biobehavioral mechanisms such as emotion, cognition, motivational processes, and interpersonal relationships. The branch emphasizes studies that combine approaches from neuroscience and behavioral science to elucidate the role of psychosocial factors in the alterations of brain functioning associated with mental disorders and to produce integrative models of risk, disorder, and recovery.

Clinical Neuroscience Research Branch

This branch supports research, training, and resource development programs aimed at understanding the neural basis of mental disorders. Specifically supported are human and animal studies on the molecular, cellular, and systems level of brain function designed to elucidate the pathophysiology of mental disease and to translate these findings to clinical diagnosis, treatment, and prevention strategies.

Geriatrics Research Branch

This branch supports research in the etiology and pathophysiology of mental disorders of late life (such as Alzheimer's disease and related dementias, neuroregulatory and hemostatic disorders, and menstrual cycle disorders), the treatment and recovery of persons with these disorders, and the prevention of these disorders and their consequences. The program encourages collaborative multidisciplinary research programs using the tools of molecular neuroscience, cognitive sciences, and social and behavioral sciences to facilitate the translation of basic science and preclinical

research to clinical research.

Experimental Therapeutics Branch

This branch supports multidisciplinary research and resource development on novel pharmacological approaches to treat mental disorders, evaluation of existing treatments for new clinical uses, novel somatic treatments, and other areas related to treatment. The branch also engages in cross-Institute activities to identify specific bottlenecks in the development of novel treatments for mental disorders and collaborates with academic, industry, and regulatory agencies to develop programmatic approaches to hasten the availability of better treatments to reduce the burden of mental illness.

Division of Pediatric Translational Research and Treatment Development (DPTR)

<http://www.nimh.nih.gov/dptr/dptr.cfm>

The DPTR supports programs of research and research training with the ultimate goal of preventing and curing childhood psychopathology. The division stimulates and promotes an integrated program of research across basic behavioral/psychological processes, environmental processes, brain development, pediatric psychopathology and therapeutic interventions. DPTR also supports research that employs a developmental perspective on a variety of related basic behavioral processes and the psychopathology that arises from their dysfunction. These efforts to translate knowledge from basic research to a new understanding of clinical disorders share the goal of developing novel treatment and prevention strategies. The division includes the following programs and branches:

Small Business Innovation Research (SBIR) Program and the Small Business Technology Transfer (STTR) Program

The SBIR program supports research and development by small businesses of innovative technologies that have the potential to succeed commercially or to provide significant societal benefits; the STTR program has the same objectives but requires academic research involvement. In the DPTR, the SBIR and STTR programs support research aimed at the development and validation of new methods and techniques to advance understanding, prevention, and treatment of child psychopathology.

Research Training and Career Development Program

This program supports research training at the pre-doctoral, post-doctoral, and early investigator level of career development in areas relevant to the DPTR, such as neurodevelopmental disorders, psychosocial stress, and affective and regulatory disorders. The program's primary goal is to ensure that sufficient numbers of highly trained, independent investigators will be available to address the complexities of developmental psychopathology.

Child Abuse and Neglect Program

This program supports research in child abuse and neglect, a subject worthy of special attention in NIMH because of the profound impact that abuse and neglect have on children's immediate and long-term mental health. This program emphasizes research that helps identify risk and protective factors that influence the development of psychopathology, aims to develop novel treatment and prevention strategies, and addresses familial aspects of traumatic stress as risk factors for psychopathology in children and adolescents.

Autism STAART Centers

NIMH supports interdisciplinary research centers through an NIH cooperative agreement in the Studies to Advance Autism Research and Treatment (STAART) Program, in cooperation with

NICHHD, NINDS, NIDCD, and NIEHS. By evaluating and treating patients, as well as enrolling them in clinical trials, each center helps expand the research base on the causes, diagnosis, early detection, prevention, and treatment of autism.

Neurodevelopmental Disorders Branch

This branch supports research of childhood psychiatric disorders such as attention deficit hyperactivity disorder, schizophrenia, obsessive-compulsive disorder, and autistic spectrum disorders, as well as development of more effective prevention and treatment strategies for these disorders. The branch also funds research on human neurodevelopment and on basic biobehavioral processes involved in these disorders, such as attentional and perceptual processing, executive function, inhibitory controls (e.g., sensory gating), social cognition and communication, and affiliative behaviors.

Psychosocial Stress and Related Disorders Branch

This branch supports research leading to a fuller understanding of pathological conditions in childhood and adolescence such as oppositional defiant disorder, post-traumatic stress disorder, anxiety disorders, and pathological shyness, as well as the development of more effective prevention and treatment strategies. In addition, the branch sponsors research on aggression, fear, inhibitory controls, learning, memory, caregiver-child relationships, the effects of acute and chronic stress, and other related issues.

Affective & Regulatory Disorders Branch

This branch provides support to research on pathological conditions in childhood and adolescence such as eating disorders, sleep disorders, major depressive disorder, dysthymia, suicide attempt and completion, and bipolar disorder, as well as on the development of more effective prevention and treatment strategies. The branch also funds research on biobehavioral processes, including emotion and mood regulation, feeding and appetite regulation, circadian rhythms, and developmental changes in neurobehavioral regulation (such as CNS maturation and neuroendocrine development), as well as environmental influences that have implications for risk or resilience, susceptibility to disorder, or strategies for preventing or treating disorders.

Division of AIDS Health and Behavior Research (DAHBR)

<http://www.nimh.nih.gov/dahbr/dahbr.cfm>

The DAHBR supports research programs that focus on developing and disseminating behavioral interventions that prevent HIV/AIDS transmission, clarifying the pathophysiology and alleviating the neuropsychiatric consequences of HIV/AIDS infection, and using a public health model to reduce the burden of mental illness from medical comorbidities, non-adherence to treatment, societal stigma, health disparities, and unhealthy behaviors. The division includes the following programs and branches:

Small Business Innovation Research (SBIR) Program and the Small Business Technology Transfer (STTR) Program

The SBIR program supports research and development by small businesses of innovative technologies that have the potential to succeed commercially or to provide significant societal benefits; the STTR program has the same objectives but requires academic research involvement. In the DAHBR, the SBIR and STTR support research aimed at changing risky behaviors, promoting strategies to reduce AIDS transmission, elucidating the pathophysiology of HIV-related neuropsychiatric dysfunction, and investigating processes that influence adherence to treatment in individuals with HIV.

Research Training and Career Development Program

This program supports research training at the pre-doctoral, post-doctoral, and early investigator level of career development in areas relevant to the DAHBR, such as research on treatment adherence and behavior change in patients with mental disorders. The program's primary goal is to ensure that sufficient numbers of highly trained independent investigators will be available to address the complexities of health behaviors involved in mental illness.

Center for Mental Health Research on AIDS (CMHRA)

This center supports domestic and international studies to develop behavior change and prevention strategies to reduce the transmission of HIV and other sexually transmitted diseases (STDs). To accomplish this goal, the CMHRA oversees research in developing and testing interventions to reduce the neuropsychiatric morbidity associated with HIV infection, clarifying the pathophysiology of HIV CNS infection and associated motor/cognitive disturbances, developing therapeutic agents to prevent or reverse the effects of HIV on the CNS, improving the effectiveness and efficiency of mental health services relevant to HIV infection and people living with HIV and co-occurring mental illness, and other related areas.

Health and Behavioral Research Branch

This branch supports research on a range of health behaviors in people with mental disorders, such as identifying potent, modifiable risk and protective factors for mental disorders that may guide the development and initial testing of theory-driven interventions. Interventions may comprise prevention, treatment, or rehabilitation and include biological, pharmacological, behavioral, psychosocial, or environmental components. Examples of supported research areas include adherence to interventions for mental disorders, ethics in mental disorders research, and functional assessment in people with mental disorders.

Division on Services and Intervention Research (DSIR)

<http://www.nimh.nih.gov/dsir/dsir.cfm>

The DSIR supports two critical areas of research: intervention research to evaluate the effectiveness of pharmacologic, psychosocial (psychotherapeutic and behavioral), somatic, rehabilitative and combination interventions on mental and behavior disorders; and mental health services research on organization, delivery (process and receipt of care), related health economics, delivery settings, clinical epidemiology, and the dissemination and implementation of evidence-based interventions into service settings. The division also provides biostatistical analysis and clinical trials operations expertise for research studies; analyzes and evaluates national mental health needs and community research partnership opportunities; and supports research on health disparities. The division includes the following programs and branches:

Small Business Innovation Research (SBIR) Program and the Small Business Technology Transfer (STTR) Program

The SBIR program supports research and development by small businesses of innovative technologies that have the potential to succeed commercially or to provide significant societal benefits; the STTR program has the same objectives but requires academic research involvement. In the DSIR, the SBIR and STTR support research and development of tools related to clinical trials (including preventive, treatment, and rehabilitative interventions alone and/or in combination), clinical epidemiology, services research, effectiveness research, health disparities (including rural populations) and the dissemination of evidence-based treatments/research into services and clinical practice in areas directly related to the mission of the NIMH.

Office of Research Training and Career Development

This office supports research training at the pre-doctoral, post-doctoral, and early investigator level

of career development in areas relevant to the DSIR. Areas of emphasis include research related to clinical trials (including preventive, treatment and rehabilitative interventions alone and/or in combination) and adapting interventions and demonstrating their utility in broad populations (ethnic and racial groups, comorbid disorders) for various service settings (primary care, schools, public sector). The office's primary goal is to ensure that sufficient, highly trained research investigators will be available to address interventions and services research questions pertinent to mental health and mental illness and thereby to reduce the burden of mental and behavioral disorders.

Clinical Trials Operations and Biostatistics Unit

This unit serves as the operations focal point for collaborative clinical trials on mental disorders in adults and children. The unit is responsible for overseeing both contract-supported and cooperative agreement-supported multisite clinical trial protocols, as well as special projects undertaken by NIMH. In addition, the unit manages over-arching matters related to clinical trials operations, such as the coordination of the ancillary protocols across the large trials and the implementation of NIMH policy for dissemination of public access datasets. The unit also consults Institute staff and grantees/contractors on biostatistical matters related to appropriateness of study design, determination of power and sample size, and approaches to statistical analysis of data from NIMH-supported clinical trials.

Adult Treatment and Preventive Intervention Research Branch

This branch supports research evaluating therapeutic (acute, maintenance, and preventive) and adverse effects of psychosocial, psychopharmacologic, and somatic interventions of proven efficacy in the treatment of mental disorders in adult populations. For example, the branch has administered trials evaluating modified or adapted forms of interventions for use with special populations (such as women, or specific ethnic or racial groups), in new settings (public sector, primary care, workplace, other non-academic sites), through new methods of treatment delivery (e.g., web or computer-based). Studies look beyond symptom reduction to include short- and long-term assessment of functioning and other outcome measures that can help identify disorder subgroups more likely to benefit from treatment, to determine the optimal length of treatment, and to evaluate the long-term impact of interventions.

Child and Adolescent Treatment and Preventive Intervention Research Branch

This branch plans, supports, and administers research programs to evaluate the effectiveness of mental health preventive, treatment and rehabilitative interventions (alone or in combination) for children and adolescents. The branch also supports research addressing the long-term effectiveness of known successful interventions, including their role in preventing relapse and recurrence of mental disorders. Types of intervention research supported by the branch include the full range of behavioral, psychotherapeutic, pharmacologic, and nonpharmacologic somatic or complementary/alternative approaches for which acute efficacy has been demonstrated, as well as rehabilitation or other adjunctive interventions.

Services Research and Clinical Epidemiology Branch

This branch administers programs of research, training, and infrastructure development, across the lifespan, on all mental health services research issues, including but not limited to: services organization, delivery (process and receipt of care), and related health economics at the individual, clinical, program, community and systems levels in specialty mental health, general health, and other delivery settings (such as the workplace); interventions to improve the quality and outcomes of care, including diagnostic, treatment, preventive, and rehabilitation services; enhanced capacity for conducting services research; clinical epidemiology of mental disorders across all clinical and service settings; and dissemination and implementation of evidence-based interventions into service settings.

Division of Extramural Activities (DEA)

<http://www.nimh.nih.gov/dea/index.cfm>

The DEA provides leadership and advice in developing, implementing, and coordinating extramural programs and policies; represents the Institute on extramural program and policy issues within the Department and with outside organizations; provides scientific and technical peer and objective review of applications for grants, cooperative agreements, and contracts; provides information and guidelines for grant applications; oversees National Advisory Mental Health Council activities and provides committee management services.

Division of Intramural Research Programs (DIRP)

<http://intramural.nimh.nih.gov/>

The DIRP is the internal research division of the NIMH. Intramural scientists conduct research ranging from studies into mechanisms of normal brain function, conducted at the behavioral, systems, cellular, and molecular levels, to clinical investigations into the diagnosis, treatment and prevention of mental illness. Major disease entities studied throughout the lifespan include mood disorders and anxiety, schizophrenia, obsessive-compulsive disorder, attention deficit hyperactivity disorder, and pediatric autoimmune neuropsychiatric disorders. Because of its outstanding resources, unique funding mechanisms, and location in the nation's capital, the DIRP is viewed as a national resource, providing unique opportunities in mental health research and research training.

This page was last reviewed on August 18, 2005 .

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National Institutes of Health (NIH)
9000 Rockville Pike
Bethesda, Maryland 20892



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The NIH Almanac – Organization

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National Institute of Neurological Disorders and Stroke

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Originally National Institute of Neurological Diseases and Blindness. Name changed 1968 to National Institute of Neurological Diseases and Stroke; March 1975 to National Institute of Neurological and Communicative Disorders and Stroke; and October 1988 to present name.

Mission

The National Institute of Neurological Disorders and Stroke (NINDS) is one of 27 Institutes and Centers comprising the National Institutes of Health (NIH). NIH, located in Bethesda, Maryland, is an agency of the Public Health Service within the U.S. Department of Health and Human Services. Created by the U.S. Congress in 1950, NINDS has occupied a central position in the world of neuroscience for more than 50 years.

The mission of NINDS is to reduce the burden of neurological disease — a burden borne by every age group, every segment of society, and people all over the world.

To accomplish this goal, the Institute supports and conducts research on the healthy and diseased nervous system, fosters the training of investigators in the basic and clinical neurosciences, and seeks better understanding, diagnosis, treatment, and prevention of neurological disorders.

The Institute's extramural program supports thousands of research project grants and research contracts. Institutional training grants and individual fellowships support hundreds of scientists in training, and provide career awards that offer a range of research experience and support for faculty members at various levels. Scientists in the Institute's laboratories and clinics in Bethesda conduct research in the major areas of neuroscience and on many of the most important and challenging neurological disorders, and collaborate with scientists in several other NIH Institutes.

This is a time of accelerating progress and increasing hope in the battle against brain disease. Advances in understanding the nervous system are beginning to pay off in the form of treatments for previously intractable problems such as spinal cord injury, acute stroke, multiple sclerosis, epilepsy, and Parkinson's disease, to name a few. It is fortunate that scientific progress is matched by unprecedented public commitment to research. NINDS is aware that increased public support and funding require visionary leadership and effective stewardship of the resources entrusted to the Institute.

The NINDS vision is:

- To lead the neuroscience community in shaping the future of research and its relationship to brain diseases.
- To build an intramural program that is the model for modern collaborative neuroscience research.

- To develop the next generation of basic and clinical neuroscientists through inspiration and resource support.
- To seize opportunities to focus our resources to rapidly translate scientific discoveries into prevention, treatment, and cures.

Important Events in NINDS History

1950 – On August 15 President Truman signed P.L. 81-692, establishing the National Institute of Neurological Diseases and Blindness.

1951 – NINDB received its first budget of \$1,232,253.

1953 – The NINDB budget became a line item in the NIH budget.

1953-54 – An intramural program of clinical investigation was initiated, including medical neurology, surgical neurology, and electroencephalography. Training programs in neurology and ophthalmology were initiated.

1955 – Basic science training grants were initiated.

1956 – The intramural clinical investigations program was expanded to include work in ophthalmology.

1957 – Training programs in otolaryngology and pediatric neurology were begun.

Field investigations involving collaborative and cooperative clinical studies were begun and the initial phase of the Collaborative Perinatal Project was started.

1960 – The joint intramural basic research program of NINDB and NIMH was divided and organized into two basic research laboratory programs.

1961 – First program projects and clinical research centers in stroke and communicative disorders were supported.

1962 – Funds were appropriated for professional and technical information assistance. Training grants in neurosurgery and neuroradiology were initiated.

1963 – Developmental graduate training grants were initiated.

1965 – A head injury research program was established.

1966 – The stroke research program was expanded; additional grants for clinical research centers were awarded. An antiepileptic drug testing program was begun.

1967 – Vision outpatient research centers were established. A program of research in neural control mechanisms and prostheses was initiated.

1968 – The NINDS blindness program became the nucleus of the National Eye Institute. The institute was renamed the National Institute of Neurological Diseases and Stroke.

1969 – Research Building 36, dedicated by DHEW Secretary Robert H. Finch, was occupied by

NINDS and NIMH research laboratories.

1971 – Programs in applied neurological research (epilepsy, head injury), infectious diseases, and biometry were added to the Collaborative and Field Research Division.

1973 – Two new communicative disorders programs were begun with establishment of a section on communicative disorders in the Collaborative and Field Research Division, and an intramural Laboratory of Neuro-Otolaryngology.

1974 – Laboratories for neuroimmunology and neuropharmacology were established.

1975 – NINDS was renamed the National Institute of Neurological and Communicative Disorders and Stroke.

The institute reorganized into six units for intramural research, fundamental neurosciences, communicative disorders, neurological disorders, stroke and trauma, and extramural activities.

1976 – Dr. D. Carleton Gajdusek, chief, Laboratory of Central Nervous System Studies, was awarded the Nobel Prize in Physiology or Medicine for work on atypical slow viruses.

1979 – A neuroepidemiology section and a section of neurotoxicology were established within the Intramural Research Program. NINCDS substantially expanded extramural support of research studies using positron emission tomography.

1982 – The institute's Neurological Disorders Program was replaced by two new program units: convulsive, developmental, and neuromuscular disorders and demyelinating, atrophic, and dementing disorders.

1984 – NINCDS established the Senator Jacob Javits Neuroscience Awards, which provide research grant support for up to 7 years in the basic and clinical neurosciences and communicative sciences.

A Laboratory of Neurobiology and a Laboratory of Experimental Neuropathology were established within the Intramural Research Program.

1986 – A Laboratory of Neural Regeneration and Implantation was established within the Intramural Research Program.

1987 – NINCDS programs were renamed divisions, reflecting major areas of research interest: communicative and neurosensory disorders; convulsive, developmental, and neuromuscular disorders; demyelinating, atrophic, and dementing disorders; fundamental neurosciences; stroke and trauma; extramural activities; and intramural research.

A Clinical Neuroscience Branch was established within the Division of Intramural Research.

1988 – The communicative disorders program became the nucleus of the National Institute of Deafness and Other Communication Disorders. NINCDS was renamed the National Institute of Neurological Disorders and Stroke.

1989 – On July 25 President Bush signed P.L. 101-58, declaring the 1990s the "Decade of the Brain."

1990 – A Stroke Branch was established within the Division of Intramural Research.

1998 – NINDS forms seven planning panels comprised of neuroscience leaders; panel members outline opportunities for research investment.

1999 – NINDS publishes Neuroscience at the *New Millennium: Priorities and Plans for the NINDS, Fiscal Years 2000-2001*.

2000 – Development of Parkinson's Disease Research Agenda

2001 – NINDS celebrates its 50th anniversary with a 2-day scientific symposium "Celebrating 50 Years of Brain Research: New Discoveries, New Hope."

2001 – Creation of the Stroke Progress Review Group (PRG)

2001 – Development of Research Agenda for Epilepsy

2002 – Publication of the Report of the Stroke PRG

2004 – Opening of the new National Neuroscience Research Center

NINDS Legislative Chronology

August 15, 1950 – Public Law 81-692 established NINDB "for research on neurological diseases (including epilepsy, cerebral palsy, and multiple sclerosis) and blindness."

August 16, 1968 – Public Law 90-489 renamed the NINDB the National Institute of Neurological Diseases.

October 24, 1968 – Public Law 90-636 changed the name of the NIND to the National Institute of Neurological Diseases and Stroke.

October 25, 1972 – Public Law 92-564 established a temporary National Commission on Multiple Sclerosis supported by NINDS.

March 14, 1975 – Part 8 of a DHEW Statement of Organization, Functions, and Delegations of Authority was amended to change the title of NINDS to the National Institute of Neurological and Communicative Disorders and Stroke.

July 29, 1975 – Public Law 94-63 established two temporary commissions to be supported by NINCDS: Commission for the Control of Epilepsy and Its Consequences, and Commission for the Control of Huntington's Disease and Its Consequences.

October 28, 1988 – Public Law 100-553 changed the name of NINCDS to the National Institute of Neurological Disorders and Stroke.

June 10, 1993 – Public Law 103-43 added language on Multiple Sclerosis research to the legislative mandate of the NINDS.

November 13, 1997 – Public Law 105-78, the Morris K. Udall Parkinson's Disease and Research Act, added language authorizing increased Parkinson's disease research and training, including research centers.

November 17, 2000 – Public Law 106-310, the Children's Health Act of 2000, amended the Public Health Service Act with regard to a wide range of issues affecting children's health. Specifically relevant to the NINDS mission, were authorizing provisions for the expansion of autism research,

including research centers of excellence, and the establishment of an interagency Autism Coordinating Committee; the establishment of a Pediatric Research Initiative; the development of a pediatric research loan repayment program; the conduct of a national longitudinal study of environmental influences on children's health and development; the study of risk factors for childhood cancers, including malignant tumors of the central nervous system; and the support of research with respect to cognitive disorders and neurobehavioral consequences arising from traumatic brain injury; the expansion and coordination of muscular dystrophy research.

December 18, 2001 – Public Law 107-084, the Muscular Dystrophy Community Assistance, Research and Education Amendments of 2001, or the "MD-CARE Act," amended the Public Health Service Act to provide for the expansion and coordination of research with respect to various forms of muscular dystrophy, including the establishment of research centers of excellence and an interagency coordinating committee.

Biographical Sketch of NINDS Director Story C. Landis Ph.D.

Dr. Landis has been Director of the National Institute of Neurological Disorders and Stroke since September 1, 2003. As Director, she oversees an annual budget of \$1.5 billion and a staff of more than 900 scientists, physician-scientists, and administrators.

Dr. Landis received her B.A. in Biology from Wellesley College in 1967 and her master's degree (1970) and her Ph.D. (1973) from Harvard University. She held postdoctoral fellowships at the National Institute of Mental Health and Harvard Medical School and also held faculty positions at Harvard Medical School and Case Western Reserve University. At Case Western Reserve, she was responsible for the creation of a Department of Neurosciences. Under five years of her leadership, the program achieved worldwide acclaim and a reputation for excellence. In 1995, Dr. Landis joined the NINDS as Scientific Director and was responsible for the direction and excellence of research conducted in the Institute's intramural program.

Dr. Landis's own research is aimed at understanding how functional connections form in the developing nervous system. Starting with evidence of surprising plasticity and environmental influences obtained in cell culture systems, her work has focused on dissecting the cellular interactions that drive synapse formation in the peripheral nervous system and to on identifying the molecular mechanisms responsible.

Dr. Landis has received distinction as an Established Investigator of the American Heart Association, a Javits Neuroscience Investigator, and a MacKnight Senior Investigator, and as an elected Fellow of the American Academy of Arts and Sciences and the American Association for the Advancement of Science. Dr. Landis has served on numerous scientific advisory committees including selection and review committees for the NIH and the Howard Hughes Medical Institute. In 2002, she was named the President-Elect of the Society for Neuroscience.

The NINDS supports research by investigators in public and private institutions across the country, as well as by scientists working in its intramural laboratories and branches in Bethesda, Maryland. The Institute's mission is to reduce the burden of neurological disease – a burden borne by every age group, by every segment of society, by people all over the world.

NINDS Directors

Name	In Office From	To
Pearce Bailey	1951	1959
Richard L. Masland	1959	1968
Edward F. MacNichol, Jr.	September 1, 1968	1973
Donald B. Tower	May 31, 1974	February 1, 1981
Murray Goldstein	December 23, 1982	October 1, 1993

Patricia A. Grady (Acting)	September 1993	August 31, 1994
Zach W. Hall	September 1, 1994	December 31, 1997
Audrey S. Penn (Acting)	January 1, 1998	July 31, 1998
Gerald D. Fischbach	August 1, 1998	January 31, 2001
Audrey S. Penn (Acting)	February 1, 2001	August 31, 2003
Story C. Landis	September 1, 2003	Present

Major Divisions

The institute is organized into a division of extramural research and a division of intramural research.

Division of Extramural Research

The Division of Extramural Research plans and directs initiatives for grant and contract support for research, research training, and career development. The Division is organized into work groups known as "program clusters." The clusters were formed to address critical cross-cutting scientific topics that hold great promise for advancing knowledge and for leading to effective ways to prevent neurological diseases, delay their onset, design effective treatments, or restore function after illness or injury. The current operational scientific clusters are: Channels, Synapses, and Circuits; Clinical Trials; Minority Health and Research; Neural Environment; Neurodegeneration; Neurogenetics; Repair and Plasticity; Systems and Cognitive Neuroscience; and Technology Development.

The Division maintains surveillance over developments in these program areas; assesses the national need for research on the cause, prevention, diagnosis, and treatment of disorders of the brain and nervous system; and pursues technological development, the application of research findings, and research training and career development. In addition to determining program priorities and recommending funding levels for programs to be supported by grants and contracts, the Division (a) collaborates with other institutes of the NIH on national research efforts related to these program areas, (b) prepares reports and analyses of national needs to assist NINDS staff and advisory groups in carrying out their responsibilities and in developing new areas of emphasis, and (c) consults with extramural scientists, voluntary health organizations, and professional associations in identifying research needs and developing programs to meet these needs.

The Division coordinates training of young investigators in all basic and clinical neurological research areas. This includes institutional and individual training programs as well as support through research career development awards and clinical investigator development awards.

Repair and Plasticity

http://www.ninds.nih.gov/funding/areas/repair_and_plasticity/index.htm

- To understand mechanisms of plasticity in the healthy nervous system and explore implications for repair.
- To develop interventions to modify the course of injury and disease progression, and improve functional outcome in individuals following injury to the nervous system.
- To understand the course of degeneration and repair following spinal cord injury and brain injury on timescales ranging from seconds to years.
- To develop interventions to permit spinal cord tracts to regrow past an injury site and establish functional connections distally.

- To understand the role of endogenous neurogenesis and to promote development of stem cell biology to repair the nervous system.
- To promote the development of neural prosthetic devices designed to restore function after neurological injury or disease.

Systems and Cognitive Neuroscience

http://www.ninds.nih.gov/funding/areas/systems_and_cognitive_neuroscience/index.htm

- To promote the understanding of higher brain functions that underlie complex behaviors such as learning, memory, attention, language, cognition, emotion, movement, wakefulness-sleep cycles and response to pain.
- To encourage research in such fields as pain, the genetic basis of complex behaviors, and neuroinformatics.
- To identify risk factors for developmental cognitive disorders.
- To develop better methods for assessing behavior and other neurological functions in animal models as a useful model for human conditions.
- To encourage research on brain circuits that control motor activity, sleep, circadian rhythms, eating and energy balance.

Channels, Synapses, and Circuits

http://www.ninds.nih.gov/funding/areas/channels_synapses_and_circuits/index.htm

- To support structural and functional studies of signaling molecules of the nervous system, including ion channels, neurotransmitter receptors and transporters, neuromodulators, second messengers, and signal transduction elements.
- To stimulate research in the study of channelopathies and their involvement in specific neurological disorders, such as the epilepsies.
- To advance our knowledge of the structure and function of central and peripheral synapses; molecular and cellular mechanisms of synaptic transmission; synaptic modulation and plasticity; and synaptogenesis, synaptic degeneration, and regeneration.
- To encourage new research approaches to the analysis of simple and complex neural circuits that mediate motor control, sensory processing, and non-cognitive activities, especially circuits with known medical consequences, such as generation of epileptiform bursts.
- To promote the development of new methodologies used to study channels, synapses, and circuits, including genetic models, high-resolution structural studies of membrane proteins, optical recording, neuroimaging, multi-electrode arrays, and neuroinformatics tools.
- To stimulate translational research to link results of basic research on channels, synapses, and circuits to medication development and clinical trials.

Neurogenetics

<http://www.ninds.nih.gov/funding/areas/neurogenetics/index.htm>

- To promote efforts to identify genes and susceptibility loci for neurological diseases.
- To promote investigation of the mechanisms by which genetic variants cause or contribute to risks for neurological disease.
- To develop gene-based assays, diagnostics, and therapeutics for neurological disorders.
- To develop cutting-edge tools and resources for neurogenetic research.
- To promote basic and translational research in neurogenetics and genomics.
- To investigate the genetic basis of normal neural development, function, and perturbations that can lead to neurological disorders.
- To promote and assist in the training of neuroscientists in molecular medicine.
- To educate the scientific and lay communities in the ethical, legal, and social issues in neurogenetics.
- To engage patient voluntary and advocacy groups in partnerships to promote research in neurogenetics.

Neural Environment

http://www.ninds.nih.gov/funding/areas/neural_environment/index.htm

- To encourage studies on the development and normal functions of glial cells including myelin formation; microglial, oligodendrocyte, and astrocyte function; and cell-cell communication among the diverse cell populations of the nervous system.
- To encourage research on infectious, immune, and inflammatory mechanisms in nervous system disorders such as multiple sclerosis, prion diseases, stroke, and neuro - AIDS.
- To encourage studies to identify the molecular mechanisms of cell injury and death in the nervous system.
- To foster studies on vascular mechanisms of neurological disorders, CNS vascular development , and the role of microvascular endothelia, extracellular matrix , and cells of hematopoietic origin within the CNS.
- To promote the development of diagnostics and of therapies that will prevent, arrest , or reverse autoimmune neurological disorders such as multiple sclerosis.
- To expand studies on the mechanisms of blood-brain and brain-CSF barrier functions and of cell migration (and/or trafficking) into the CNS in stroke, immune disorders, and CNS infections.
- To encourage the development of animal models for infectious and immune disorders and stroke (e.g., transgenic or knockout/in models, viral models).
- To promote the study of biomarkers for vascular and immune diseases of the nervous system.
- To strongly encourage bi-directional translational research that transfers insights gained from

basic research and clinical investigations.

Neurodegeneration

<http://www.ninds.nih.gov/funding/areas/neurodegeneration/index.htm>

- To stimulate basic and clinical research on the mechanisms of neuron death and neurodegeneration underlying a wide range of neurodegenerative disorders including Parkinson's and Alzheimer's diseases, amyotrophic lateral sclerosis, Huntington's disease, frontotemporal dementia, progressive supranuclear palsy and Pick's disease, Lewy body diseases, multiple system atrophy, corticobasal degeneration, etc.
- To encourage the translation of basic research to the development and testing of therapeutics for the treatment and cure of neurodegenerative diseases.
- To encourage gene discovery and population-based epidemiological studies of neurological disorders in order to elucidate the natural history of neurodegeneration and to identify biomarkers for neurodegenerative disorders.
- To support the rigorous testing of candidate therapies in controlled clinical trials in conjunction with the NINDS clinical trials group.
- To promote the development of advanced research technologies necessary for achieving new breakthroughs in neurodegeneration research.

Clinical Trials

http://www.ninds.nih.gov/funding/areas/clinical_trials/index.htm

- To promote the development of clinical interventions for neurological disorders and stroke.
- To stimulate the translation of findings in the laboratory to clinical research and clinical interventions.
- To ensure measures for protection of human subjects and safety monitoring.
- To encourage innovation in clinical research methodology.
- To support the development of neurology clinical researchers with training in biostatistics, epidemiology, and clinical trial methodology.

Minority Health and Research

www.ninds.nih.gov/funding/office_of_minority_health_and_research/index.htm

- To assist in infrastructure development leading to well-established, state-of-the-art neuroscience research programs at minority institutions.
- To foster innovative and effective partnerships and collaboration between minority institutions and established neuroscience laboratories at federal and non-federal research institutions.
- To create, support and maintain a stimulating academic and intellectual milieu to inspire and prepare minority students and fellows to pursue research careers in neuroscience.

- To provide support to develop and sustain competitively funded neuroscience research projects and programs at minority institutions.

Technology Development

http://www.ninds.nih.gov/funding/areas/technology_development/index.htm

<http://www.ninds.nih.gov/funding/research/asp/index.htm>

http://www.ninds.nih.gov/funding/technology_development/HTS_Facility.htm

- To advance understanding of the basic molecular and cellular mechanisms of nervous system function through the development and use of new technologies, such as gene microarrays and other genetic tools, proteomics, electrode arrays, imaging, and informatics.
- To facilitate the discovery and development of new therapeutic interventions for neurological disorders through the use of molecular libraries, screening assays, and gene transfer.
- To develop new molecular, cellular, and animal models of neurological function and disease.
- To facilitate testing of chemical compounds as mechanistic tools and as therapeutic candidates with high-throughput screening and in vivo testing for efficacy and toxicity.
- To facilitate advances in neuroscience research through sharing and distribution of data and resources.
- To promote the development of novel and powerful computational tools and theoretical neuroscience approaches for the analysis, interpretation, and modeling of complex neural data within and across all levels of organization.

Division of Intramural Research

A full description of the NINDS Division of Intramural Research can be found at <http://intra.ninds.nih.gov>.

Additional information on NIH neuroscience programs, including programs sponsored by the NINDS, is available at <http://neuroscience.nih.gov>.

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National Library of Medicine

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Mission

The National Library of Medicine (NLM), the world's largest research library of the health sciences, serves scientists, health professionals, and the public.

The Library has a statutory mandate from Congress to apply its resources broadly to the advancement of medical and health-related sciences. It collects, organizes, and makes available biomedical information to investigators, educators, and practitioners, and carries out programs designed to strengthen existing and develop new medical library services in the United States. It conducts research in health communications, supports medical informatics, and provides information services and sophisticated tools in the areas of molecular biology and toxicology/environmental health. The Library creates Web-based services for the general public containing information from the NIH and other reliable sources.

Important Events in NLM History

1836 – The Library of the Office of the Surgeon General of the Army was established (the present NLM).

1865 – John Shaw Billings, M.D., was assigned to supervise the Surgeon General's Library, which he developed into a national resource of biomedical literature.

1879 – The first volume of *Index Medicus* was published.

January 1922 – The Library of the Office of the Surgeon General (Army) was renamed Army Medical Library.

April 1952 – The Army Medical Library was renamed the Armed Forces Medical Library.

October 1, 1956 – The Armed Forces Medical Library was designated the National Library of Medicine and placed under PHS.

December 1961 – The new building at 8600 Rockville Pike was dedicated.

January 1964 – The Medical Literature Analysis and Retrieval System (MEDLARS) became operational at NLM.

October 22, 1965 – The Medical Library Assistance Act gave NLM the responsibility of helping the Nation's medical libraries through a grant program and created a Regional Medical Library Network.

January 1, 1967 – A Toxicology Information Program was established at NLM in response to recommendations of the President's science advisory committee.

1968 – NLM became a component of NIH. The Lister Hill National Center for Biomedical Communications, NLM's R&D component, was created by Congress.

October 1971 – MEDLINE (MEDLARS Online) was initiated to provide online access to a major portion of the MEDLARS database.

May 22, 1980 – NLM's Lister Hill National Center for Biomedical Communications building was dedicated. The new building, adjacent to the Library, houses NLM's research and development components, as well as its toxicology and biotechnology programs.

February 5, 1986 – Grateful Med, a PC-based user-friendly software for accessing MEDLARS, was introduced to the health community.

October 1993 – NLM's Internet WWW site appeared (www.nlm.nih.gov).

November 25, 1994 – The "Visible Human Male," a large computer dataset of images based on a cadaver, was introduced. The "Visible Human Female" appeared 1 year later.

June 26, 1997 – All web-based access to NLM's MEDLINE was made free.

October 1998 – MedlinePlus created to provide access to consumer health information.

NLM Legislative Chronology

August 3, 1956 — An amendment to Title III of the PHS act, the National Library of Medicine Act, placed the Armed Forces Medical Library under the PHS, and renamed it the National Library of Medicine (P.L. 84-941).

October 22, 1965 – The Medical Library Assistance Act of 1965 (P.L. 89-291) was signed into law, authorizing NLM's extramural programs of grant assistance to help expand and improve the Nation's medical library and health communications resources, technology, and manpower for service to the health community.

August 3, 1968 – Public Law 90-456 authorized the designation of the Lister Hill National Center for Biomedical Communications.

November 4, 1988 – Public Law 100-607 authorized the establishment of a National Center for Biotechnology Information at the NLM.

June 10, 1993 – Public Law 103-43 authorized the establishment of the National Information Center on Health Services Research and Health Care Technology at NLM.

December 2004 – The last issue of Index Medicus is published.

Biographical Sketch of NLM Director Donald A.B. Lindberg, M.D.

Dr. Lindberg assumed the directorship of NLM in August 1984. He received his A.B. degree (magna cum laude) from Amherst College and his M.D. degree from the College of Physicians and Surgeons of Columbia University. He received his specialty training in anatomic and clinical pathology at Columbia-Presbyterian Medical Center in New York. He also holds honorary degrees from Amherst College, State University of New York Health Science Center (Syracuse), and the University for

Health Sciences, Medical Informatics and Technology (Innsbruck, Austria).

Following early research in experimental pathology, he later began a long-term investigation of the use of computers in medicine, founding in 1963 one of the Nation's first medical computer centers at the University of Missouri in Columbia. Prior to joining the Library, Dr. Lindberg was director of the Information Science Group at Missouri and he taught pathology there from 1962 until his present appointment. He also served as chairman of the department of information science at the university's School of Library and Information Science.

Dr. Lindberg has published extensively in the fields of pathology and medical information. He is the author of two books – *The Computer and Medical Care* (1968) and *The Growth of Medical Information Systems in the United States*.

From 1992 to 1995 he served in the concurrent position of director of the National Coordination Office for High Performance Computing and Communications, Executive Office of the President. In 1996 he was appointed by the HHS Secretary as the U.S. national coordinator for global health care applications (G-7).

Directors of NLM

Name	In Office From	To
Frank B. Rogers	1956	1963
Martin M. Cummings	1964	August 1984
Donald A.B. Lindberg	August 1984	Present

Major Programs

MEDLARS

The Library's computer-based MEDLARS was established in January 1964 to achieve rapid access to NLM's vast store of biomedical information. Today this is accomplished through the web: provision of online search services through MEDLINE/PubMed, NLM Gateway, MedlinePlus, and other databases and services.

Web-based Services

MEDLINE was put on the Web free using the PubMed system in 1997. Heavy use by the public led to the development in 1998 of an extensive consumer health information service called MedlinePlus. Databases of gene sequence and other molecular information, clinical trials information, and toxicology and environmental health, are also on the Web. The NLM Web site is at www.nlm.nih.gov.

National Network of Libraries of Medicine

To provide more efficient dissemination of biomedical information, NLM has developed a network arrangement through which interlibrary loan and other information services can be shared efficiently by medical libraries. The National Network of Libraries of Medicine (NNLM) consists of eight Regional Medical Libraries and more than 45,000 hospital and other medical libraries. Although NLM remains the heart of the network, more and more services are being provided directly through the network. The NNLM toll-free number is 1-800-338-7657.

Lister Hill National Center for Biomedical Communications

The center explores the use of computer, communication, and audiovisual technologies to improve the organization, dissemination, and utilization of biomedical information, and is the focus of the

Library's high performance computing and communications initiatives.

Toxicology and Environmental Health Information Program

The general objectives of the program are to create computer-based toxicology and environmental health data banks from scientific literature and from files of collaborating industrial, academic, and governmental agencies, and to establish toxicology information services for scientists and the public.

National Center for Biotechnology Information

The NCBI, created in 1988, builds databases and information analysis/retrieval systems for genomic information and does research into advanced information-handling methods for biotechnology and related information.

National Information Center on Health Services Research and Health Care Technology

The goal of this program is to create information services that make the results of health services research readily available – including clinical guidelines, technology assessments, and health care technology.

Extramural Programs

The extramural grant and contract programs of NLM were originally authorized by the Medical Library Assistance Act of 1965 (P.L. 89-291) to provide better health information services through grant support to the Nation's medical libraries. The act, since extended by Congress, offers assistance for library resources, research in biomedical communications, biomedical publications, training for research careers in medical informatics, and Regional Medical Libraries. Research project grants in medical informatics are awarded under authority of title III, part A, sec. 301, of the PHS act.

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Center for Information Technology

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Mission

The Center for Information Technology's (CIT) mission is to provide, coordinate, and manage information technology and to advance computational science. CIT supports NIH's research and management programs with efficient, cost-effective information systems, networking services, and telecommunications services. Among its activities, the CIT:

- engages in collaborative research and provides collaborative support to NIH investigators in the area of computational bioscience;
- provides efficient, cost-effective information systems and networking services;
- provides state-of-the-art scientific and administrative computing facilities;
- identifies new computing technologies with innovative applications to biomedical research;
- creates, purchases, and distributes software applications;
- provides NIH staff with computing information, expertise, and training;
- provides data processing and high-performance computing facilities, integrated telecommunications data networks, and services to the U.S. Department of Health and Human Service (HHS) and other Federal agencies;
- serves as a data center to HHS and other Federal agencies; and
- develops, administers, and manages NIH systems and provides consulting services to NIH Institutes and Centers (ICs), in support of administrative and business applications.

Important Events in CIT History

1954 – A central data processing facility was established in the Office of the Director, NIH, under Dr. Harold Dorn, combining EAM (punched card) equipment and biometric expertise.

1956 – The biometric facility became the Biometrics Branch in the new Division of Research Services (DRS).

May 1956 – The NIH Director established a committee on electronic data processing and computers.

1958 – NIH installed its first electronic digital computer as an experimental device.

March 1960 – The Surgeon General approved the establishment of a Computation and Data

Processing Branch in DRS.

October 1961 – NIH installed its first "second generation" computer.

April 1963 – The NIH Director appointed a steering committee to undertake a comprehensive study of data processing activities at NIH.

April 1963 – The NIH steering committee recommended the establishment of a Division of Computer and Information Sciences (subsequently changed to the Division of Computer Research and Technology (DCRT), including provision for the transfer of the Computation and Data Processing Branch, DRS, to the new organization.

1964 – DCRT was established, with James King as Interim Acting Director.

1966 – Dr. Arnold W. Pratt was named DCRT's first Director.

April 1966 – Components of the "third-generation" computer system were installed.

April 1969 – NIH research community received the first time-sharing computers.

June 1969 – Minicomputers designed by the DCRT were installed in NIH laboratories.

May 1979 – An interagency agreement between HEW and GSA established the NIH Central Computer Utility as a Federal Data Processing Center.

April 1983 – The Personal Workstation Project was founded to determine how effectively NIH personnel could use personal computers.

1988 – The Convex Unix-based supermini-computer was installed, and the network task group was created.

1990 – Extensive networking (NIHnet) was installed at NIH, providing connectivity for 60 local area networks.

March 1992 – Department of Health and Human Services (DHHS) Secretary Lewis Sullivan, in a letter to Congress, committed to creating a new office to improve management and coordination of NIH's information resources.

June 1992 – The NIH Director approved creation of the Office of Information Resources Management (OIRM) in OD.

Dr. Francis W. Hartel, Ph.D. was selected as the NIH Senior IRM official and the Director of OIRM.

September 1993 – The Information Systems Security Officers (ISSO) committee was established to handle NIH IT security issues.

January 1994 – DCRT celebrated its 30th anniversary.

February 1994 – To help customers obtain computer-related information, a help desk was inaugurated.

October 1994 – OIRM sponsored the first Internet conference on legal and policy issues related to the increased use of Internet resources at NIH.

May 1995 – DCRT sponsored Internet Expo Day to help NIH staff discover the World Wide Web and its enormous potential to disseminate and exchange information.

June 1995 – The NIH Director approved a revised charter for the Office of Information Resource Management (IRM) council and increased its role in providing management leadership on NIH-wide information technology (IT) initiatives.

July 1995 – OIRM, the National Science Foundation, and the World Wide Web Federal Consortium sponsored a Federal Webmaster workshop on legal, ethical, and security issues related to increase Web use by Federal agencies.

August 1995 – The first NIH electronic store was established to provide efficient acquisition of personal computers, hardware, software, and on-line components to NIH personnel.

May 1996 – The IRM council established the NIH Year 2000 Work Group (Y2K) to provide NIH with leadership and direction on initiatives modifying computer systems and applications to accommodate problems related to a two-digit date field.

June 1996 – NIH's Computer Center was designated as a major DHHS data center.

July 1996 – The NIH Data Warehouse, which provides a one-stop-shop graphical user interface to NIH administrative and accounting information, was introduced to NIH.

1996 – A telecommunications committee was established to provide the IRM council with advice about crosscutting telecommunication issues affecting a large number of NIH staff. Issues included telephone features and services, pagers, cellular services, video teleconferencing, remote access, audio conferencing, and switchboard operator services. Responsibilities were shared by DCRT and the Telecommunications Branch located in NIH's Office of Research Services; DCRT introduces a subscription based program for the acquisition and distribution of brand-name software to NIH and HHS personnel, with the result of significant cost reduction for software licensing.

August 1996 – The Information Technology Management Reform Act of 1996 (ITMRA, also known as the Clinger-Cohen Act) became effective. ITMRA assigned overall responsibility for the acquisition and management of government IT resources to the Director, Office of Management and Budget. Additionally, ITMRA gave authority to heads of executive agencies to acquire IT resources, and directed agencies to appoint a Chief Information Officer (CIO) to provide advice to each agency on the effective management of IT investments.

1996 – NIH Director named Anthony Itteilag, NIH Deputy Director for Management, to serve as interim NIH Chief Information Officer (CIO).

September 1996 – The NIH Director's leadership forum on the management of IT at NIH formed an IT Central Committee (ITCC) to provide recommendations on improving the management of NIH IT resources.

December 1996 – A final ITCC report was submitted to the NIH Director. The report recommended appointing a CIO and combining DCRT, OIRM, and TCB into a single organizational structure.

1996 – Dona R. Lenkin was appointed to serve as OIRM Acting Director and alternate NIH CIO.

July 1997 – DCRT introduced the NIH Human Resources Information and Benefits System (HRIBS), a Web service that gave employees easy access to personnel data, including benefits, salary, awards, leave, savings, performance and retirement.

September 1997 – DCRT completed consolidation of two HHS data centers --- the Program Support

Center Information Technology Service and the Administration for Children and Families National Computer Center --- into the NIH Computer Center.

1997 – A review of NIH's administrative structure, conducted in response to a request from Congressman John Porter (Ill.), was completed. The report recommended that the NIH implement the ITCC recommendations by appointing a permanent CIO and establishing a CIO organization.

October 1997 – Vice President Albert Gore awarded OIRM staff the National Performance Review "Hammer" Award for the development of an automated security risk assessment tool for networks.

1997 – NIH's first electronic magazine, *LiveWire*, was launched by DCRT. The on-line magazine offered easy access to key services and computer information.

November 1997 – DCRT inaugurated SILK (Secure Internet-Linked) technology to provide Web access to enterprise data.

February 1998 – The Center for Information Technology (CIT) was formed, combining the functions of the DCRT, the Office of Information Resources Management (OIRM), and the Telecommunications Branch.

March 1998 – Alan S. Graeff was named NIH's first Chief Information Officer (CIO) and Director of the newly formed Center for Information Technology (CIT).

April 1998 – CIT's OIRM sponsored an IT security conference to provide IT security officers and others with essential information for moving towards the 21st century; CIT renames its original acquisition and distribution project to the Software Distribution Project (SDP). The SDP provides software to more than 24,000 customers, including more than 80% of all personnel.

October 1998 – The NIH IT Board of Governors (BoG) was established to advise the NIH and the NIH CIO on NIH-wide IT management and to make recommendations on IT activities and priorities.

May 1999 – The Information Technology Management Committee (ITMC) was formed to develop and communicate recommendations and decisions at the IC level, provided a forum for building consensus across the NIH, and served as an umbrella organization to the NIH IT process management and technical committees.

December 1999 – NIH successfully prepared for the Year 2000, thus bringing to fruition four-years of effort preparing for the largest information management project in history. The NIH strategy of aggressive renovation and validation of information systems, biomedical equipment, facilities, utilities, and telecommunications provided a smooth transition that ensured the integrity of the NIH mission.

January 1999 – CIT completed development of the predecessor to the TELESYNERGY(TM) Medical Consultation WorkStation, a multimedia, medical imaging workstation. This system provided an electronic imaging environment, utilizing a prototype Asynchronous Transfer Mode (ATM) telemedicine network. The TELESYNERGY(TM) environment included a scientific workstation as the computing platform that transmits simultaneous high-resolution images to all sites participating in a medical consultation.

January 2000 – CIT joined forces with NCI in a pioneering TELESYNERGY(TM) collaboration to reach out to distant community hospitals. Patients in remote areas were now able to participate in selected NCI phase I and phase II protocols. Collaborating sites, with TELESYNERGY(TM) Systems either installed or under construction, included hospitals in Fort Lauderdale, Florida; Wheeling, West Virginia; Belfast, Northern Ireland, United Kingdom; and Dublin, the Republic of Ireland.

2000 – CIT renames the Software Distribution Project (SDP) to the Information Systems Designated Procurement (iSDP) to acquire and deliver brand-name software, hardware and services to NIH and DHHS personnel. The iSDP takes advantage of large volume purchasing agreements to provide significantly discounted prices to its customers. The iSDP also saves its participants time and money by eliminating the need to search for the best information systems deals. iSDP provides major software titles, hardware and services to more than 54,000 customers, including 84 percent of DHHS personnel, and all of NIH.

2001 – The NIH Incident Response Team (IRT) was the first civilian Federal agency to receive the prestigious Office of Personnel Management (OPM) Guardian Award, for exceptional contributions in ensuring the confidentiality, availability, and integrity of NIH information resources.

2002 - Dr. John F. (Jack) Jones, Jr., joined CIT as Chief IT Architect for NIH, to focus on NIH enterprise systems critical to the mission of NIH and lead Enterprise Architecture; CIT took a leadership role in forging NIH's strategy for common services, including hosting the improved and expanded NIH Portal. CIT supported the development and staged implementation of the NIH Portal as a single, user-friendly customizable web interface by which data and documents can be readily accessed by NIH staff and associated personnel; CIT successfully implemented the NIH Administrative Restructuring Advisory Committee (ARAC) recommendations for IT Consolidation (Phase I).

2003 – The National Institutes of Health (NIH) Information Technology Working Group (ITWG), established by the NIH Director as part of the NIH Steering Committee, provides governance and oversight on NIH IT management issues. The ITWG is advisory to the NIH Director, NIH Steering Committee, and NIH Chief Information Officer (CIO).

As an advisory group to the NIH Director, NIH Steering Committee, and NIH CIO on IT management, the ITWG establishes governance over the five IT Domain Areas below, representing the areas where decisions need to be made at the intersection of business and information technology.

- IT Principles Domain – includes alignment of IT to the NIH mission of the NIH, corporate policies and oversight of the use of IT, and determination of ownership of IT initiatives
- IT Infrastructure Strategies Domain – includes the IT “public utility” and secure, robust, and manageable common services
- IT Architecture Domain – includes data standards and application standards
- Business Application Needs Domain – includes all enterprise, non-scientific administrative, grants/extramural, and Intramural IT systems
- IT Investment and Prioritization Domain – includes funding mechanisms and priorities

2004 – CIT successfully implemented the NIH ARAC recommendations for IT Consolidation Phase II; CIT continues to implement and oversee NIH enterprise-wide applications like:

- Integrated Time and Attendance System (ITAS)
- NIH Enterprise Common Services (NECS); including NIH Login and NIH Portal
- NIH Intramural Data Base (NIDB)
- Contractor Performance System (CPS)
- Vulnerability Tracking System (VTS)
- Human Resources Data Base (HRDB)

Biographical Sketch of NIH CIO and CIT Director Alan S. Graeff

Alan S. Graeff was named Chief Information Officer (CIO) of the National Institutes of Health (NIH) and Director of the newly formed Center for Information Technology (CIT) on March 6, 1998.

Graeff previously served as Chief of the Clinical Center's (CC) Information Systems Department,

where he oversaw a major Information Technology (IT) reorganization that introduced a centralized infrastructure based on technical standards, reliable architecture, and high levels of customer support. Graeff created a unified support structure for IT in the CC's diverse environment of clinical research, patient services, and administration.

As Chief of the National Institute of Allergy and Infectious Diseases' (NIAID) Technical Systems Section from 1989 - 1991, Graeff was responsible for building the Institute's first wide-area network, comprising twelve locations across the country and serving 1,400 computer users. He also designed and implemented an NIAID acquisition workflow system that streamlined the Institute's acquisition and planning processes. In earlier positions, Graeff worked as a biologist for the National Cancer Institute's (NCI) Metabolism Branch and NIAID's Laboratory of Cellular Immunology. Graeff holds a B.S. in distributed sciences from American University.

CIT Directors

Name	In Office From	To
James King (Acting)	N/A	N/A
Dr. Eugene Harris (Acting)	N/A	August 1966
Dr. Arnold W. Pratt	August 1966	May 1990
Dr. David Rodbard	November 1990	April 1996
William L. Risso (Acting)	April 1996	March 1998
Alan S. Graeff	March 1998	Present

NIH Chief Information Officer

Name	In Office From	To
Alan S. Graeff	March 1998	Present

Programs

CIT consists of the Office of the Director (OD), the Office of the Deputy Chief Information Officer (ODCIO), the Division of Computational Bioscience (DCB), the Division of Customer Support (DCS), the Division of Computer System Services (DCSS), the Division of Enterprise and Custom Applications (DECA), and the Division of Network Systems and Telecommunications (DNST).

Office of the Director (OD)

The Office of the Director plans, directs, coordinates, and evaluates the Center's programs, policies, and procedures and provides analysis and guidance in the development of systems for the effective use of IT techniques and equipment in support of NIH programs. The Chief Technology Officer (CTO) provides advice on the computational and telecommunications needs of the NIH community and provides analysis and guidance in developing systems supporting NIH-wide IT initiatives. In addition, the CTO evaluates new technologies, provides planning guidance for CIT programs and services, and coordinates IT architectural management for the NIH.

Office of the Deputy Chief Information Officer (ODCIO)

The Deputy Chief Information Officer advises the Chief Information Officer (CIO) on the direction and management of significant NIH IT program and policy activities under relevant Federal statutes, regulations and policies. The ODCIO also develops, implements, manages, and oversees NIH IT activities related to IT legislation, regulations, and NIH and other Federal policies:

- ODCIO directs NIH's IT capital planning processes with regard to major IT investments and

provides leadership to NIH ICs to enhance and strengthen their IT program management so they comply with legislative and policy requirements.

- The office serves as principal NIH liaison to HHS, its OPDIVs, and other Federal agencies on IT matters.
- In addition, ODCIO identifies critical IT issues and analyzes, plans, leads, and manages the implementation of special HHS or Federal initiatives as they relate to the management of NIH's IT resources.
- ODCIO also collaborates with NIH managers responsible for IT-related functions, in particular, IT security. ODCIO staffs and supports NIH's Incident Response Team (IRT). The IRT serves as the focal point for IT security incidents by identifying and characterizing incidents, and providing immediate diagnostic and corrective action when appropriate.

Division of Computational Bioscience (DCB)

DCB is a research and development organization that provides scientific and technical expertise in computational science and engineering to support biomedical research activities at the NIH:

- DCB applies the concepts and technologies of computer, engineering, physical and mathematical science to biomedical applications including the areas of image processing, bioinformatics, genetic databases, structural biology, scientific visualization, medical imaging, telemedicine, signal processing, biomedical instrumentation, and biomathematics.
- DCB develops computational methods and tools for solving biomedical laboratory and clinical research problems.
- DCB promotes the application of high-performance computing and high-speed communications to biomedical research and provides these resources for the NIH scientific staff.
- DCB evaluates the overall effectiveness of these programs and represents CIT to the national Information Technology Research and Development (IT R&D) Program.

Division of Computer System Services (DCSS)

DCSS plans, implements, operates, and supports centrally owned or administered computing resources for NIH enterprises use, ensuring interoperability among those resources and between them and other computing facilities owned by customer organizations.

- DCSS promotes awareness and efficient and effective use of these computing resources by customer personnel through training, presentations, consultations, and documentation.
- DCSS investigates new and emerging computing requirements of customer programs. It conducts research and development to identify, evaluate, and adapt new computer architectures and technologies to meet identified customer requirements and to enhance current service offerings.
- Additionally, where appropriate, DCSS manages and operates departmental computing resources for IC, Office, or Center use.

Division of Customer Support (DCS)

DCS provides centralized, integrated computer support services to the NIH computing community:

- DCS advocates customer needs to CIT management and represents services and policies to CIT's customers.
- It plays an active and participatory role in supporting desktop computing to the end-user in the areas of software and hardware, including internet, communications, and access technologies.
- The Division also coordinates and oversees CIT's Training Program for the benefit of the NIH computing community. The training program is delivered at no charge to the user.
- In addition to providing a central account establishment and management services for access to CIT systems, DCS also manages an emergency 24x7 NIH-wide help desk and implements problem tracking systems.

Division of Enterprise and Custom Applications (DECA)

DECA supports the NIH enterprise business process through the development and management of transaction and decision-support environments for administrative and business applications of the NIH, such as procurement, budget, accounting and human resource activities, as well as systems that support extramural and intramural business processes:

- The Division provides complete information systems management services to the NIH including technical project management, systems analysis, programming, data integration and conversion, quality assurance, testing, and production support.
- DECA also provides the NIH community with World Wide Web development, support services, and consulting services for applications development.

Division of Network Systems and Telecommunications (DNST)

DNST directs the engineering, design, implementation, and support of network infrastructure and services for the NIH wide area network (NIHnet) to facilitate the use of scientific, administrative, and other business applications:

- DNST manages and directs NIH telecommunications systems and technical requirements for the NIH ICs and implements telecommunications programs to meet the needs of the NIH community.
- The Division researches, develops, and tests next-generation networking/ telecommunications technologies and develops and supports applications using new network technologies, such as telemedicine and video conferencing.
- It provides consulting, guidance and support to the ICs, helping them to meet their network requirements.
- To improve the information infrastructure on networking/telecommunications activities, DNST serves as liaison to the NIH ICs and other DHHS components.
- DNST serves as a focal point for telecommunications service orders, and develops and disseminates recommended standards, policies, and procedures for the nationwide implementation and management of NIH networking and telecommunications systems.
- The Division also develops, implements, and supports remote access services to NIHnet, provides technical support for wireless services, and a 24-hour telephone/network support

service.

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Center for
Scientific
Review

Center for Scientific Review

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Mission

The Center for Scientific Review (CSR):

- Serves as the central receipt point for all research and training grant applications submitted to the NIH. Also receives some of the applications submitted to other components of the Department of Health and Human Services (DHHS) and refers them to these components;
- Assigns all NIH applications to the appropriate institutes or centers for consideration for funding and also to the scientific review groups within CSR or other institutes or centers for review;
- Provides the scientific merit review of most research grant and fellowship applications submitted to the NIH;
- Provides staff support to the Office of the Director, NIH, in the formulation of grant and award policies and procedures; and
- Assists other NIH components in providing information on the NIH peer review system and information about the research grant and fellowship application process and procedures to the scientific community, the Congress, other NIH staff, and the general public.

Important Events in CSR History

1944 – Public Health Service Act (P.L. 78-410, sec. 301, July 1) authorized the Surgeon General to "make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the National Advisory Health Council, or, with respect to cancer, recommended by the National Advisory Cancer Council." The act also authorized the award of fellowships in the health sciences.

1946 – The Research Grants Office was established January 1 under authority of section 301 of the PHS act to administer a number of research projects transferred to PHS at the end of World War II and to operate a program of extramural research grants and fellowship awards. The office was elevated to division status at the end of 1946.

The Division of Research Grants (DRG) was responsible for operating and administering a program of extramural research and training through grants-in-aid of research in the biomedical and health-related sciences. DRG retained the operating responsibility until each successive institute was established and took over the programs in its categorical fields. NCI, which already ran an extramural research program on its own, continued to do so.

DRG was instructed by the National Advisory Health Council to establish study sections for scientific

and technical review of research grant applications, and to explore neglected areas of research in the health sciences.

1958 – Responsibility for research grant and training programs in noncategorical areas, operated by the division since 1946, was transferred to the new Division of General Medical Sciences (DGMS). DRG then reorganized to concentrate on the review of research grant and fellowship applications, coordination of all extramural programs operated by the institutes and DGMS, and operation of the health research facilities program and grants management.

1961 – The Grants Associates Program began recruitment and training of professional staff for the extramural branches of all PHS granting divisions, with DRG serving as a primary training focus.

1962 – DRG was assigned overall responsibility for coordinating policies and practices for administration of grants and awards for all PHS extramural programs.

1965 – The Civil Rights Liaison Office was established.

1966 – DRG assumed additional responsibilities for review with the transfer from the institutes of the committee on scientific publications, the NCI collaborative research panel, the environmental sciences review committee and the review functions of six panels of the U.S.-Japan Cooperative Medical Science program.

1968 – DRG expanded the computer-based central data system, information for management planning analysis and coordination (IMPAC), to include the fellowship programs in addition to research, training grant, and research career award programs.

1969 – DRG became a part of the Office of the Associate Director for Extramural Research and Training. Grants management responsibilities were transferred to the Office of Financial Management in the Office of the Associate Director for Administration.

1970 – DRG coordinated the initial review of all FDA applications for research grants.

1971 – The computer retrieval of information on scientific projects (CRISP) system was designed to provide scientific and associated grant identification information.

1978 – The Extramural Associates Program was established under the Intergovernmental Personnel Act (P.L. 91-648) to promote participation of ethnic minorities and women in NIH-supported research.

1983 – The Scientific Review Branch, Referral Branch, and Office of Research Manpower were consolidated into the Referral and Review Branch.

DRG became the central information source for the new Small Business Innovative Research (SBIR) Program and coordinated the scientific review of SBIR applications.

1995/96 – DRG moved from the Westwood Building, where it had been since 1965, to the Rockledge Center, located near the NIH campus in Bethesda. Most of the Information Systems Branch was transferred to the Office of Extramural Research in the Office of the Director, NIH.

1997 – Under a new Director, Dr. Ellie Ehrenfeld, DRG underwent a major reorganization and received a new name: the Center for Scientific Review (CSR). The name change reflected the Center's primary mission – scientific review of grant applications – and signaled an expanded focus on developing and implementing flexible and innovative ways for referral and scientific review. The Center was divided into three review divisions (Molecular and Cellular Mechanisms; Physiological Systems; and Clinical and Population-based Studies) plus the Division of Receipt and Referral; the

Division of Management Services; the Office of Planning, Analysis, and Evaluation; and the Office of Outreach.

CSR also began a thorough examination of its Integrated Review Groups (IRGs) and their study sections. CSR received assistance from two types of external advisory groups that reported to the CSR Advisory Committee: (1) IRG working groups, which were established to evaluate individual IRGs (2) the Panel on Scientific Boundaries for Review (PSBR), which was established to assess the overall structure and function of the IRGs.

The review activities of the former ADAMHA Institutes (the National Institute on Alcohol Abuse and Alcoholism, the National Institute on Drug Abuse, and the National Institute of Mental Health) were being integrated into CSR.

1999 – The PSBR completed its Phase 1 report, which defined organizing principles for a rigorous yet fair review and provided recommendations for reconfiguring the IRGs. In addition, eight IRG Working Groups were developed or under development to assess current IRGs.

2000 – Phase 2 of the PSBR effort was initiated to implement the Panel's recommendations. A Study Section Boundary (SSB) Team of extramural scientists with a small number of NIH and CSR staff members was formed to design the first new IRG (Hematology). A 3-year plan was developed to initiate additional SSB Teams and complete the reorganization of the 24 IRGs proposed by PSBR.

A reviewer survey was distributed to all CSR review groups to assess reviewer satisfaction and workload burdens. Ninety percent of the respondents reported that they were at least "satisfied" with their service, and a majority of respondents reported that they were "very satisfied." Reviewers indicated that it takes an average of 30 hours to prepare an average of six written critiques and an additional 8 hours to prepare as a reader of approximately 2.5 applications.

2001 – Major strides were made in completing CSR evaluation and reorganization efforts. IRG Working Group reports for nearly all existing IRGs were completed. Three SSB Teams completed the design of their IRGs: Hematology; Biology of Development and Aging; Musculoskeletal, Oral and Skin Sciences; and Cardiovascular Sciences. SSB Teams were developed to design four additional IRGs.

The number of CSR study sections increased to 153 with the addition of new review groups in the areas of biomedical information science and technology development, epidemiology, muscle biology, and oncological sciences. CSR also developed 12 new study sections to review fellowship applications.

2002 – CSR further advanced its efforts to reorganize its IRGs. SSB Teams completed the design for 8 of the remaining 12 IRGs to be reorganized: (1) Bioengineering Sciences and Technologies; (2) Surgical Sciences, Biomedical Imaging and Bioengineering; (3) Oncological Sciences; (4) Digestive Sciences; (5) Immunology; (6) Renal and Urological Sciences; (7) Endocrinology, Metabolism, Nutrition and Reproductive Sciences; and (8) Infectious Diseases and Microbiology.

Responding to the need to advance clinical research, CSR recruited a Special Advisor on Clinical Research Review, Dr. Theodore Kotchen, who is Professor of Medicine and Epidemiology and Associate Dean for Clinical Research at the Medical College of Wisconsin.

Strides were made in using new technologies to enhance CSR reviews. All chartered study sections were given access to the Internet Assisted Peer Review System, which allows reviewers to post their critiques and later read the critiques posted by others in their study section. In addition, the vast majority of CSR reviewers were given CDs with electronic copies of the grant applications to be considered by their review panel. The CDs are easier to transport and are bookmarked for easy navigation.

2003 – Important milestones were reached in CSR's reorganization efforts. SSB teams completed their recommendations for the last IRGs to be designed: (1) Respiratory Sciences IRG; (2) Genes, Genomes and Genetics IRG, (3) Biological Chemistry and Macromolecular Biophysics IRG; and (4) Cell Biology IRG. CSR also implemented its first redesigned IRG—the Hematology IRG—and advanced efforts to implement other IRGs.

Dr. Ellie Ehrenfeld stepped down as CSR's Director. Dr. Elias Zerhouni appointed CSR's Deputy Director, [Dr. Brent Stanfield](#), to be the new Acting Director.

A CSR-coordinated effort to develop new ways to encourage, review, and fund innovative research grant applications was advanced and incorporated into the NIH Director's Roadmap initiative.

CSR restructured its three review divisions into four new divisions: (1) Division of Biologic Basis of Disease, (2) Division of Molecular and Cellular Mechanisms, (3) Division of Physiology and Pathology, and (4) Division of Clinical and Population-Based Studies.

In an effort to make the review focus of study sections more transparent, CSR gave names to study sections that were previously designated by their IRG affiliation and a number.

The Internet Assisted Review system was built into IMPAC, the grants system used by NIH. Reviewers now access the system through the NIH Commons, the venue for electronic communications between NIH and its principal investigators.

2004 – The formal design stage for reorganizing CSR's scientific review groups as proposed by PSBR was completed in January 2004 after the CSR Advisory Committee endorsed the guidelines for the last groups to be reorganized. Study sections within all but three of the new IRGs met at least once.

CSR advanced outreach efforts to educate applicants, reviewers, and NIH staff by developing (1) an online video of a mock study section; (2) a new CSR exhibit booth, which was deployed at six major scientific meetings across the country; (3) CSR's first Annual Report; and (4) a new CSR logo.

All CSR study sections used the Internet-Assisted Review Peer Review system, and CSR helped advance pilot studies for the electronic submission of grant applications.

CSR's Special Advisor on Clinical Research Review (1) completed a study of review outcomes for clinical vs. nonclinical research applications and published the results in the *Journal of the American Medical Association*, (2) initiated a mechanism to track review outcomes of clinical grant applications on an ongoing basis, (3) developed a Web page to provide "Advice to Investigators Submitting Clinical Research Applications," (3) helped revise the review criteria for NIH grant applications to improve the assessment of clinical research applications, and (4) provided presentations on the review of these applications at five meetings of clinical scientists.

The CSR Advisory Committee held its last meeting on September 20, 2004. A new Peer Review Advisory Committee will advise the CSR and NIH on peer review issues and operations.

2005 – The Peer Review Advisory Committee held its first meetings to provide comprehensive guidance to the NIH Director, CSR Director, and Deputy Director for Extramural Research on all NIH peer review policies and operations.

Dr. Antonio Scarpa assumed the responsibilities of CSR's Director on July 1, 2005.

CSR received the first electronic grant applications via grants.gov and prepared to receive most applications by October 1, 2006.

A new payment system was developed to replace the Scientific Review and Evaluation Awards system. Under the new system, reviewers attending study section meetings receive their honoraria and "flat-rate" reimbursements for meals and incidental expenses without having to submit vouchers. Reviewers will no longer need to submit vouchers for hotel expenses, which will be paid directly by NIH. All reviewer payments will be made electronically.

Biographical Sketch of CSR Director, Dr. Antonio Scarpa, M.D., Ph.D.

On March 21, 2005, Dr. Antonio Scarpa was named Director of the Center for Scientific Review (CSR) at the National Institutes of Health (NIH). He now leads CSR's efforts to better manage the receipt and referral of NIH grant applications and coordinate their review in CSR peer review groups. Dr. Scarpa has served as a permanent member of three NIH peer review committees between 1983 and 2003 as well as a member of peer review committees for the American Heart Association.

He came to NIH from Case Western Reserve University in Cleveland, where he was the David and Inez Myers professor and chair of the Department of Physiology. He oversaw the development of a small physiology and biophysics department into one now ranked among the best in the country. His research there was focused on the cellular and molecular mechanisms of ion transport and homeostasis and the metabolic consequences induced by transport. His studies were supported by grants from the National Heart, Lung and Blood Institute, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute of Diabetes and Digestive and Kidney Diseases, as well as the American Heart Association.

Dr. Scarpa has more than 225 peer-reviewed publications and has edited or co-edited 9 books or special journal supplements. He has been an officer or board member of many scientific societies, including The Biophysical Society, the Federation of American Societies for Experimental Biology, and the Association of American Medical Colleges. Over the years, Scarpa also has served on the editorial boards of 13 scientific journals and served as editor or co-editor for 5 journals.

Dr. Scarpa received his M.D. and Ph.D. (Libera Docenza) in general pathology from the University of Padua School of Medicine, and he conducted postdoctoral studies at the Weizmann Institute of Science in Israel, the University of Utrecht in The Netherlands, and the University of Pennsylvania in Philadelphia. Scarpa continued his research and academic career for 17 years at the University of Pennsylvania before moving to Case Western Reserve in 1986.

CSR Directors

Name	In Office From	To
Cassius James Van Slyke	January 1946	December 1, 1959
David E. Price	1948	1950
Ernest M. Allen	1951	1960
Dale R. Lindsay	1960	1963
Eugene A. Confrey	October 1963	1969
Stephen P. Hatchett	1969	August 1976
Carl D. Douglass	August 1976	December 1985
Jerome G. Green	January 1986	June 1, 1995
Ellie Ehrenfeld	January 1997	September 30, 2003
Brent Stanfield (Acting)	October 1, 2003	June 30, 2005
Antonio Scarpa	July 1, 2005	present

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The NIH Almanac – Organization

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John E. Fogarty International Center for Advanced Study in the Health Sciences

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Mission

The John E. Fogarty International Center (FIC) for Advanced Study in the Health Sciences, the international component of the NIH, addresses global health challenges through innovative and collaborative research and training programs and supports and advances the NIH mission through international partnerships.

[Important Events in FIC History](#)

[Biographical Sketch of FIC Acting Director Sharon H. Hrynkow, Ph.D.](#)

Dr. Sharon Hrynkow became Acting Director of the Fogarty International Center (FIC) January 1, 2004. She joined the Center in 1995 and has served as Deputy Director since 2000.

Among Dr. Hrynkow's specific areas of focus at FIC are efforts to combat brain drain for junior scientists from developing nations who are trained in the U.S., efforts to enhance recruitment and retention of women in science in the developing world, initiatives to build capacity in the neurosciences in low- and middle-income nations, and efforts to build partnerships with private groups, other U.S. agencies and foreign counterparts to support novel initiatives in global health.

Dr. Hrynkow, a native of Rhode Island, attended Rhode Island College. She received her Ph.D. in neuroscience from the University of Connecticut, and completed postdoctoral training in the area of brain development at the University of Oslo. Her scientific publications include those examining the role of extracellular matrix molecules on the formation of neural connections during embryogenesis and in the role of cell lineage as a determinant for neuronal differentiation. Dr. Hrynkow became a Science Officer at the U.S. Department of State, where she worked on a range of health and science issues of import to the U.S. foreign policy community, including HIV/AIDS, chemical safety, and biotechnology. Her work with State Department leadership, interagency partners, NGOs, and business leaders culminated in the production of the first "U.S. International Strategy on HIV/AIDS."

Dr. Hrynkow is a member of several professional organizations and has published numerous articles on capacity building in the developing world and on brain development. She was elected to the Council of Foreign Relations in 1996.

FIC Directors

Name	In Office From	To
Milo D. Leavitt, Jr.	June 16, 1968	July 1978
Leon Jacobs	July 1, 1978	June 29, 1979

Edwin D. Becker (Acting)	July 1979	April 1980
Vida H. Beaven (Acting)	April 1980	January 1981
Claude Lenfant	February 1981	July 1982
Mark S. Beaubien (Acting)	July 1, 1982	January 1984
Craig K. Wallace	January 1984	December 1987
Carl Kupfer (Acting)	January 1, 1988	July 1988
Philip E. Schambra	August 1988	September 30, 1998
Gerald T. Keusch	October 1, 1998	December 31, 2003
Sharon H. Hrynkow (Acting)	January 1, 2004	Present

[Research and Research Training Programs](#)

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Special Initiatives

- [Multilateral Initiative on Malaria](#)

Training Grants

[AIDS International Training and Research Program \(AITRP\)](#)

This program supports HIV/AIDS–related research training to strengthen the capacity of institutions in low and middle income countries to conduct multi-disciplinary biomedical and behavioral research capacity to address the AIDS epidemic in the collaborating country. Grants are awarded to US and developed country institutions with strong HIV-related research training experience and with HIV-related research collaborations with institutions in low and middle income countries. These institutions, in partnership with their foreign collaborating institutions, identify foreign health scientists, clinicians, and allied health workers from the foreign countries to participate in their joint research training programs. Individuals from foreign nations who wish to become trainees must apply to the project director of an awarded grant.

[FIC / Ellison Clinical Research for U.S. Graduate Students](#)

The Fogarty International Center, with support from the Ellison Medical Foundation and NCMHD, is offering a one-year clinical research training experience abroad for graduate level U.S. students in the health professions.

[Fogarty International Collaborative Trauma and Injury Research Training Program \(ICTIRT\)](#)

This new program addresses the growing burden of morbidity and mortality in the developing world due to trauma and injury. The program is supported by FIC, seven NIH partners, the Center for Disease Control and Prevention's National Center for Injury Prevention and Control, the Pan American Health Organization, and the World Health Organization (WHO). It addresses training across the range of basic to applied science, the epidemiology of risk factors, acute care and survival, rehabilitation, and long-term mental health consequences.

[Framework Programs for Global Health](#)

This new initiative builds global health research capacity in the United States and abroad. Through the "Framework Programs for Global Health," institutions create administrative frameworks to bring multiple schools (such as engineering, business, chemistry, biology, communication, public health, medicine and environmental studies) together on the topic of Global Health and develop multidisciplinary Global Health curricula for undergraduates, graduates and professional school students. Each program leverages and enhances currently funded Global Health projects at the institution supported by NIH and other sponsors as well as encourages new training opportunities,

collaborations and research.

[Global Infectious Disease Research Training Program \(GID\)](#)

This program enables institutions in the United States or in developing foreign countries to support current and future collaborative research related training on infectious diseases that are predominately endemic in or impact upon people living in developing countries.

[Informatics Training for Global Health](#)

This RFA is intended to encourage the development of informatics training programs that will contribute to global health research and informatics capacity in low- to middle-income countries in partnership with U.S. institutions.

[International Bioethics Education and Career Development Award](#)

This program allows nonprofit, private or public, domestic or international, educational and research institutions to develop or expand on current graduate curricula in international bioethics related to performing research in low- and middle-income nations. Applications are accepted in response to a Request for Applications (RFA).

[International Clinical, Operational, and Health Services Research and Training Award \(ICOHRTA\)](#)

This program supports training to facilitate collaborative, multidisciplinary, international clinical, operational, health services and prevention science research between U.S. institutions and those in developing countries, as well as emerging democracies of Eastern Europe, Russia, and the Newly Independent States (NIS). Information about current ICOHRTA programs and instructions for prospective trainees hoping to participate in this program are available at this website.

[International Clinical, Operational, and Health Services Research and Training Award for AIDS and Tuberculosis \(ICOHRTA-AIDS/TB\)](#)

This program supports research training to strengthen the capacity of institutions to conduct clinical, operational and health services research. These institutions are located in low- and middle-income countries where AIDS, TB, or both are significant problems. In Phase I, one-year planning grants to support the development of full research training applications in Phase II are awarded to institutions in low and middle income countries with strong HIV- or TB-related research experience. In Phase II, grants to support a research training program are awarded to Phase I awardees and to their United States or other developed country institutional partner with whom they have strong HIV- or TB-related research collaborations. Individuals who wish to become trainees must apply to the project director of an awarded grant.

[International Collaborative Genetics Research Training Program](#)

This program will enhance and promote equitable international collaborations between investigators in the developed world and those in developing countries where a base level of institutional infrastructure for the advancement of sustainable genetic science is already established. Applications are being solicited to create innovative research training programs within existing scientific collaborations between developed and developing country researchers to begin to build a critical mass of scientists, health professionals and academics with human genetics expertise and a sustainable research environment at the collaborating developing country institution.

[International Maternal and Child Health Research and Training Program \(MCH\)](#)

This program enables U.S. institutions to support research training on maternal and child health issues that are predominately endemic in or impact upon people living in low and middle income countries. This is an institutional research training grant and applications are accepted from U.S. institutions in response to a specific request for applications (RFA). Individuals from foreign nations who wish to become trainees must apply to the project director of an awarded grant.

[International Training and Research Program in Environmental and Occupational Health](#)

This program enables U.S. universities and non-profit research institutions to support international training and research programs for foreign scientists from developing nations in general

environmental health and occupational health. This is an institutional training grant. Applications are accepted from U.S. institutions in response to a specific request for applications which is published once every five years; the first awards were made in 1995. Individuals from foreign countries who wish to become trainees must apply to the project director of an awarded grant.

[International Training and Research Program in Population and Health](#)

This program enables U.S. universities and non-profit research institutions to support international training and research programs for foreign scientists from developing nations in population-related sciences. This is an institutional training grant. Applications are accepted from U.S. institutions who are current NIH grant recipients in response to a specific request for applications which is published once every five years. Individuals from foreign countries who wish to become trainees must apply to the project director of an awarded grant.

Research Grants

[Brain Disorders in the Developing World: Research Across the Lifespan](#)

This program supports collaborative research and capacity building projects on brain disorders throughout life, relevant to low- and middle-income nations. Applicants are expected to develop innovative, collaborative research programs that would contribute to the long-term goal of building sustainable research capacity in neurological (including sensory, motor, cognitive and behavioral) impairment throughout life.

[Ecology of Infectious Diseases](#)

This program funds interdisciplinary research programs that strive to elucidate the underlying ecological and biological mechanisms that govern the relationships between anthropogenic environmental changes and the transmission dynamics of infectious diseases. The focus of this program is on the development of predictive models for the emergence and transmission of diseases in humans and other animals, and ultimately the development of strategies to prevent or control them.

[Fogarty International Research Collaboration Award \(FIRCA\)](#)

This program provides funds (\$32,000/year direct costs) to foster international research partnerships between NIH-supported U.S. scientists and their collaborators in countries of the developing world. The FIRCA program aims to benefit the research interests of both the U.S. and foreign collaborators while increasing research capacity at the foreign site. U.S. scientists who have an eligible NIH grant may apply. All areas of biomedical and behavioral research supported by NIH are eligible FIRCA research topics.

[Global Health Research Initiative Program for New Foreign Investigators \(GRIP\)](#)

This initiative promotes productive re-entry of NIH-trained foreign investigators into their home countries as part of a program to enhance the scientific research infrastructure in developing countries, to stimulate research on high priority health-related issues in these countries, and to advance NIH efforts to address health issues of global import. The GRIP provides partial salaries to the foreign researcher returning home and support for research projects. To make the review of this program more robust, we divided the program into two components: Behavioral and Social Science; and Basic Science. Both programs have a September receipt date each year. Applicants should carefully choose which program to send their application.

[International Cooperative Biodiversity Groups \(ICBG\)](#)

This program integrates drug discovery from natural products with conservation of biodiversity and economic development in source countries. The program is jointly funded by the National Institutes of Health, the National Science Foundation, and the Foreign Agriculture Service of the USDA. There are currently six active projects.

[International Studies on Health and Economic Development](#)

This program supports projects that examine the effects of health on microeconomic agents

(individuals, households and enterprises) and aggregate growth (cross-country growth analysis), as well as explores how health finance and delivery systems are a source of variation in health outcomes. Studies will focus on issues relevant to populations in low- and middle-income nations.

[International Tobacco and Health Research and Capacity Building Program](#)

This program encourages transdisciplinary approaches to the international tobacco epidemic to reduce the global burden of tobacco related illness. The program is designed to promote international cooperation between investigators in the U.S. and other high-income nation(s) pursuing research programs on tobacco control, and scientists and institutions in low- and middle-income nation(s), where tobacco consumption is a current or anticipated public health urgency.

[Stigma and Global Health Research Program](#)

The purpose of this program is to stimulate interdisciplinary, investigator-initiated research on the role of stigma in health, and on how to intervene to prevent or mitigate its negative effects on the health and welfare of individuals, groups and societies world-wide.

Career Awards

[International Research Scientist Development Award for U.S. Postdoctoral Scientists \(IRSDA\)](#) (K01 mechanism)

This program supports basic research, behavioral and clinical scientists at the postdoctoral level who are committed to a career in international health research and would benefit from an additional period of mentored research as part of a strong, established collaboration between a U.S. sponsor and leading scientists at a developing country center of scientific excellence.

[Fellowship Opportunities in Japan \(JSPS\)](#)

The Japan Society for the Promotion of Science (JSPS), as the funding agency, provides three types of scientific collaboration fellowships using the NIH as a nominating authority. One type of Fellowship Program allows Japanese Biomedical and Behavioral Scientists to conduct research at NIH. The other two types allow U.S. (and permanent resident) Scientists to participate in research in eligible universities and institutes in Japan.

[NIH Visiting Program](#)

This program provides support for scientists who wish to conduct research at NIH intramural laboratories. Interested applicants should directly contact the institute at which they would like to work.

Individuals interested in applying for a foreign research grant, a research grant with a foreign component, or a National Research Service Award (NRSA) through other [NIH Institutes and Centers](#) may contact program officers in the relevant area of science to inquire about the possibility.

The [NIH Office of Education](#) provides information on training opportunities at the NIH and searchable abstracts on the research being conducted in NIH laboratories.

[The Oncology Research Faculty Development Program](#)

The [National Cancer Institute \(NCI\)](#) supports this program for cancer researchers from developing countries.

[Short-Term Scientist Exchange Program](#)

The NCI handles this exchange program that promotes collaborative research between U.S. and foreign scientists through short exchange visits.

NIDA Fellowships

The [National Institute of Drug Abuse \(NIDA\)](#) provides international opportunities. Visit the [NIDA](#)

[International Page](#) for information about these programs.

NIDCR Programs

The [National Institute of Dental and Craniofacial Research \(NIDCR\)](#) provides international opportunities. Visit the [NIDCR Office of International Health Page](#) for information on these programs.

International Neuroscience Fellowship Program

The [National Institute of Neurological Disorders and Stroke \(NINDS\)](#) F05 Fellowship program provides opportunities for foreign scientists in low and middle income countries and emerging democracies to enhance their knowledge and skills in the neurosciences. For information on the provisions of the fellowship, contact:

Stacey Chambers

Program Analyst, Office of International Activities

National Institute of Neurological Disorders and Stroke

National Institutes of Health

Neuroscience Center

6001 Executive Boulevard, Room 2184

Bethesda, MD 20892-9521

Rockville, MD 20852 (Courier)

Phone: (301) 496-0690

FAX: (301) 480-2424

chambers@ninds.nih.gov

[Fogarty Organization](#)

International Relations

The FIC serves as the coordinating link between NIH and other U.S. agencies, foreign governments and international organizations on international biomedical research matters. It is responsible for the administrative oversight of all inter- governmental agreements in which the NIH participates.

The center also fosters and facilitates international cooperation in biomedical research by disseminating information on foreign biomedical research activities to the NIH research institutes and informing foreign agencies and institutions, including WHO, about the international activities of the NIH; initiating, developing and supporting, in cooperation with other NIH offices, new activities to address international health problems; preparing background materials for NIH senior staff participation in international meetings and discussions; providing advice to the director and deputy director, NIH, and to senior staff of the NIH research institutes on policies and procedures relating to international activities; assisting the institutes by obtaining clearances for awards requiring State Department approval and by interpreting DHHS and State Department procedures relating to international travel; serving as a channel for communications to and from U.S. embassies abroad and foreign embassies in Washington; and coordinating responses to inquiries on international issues.

The FIC ensures that NIH interests are represented as new opportunities for research collaboration in the life sciences arise through initiatives of the U.S. Government, foreign governments, multilateral and international organizations. FIC serves as the secretariat for the Disease Control Priorities Project, a partnership supported by FIC, The Gates Foundation, the WHO, and the World Bank to develop recommendations on effective health care interventions for resource-poor settings.

In its role as a WHO Collaborating Center for Research and Training in Biomedicine, the FIC provides research fellowships and grants, conducts studies, and sponsors workshops involving the NIH, WHO, PAHO and U.S. and foreign biomedical research organizations to identify and further strengthen the health of the U.S. population and contribute to the enhancement of health worldwide.

As the NIH focus of international activities, the FIC has both an integrative and administrative role in activities supported by other PHS components and other Federal agencies. The FIC is the NIH representative in maintaining liaison with such international organizations as WHO, PAHO, the European Union, and the European Medical Research Councils.

The FIC director and deputy director meet regularly with IC directors and international representatives of the NIH IC's to exchange information and views on ongoing and prospective NIH international activities.

International Epidemiology and Population Studies

The Division of International Epidemiology and Population Studies (EPS) plans, designs, and conducts studies to examine factors affecting the application of health science advances for the benefit of populations, particularly in developing countries. EPS develops strategic partnerships with the categorical institutes of the NIH and other governmental and non-governmental organizations to advance a common research agenda.

This page was last reviewed on January 6, 2006 .

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F O G A R T Y A T 3 5

IN THE LAST 10 YEARS FOGARTY-TRAINED PERSONNEL HAVE TRAINED OVER 6,000 HEALTH WORKERS THROUGHOUT HAITI, ENABLING US TO APPLY SUCCESSFULLY TO THE GLOBAL FUND FOR AIDS, TB AND MALARIA AND TO EXPAND INTERVENTIONS, INCLUDING ANTIRETROVIRAL TREATMENT, TO 25 CENTERS. THE FOGARTY PROJECT WE HAVE WITH THE HAITIAN RED CROSS TO TRAIN LABORATORY PERSONNEL HAS MADE THE BLOOD TRANSFUSION SYSTEM SAFE. OUR NEW FOGARTY PROJECT WILL ALLOW US TO INTRODUCE YOUNG HAITIANS TO PUBLIC HEALTH ISSUES AND RESEARCH TO RESOLVE THEM AT AN EARLY STAGE IN THEIR CAREERS AND HELP US RETAIN THE BRIGHTEST STARS WHERE THEY ARE MOST NEEDED—HERE IN HAITI. THERE IS NO WAY WE COULD HAVE DONE IT WITHOUT YOU.

Jean Pape, Director
GHESKIO Center
Port-au-Prince, Haiti

The John E. Fogarty International Center for Advanced Study in the Health Sciences gratefully acknowledges the support of the Foundation for the National Institutes of Health in publishing this 35th anniversary history.

Joan Wilentz, Editor

“AT BETHESDA A GREAT INTERNATIONAL CENTER FOR RESEARCH
IN BIOLOGY AND MEDICINE DEDICATED TO INTERNATIONAL
COOPERATION IN THE INTERESTS OF THE HEALTH OF MANKIND”



F O G A R T Y A T 3 5

NO COUNTRY IS AN ISLAND

The paraphrase of John Donne’s memorable line serves to highlight why international health is so important today and *why countries need to act*. It is not just a question of the demographic facts of life—that there are so many more people alive today and on the move, raising the risk of the global spread of disease. Nor is it only that worldwide environmental degradation is polluting the air we breathe, the water we drink, and depleting the earth’s natural resources. It is that societies worldwide—especially in the developing world—are experiencing extremes of economic, social, and political upheaval that are shattering whatever infrastructure existed to protect health and well-being and further widening the gap between rich and poor. It is no exaggeration to say that the world faces the specter of social unrest, religious strife, and the familiar four horsemen of war, pestilence—perhaps in the form of bioterrorism as well as nature’s calamities—famine and death. All countries have an obligation to do what they can to prevent catastrophe and work to ameliorate global health problems—for their own and the world’s good. The challenges are formidable:

- The earth’s population is expanding at the rate of nearly 1 billion a decade with almost all this growth occurring in developing countries in Africa, Asia, and Latin America. People are also migrating from rural to expanded mega-urban areas, and emigrating from developing to developed nations at unprecedented rates, generally exchanging one form of poverty for another.
- People in low- and middle-income countries—representing three-fourths of the world’s population—suffer over 90 percent of the burden of premature mortality as measured by lost years of life.
- Tuberculosis is responsible for 2 million deaths a year and accounts for one fourth of all preventable deaths in the developing world.
- Pneumococcal pneumonia causes nearly as many deaths as TB, with a higher disease burden.
- Malaria kills close to 3 million people every year, primarily children five and under in Africa.
- Childhood infections, poor reproductive health, and malnutrition account for over a third of the global burden of disease, a figure based on disability adjusted life years (DALYs), a metric developed by the World Health Organization that calculates the economic, social, and human impact of premature death and lifelong disability.
- In 1990 non-communicable diseases accounted for just over 40 percent of the global burden of disease. By the year 2020 their share is expected to reach 60 percent, eclipsing infectious diseases as major causes of lost years of healthy life—if, as hoped, the infectious diseases come under better control.
- Diabetes is approaching epidemic proportions in many populations and the global figure of affected individuals is expected to double from 150 million to 300 million by 2025, accelerating with the current trends towards overweight and obesity, even in developing countries.
- Hypertension and vascular diseases are rapidly increasing problems in many African, Asian, and Caribbean countries.
- Loss of biodiversity due to deforestation has introduced new infectious diseases into human populations and a loss of sources of natural products to treat or prevent them.
- Monoculture farming requiring heavy uses of nitrogenous fertilizers releases nitrous oxide into the atmosphere, contributing to the depletion of the ozone layer which protects against the potential cancer-inducing effects of ultraviolet B radiation and contributes to global warming and marked ecological changes with implications for burdens and range of vector-borne diseases.

These, and other global disease burdens, sometimes appear to be overwhelming, but to succumb to the wailing voices would be to ignore the greatest resource in the world: the power of people and the ability of science to show the way. These two principles guide the work of today’s Fogarty International Center in investing in the training of people in low- and middle-income nations who, through research, will find the solutions needed. Margaret Mead, the anthropologist and one-time Fogarty Scholar in Residence, knew that partnerships between and among nations were essential to improving human civilization. As she put it, “Never doubt that a small group of thoughtful citizens can change the world. Indeed, it’s the only thing that ever has.” Translating this to today, and to the impact that modern science carried out by modern scientists can have, it is possible to observe that whereas each of us, working alone, can make a difference, all of us, working together, can make an enormous difference.

Gerald Keusch

“AT BETHESDA A GREAT INTERNATIONAL CENTER FOR RESEARCH
IN BIOLOGY AND MEDICINE DEDICATED TO INTERNATIONAL
COOPERATION IN THE INTERESTS OF THE HEALTH OF MANKIND”



These words expressed Rhode Island Congressman John Edward Fogarty’s vision 40 years ago. Five years later that vision would become reality, for on July 1, 1968 President Lyndon Johnson issued an Executive Order establishing the John E. Fogarty International Center for Advanced Study in the Health Sciences at the National Institutes of Health. In the 35 years since—the span of a single generation—support for international biomedical and behavioral research and research training by the Fogarty International Center has grown from modest roots laid down at the outset—FIC’s first year budget totaled \$500,000—to a globe-encircling \$64 million research, training, and capacity-building enterprise extending to over 100 countries and involving some 5,000 scientists in the U.S. and abroad.

John Fogarty was a lifelong advocate of international biomedical research, “as disease knows no national boundaries,” and “because we care.” Starting with his freshman term in Congress in 1941—on the eve of America’s entry into World War II—throughout the 16 years he served as Chairman of the House Health Appropriations Subcommittee—the Irish bricklayer who rose from the ranks was eloquent in arguing the health and economic benefits of supporting biomedical research. As Subcommittee Chairman, he presided over the early days of growth of the National Institutes of Health, sharing his great expectations with the equally visionary NIH Director, James Shannon. But it was not until a week after Fogarty’s death on January 10, 1967 that his dream of a “global laboratory” began to materialize. On January 18, 1967, Appropriations Subcommittee Member Melvin Laird (R. WI) addressed Congress stating that the Committee “has provided funds to plan a lasting memorial to a man who, for more than a quarter of a century, worked tirelessly for a healthy America, in a healthier world.”

“AS DISEASE KNOWS NO NATIONAL BOUNDARIES”

Major Fogarty International Center research and training sites around the world and at U.S. collaborating institutions.



IN THE BEGINNING

To be sure, there was an early precedent for government support of international research. NIH historians are quick to point out that the leading Federal health research agency began as the Laboratory of Hygiene on Staten Island, New York, in 1887. At the time, countries throughout the world were plagued by epidemic diseases—tuberculosis, cholera, yellow fever, diphtheria—which pioneers like Louis Pasteur and Robert Koch were associating with newly discovered infectious agents: “germs.” Joseph Kinyoun, the first NIH Director, went abroad to Berlin and Paris to learn bacteriology from Koch and Pasteur and returned with the latest model Zeiss microscope to study *Vibrio cholerae*, the bacterial species Koch had identified and that was the cause of devastating outbreaks of cholera in New York and other major American cities throughout the 19th century. The application of science to diagnosis, treatment, and prevention through vaccines has had a remarkable effect on reducing the incidence of these diseases in the U.S.

Plus ça change... Today, the world again faces the devastation of epidemic infectious disease that “knows no national boundaries.” Some diseases, like AIDS, Ebola, and SARS are new threats; others, like malaria and influenza, have been known for millennia. Equally familiar are the respiratory infections and diarrheal diseases of childhood—no more than a nuisance burden in the U.S.—but responsible for the deaths of millions of children in low-income countries. Still others—smallpox, anthrax—have alerted the world to the threat of the bioterrorist release of disease-causing organisms long thought to be eradicated or under control. Indeed, for a time, as medical science distinguished viruses, bacteria, and parasites among “germs” and developed countermeasures in the form of vaccines and effective drugs, it seemed possible that infectious diseases might be vanquished. Such hopes were dashed, however, as it became clear that microorganisms had countermeasures of their own. Not only could they exchange genes and acquire virulence factors and antibiotic resistance, but they also could mutate into forms enabling them to elude detection by the immune system.



Malaria, known for millennia, is once again on the increase.

Aiding the spread of disease worldwide are advances and technologies that have reduced the world map to terrain easily traversed by jet plane in a day, seen world population grow by 58 percent from 3.6 billion in 1968 to 5.7 billion today, and witnessed the increasing movements of people, particularly from rural areas to urban centers, and from developing to developed countries. For many, the motivation is to escape poverty or political turmoil. All too often, however, life in a new city or country is no better or even worse than before, further accentuating the gulf between rich and poor; further widening global and local disparities in health and health care.

THE MISSION OF FIC TODAY IS TO IDENTIFY THESE GLOBAL CHANGES, ANTICIPATE THEIR EFFECTS ON HEALTH AND WELL-BEING, AND MOBILIZE SCIENTIFIC RESOURCES TO REDUCE DISPARITIES IN GLOBAL HEALTH.



RESEARCH CAPACITY-BUILDING IN THE DEVELOPING WORLD

The Fogarty Center's program to stem the tide of AIDS is a prime example of how it addresses this mission. In 1988, under the leadership of its then newly appointed Director, Philip Schambra, the Center developed the AIDS International Training and Research Program, AITRP ("A-trip") aimed at building research capacity in the developing world. The program, with co-sponsorship by other NIH components, began as a competitive five-year institutional training grant to a small number of U.S. universities, allowing post-doctoral students from developing countries to come to America for AIDS research training, and return home to practice their new-found skills. Congress was so enthusiastic about the potential of empowering health personnel to fight AIDS in parts of the world where the need was greatest that it increased the first year budget for AITRP to \$4.5 million, more than five times the original request.

Now in its 15th year, AITRP exemplifies a program that is long-term and flexible by design. U.S. institutions and their foreign partners are committed to enduring collaborations based on mutual respect and a readiness to adapt to changing needs and priorities. The partners are well aware, for example, that the priorities for AIDS interventions in resource-poor countries call for approaches that are realistic, practical, and affordable. Many grantees are about to enter their 4th round of the five-year grant cycle periods and many more have joined in the program for a total of 23 institutions around the country. The programs also allow for additional periods of short- and long-term training, either in the U.S. or the home country, as the need for new skills arises or new technologies emerge. Foreign nationals trained in the programs are further encouraged to develop research collaborations with partners in other developing

countries. In Africa these so-called “South-South” collaborations are now contributing to training on-site for greater numbers of beneficiaries. AITRP program managers have also seized the opportunity of extending programs to China and India as these countries began to experience the second great wave of HIV infection and AIDS, and now to Russia and the former Soviet States.

Early on, FIC saw the importance of funding “re-entry” research support so that trainees could learn research by being responsible, scientifically and fiscally, for *doing* research in their home country. Starting with the second five-year funding cycle, AITRP included funds for small pilot research projects proposed by trainees. Not only has this feature strengthened in-country research resources, it has also provided key personnel who are able to respond to a growing number of AIDS international research initiatives proposed by other NIH components as well as by outside groups, such as the Bill and Melinda Gates Foundation, the Elizabeth Glaser Pediatric Aids Foundation and the International AIDS Vaccine Initiative. In this arena of building local human research resources, FIC has had greater impact than probably all other capacity-building programs combined.

In 1998 AITRP expanded to include research and research training on tuberculosis as well as AIDS. Not only has tuberculosis remained a serious threat, with close to two million deaths a year worldwide, but HIV-infected patients are at high risk of developing the disease, which has become increasingly drug-resistant. The programs are currently emphasizing, along with the epidemiologic studies that were the focus of the earliest training programs, studies to integrate prevention with clinical research on diagnosis, care, and treatment, including the use of antiretroviral drugs, in the next major phase. Early fears that bringing foreign nationals to America might result in a brain drain have not materialized. “Not a brain drain, but a brain train,” as FIC’s current Director, Dr. Gerald Keusch, declared, as the records document that more than 85 percent of AITRP trainees return home to work in controlling and reducing the burden of HIV/AIDS. Indeed, the first graduates of AITRPs are among world leaders in the fight against AIDS, assuming senior roles in health administration and policy in such countries as Uganda, Malawi, Senegal, Kenya, South Africa, Thailand, and Brazil, or becoming directors of individual programs and institutions. Trainees are also well represented in the peer-reviewed scientific literature and as authors and presenters at international AIDS and TB conferences. Today, with over 2,000 research trainees from over 100 countries having received training in the U.S., AITRP stands as the world’s leading program to develop the health and research workforce needed to combat global AIDS. (continued on page 16)

THE LAWTON CHILES INTERNATIONAL HOUSE

Visitors to the National Institutes of Health in Bethesda, Maryland are impressed at the expanse of its more than 50 buildings spread out over 322 acres with lawns, greenery, and a running brook – much like a university campus. Situated on a hill near the center of the campus, for all the world like a Dean’s or University President’s residence, lies a former privately owned mansion that is now a part of the Fogarty International Center and used for prestigious international receptions, seminars, and conferences, as well as housing two Divisions of the Center and a major global project. Still colloquially referred to as “Stone House” by NIH staff, after the native Maryland bluestone used in its construction, the mansion was officially named the Lawton Chiles International House by an Act of Congress in November 1989, to honor the internationally minded Florida Senator who served from 1971 to 1989.

The house and adjacent acreage were originally part of a 200-acre property that had been acquired in a land grant to Robert Peter, a Scot arriving in America around 1745, and had remained in the Peter family for the next two centuries. Robert Peter’s descendants included a physician grandson, Armistead Peter, who headed a smallpox hospital in the Civil War. When he died in 1902, the family property was divided among his five children. Son Walter G. Peter was a prominent Washington architect and it was he who designed the mansion that another son, George Freeland Peter, a canon of Washington Cathedral, built on his 47.9 acre share of the inheritance in 1930. The Peter family remained in residence until 1949, when the Federal government acquired the estate and the 47.9 acres

as grounds for a growing NIH—which had already gained 92 acres in the late 30s and early 40s as a gift of Helen Woodward Wilson and Luke I. Wilson for the original buildings of the NIH.

The 3-story Chiles house is characteristic of Colonial Revival architecture set against formal landscaping that includes a rose garden and holly hedges. Corinthian columns flank the main entrance which opens into a foyer which features an exquisite elliptically



Senator Lawton Chiles and his daughter attended the official naming ceremonies.



shaped freestanding staircase leading to the second floor. The first floor, used for international receptions and scientific events, includes a library, drawing room, dining room, and kitchen. The former living room at the south end now serves as a meeting room and extends the length of the south wing, opening onto a veranda and formal garden.

MARGARET MEAD SLEPT HERE

The seven bedrooms originally on the second floor were used by Scholars in Residence from 1970 to 1977, including Margaret Mead, who did sleep in Stone House, as well as other notables, such as Oxford's Regius Professor of Medicine, Sir George Pickering, and the Nobel laureate Daniel Bovet. But as the program evolved, and the house no longer met the code for a residence, the Scholars were incorporated into the sponsoring NIH Institutes, even for their offices, and were housed elsewhere as well. The bedrooms on both the second and third floors were converted to offices which are now occupied by two Divisions of the Fogarty Center and staff for a major multilateral initiative: the Disease Control Priorities Project. Near the main house is a smaller building—the "Cottage"—which housed the Peter family staff. It, too, was converted to offices for FIC staff and is currently used for the International Services Branch, formerly a part of FIC and currently within the Office of Research Services, handling visas and immigration issues for visiting scientists at the NIH.





JOHN FOGARTY: THE LIFE

John E. Fogarty was born on March 23, 1913 in Providence, Rhode Island to a second generation Irish immigrant family. The family moved to a small farm in rural Gloucester, R.I. when he was seven and where his mother died when he was twelve. Fogarty's formal education was limited and during the Depression he made his living as a master bricklayer, following in the footsteps of his father and his older brother, who were both master bricklayers.

A taste for politics was also in the family tradition. Fogarty's father had been active in ward politics in Providence and in 1936 Fogarty was elected President of Local Bricklayers Union No. 1. Three years later he defeated five prominent Democrats for the congressional nomination and went on to victory in the general election. The year was 1939 and Fogarty was 26 years old.

He was appointed to the Naval Affairs Committee in 1940, remaining on the committee throughout World War II. Fogarty briefly joined the Navy Seabees in 1944 to investigate conditions of servicemen in the South Pacific. After the war, he was appointed to the House Appropriations Subcommittee for Labor, Health, Education and Welfare, and related agencies, succeeding Frank Keefe (D. WI), whom he credited as his most important mentor. He was appointed Chairman of the Subcommittee two years later—the youngest Labor HEW chair in history.

During his 27-year career in the House, Fogarty was an outspoken advocate for NIH and the value of medical research. He urged funding for the disabled and those with mental and physical impairments, for libraries, and for research to address

global health problems—a message he brought on five separate occasions to the Ministers of Health of every nation, convened at the annual World Health Assembly of the World Health Organization.

Over his years as Subcommittee chair, appropriations for NIH increased a thousand-fold, with the bulk of the funds distributed to the nation’s researchers in academic institutions, health professional schools, and hospitals. The advances in health they and successive investigators achieved would continue as NIH grew over the decades, with worldwide benefits on health and well-being.

John Fogarty died at his desk of a heart attack on January 10, 1967, the day before the opening of Congress. He had characteristically come in early to do some last-minute preparations for the opening session.

Fogarty was a modest man who preferred to say little about himself or his motivations. Shortly after his death, his family found a prayer in his wallet written by Martin de Porres, a 16th century priest who ministered to the sick and homeless in Lima, Peru and who became the Americas’ first black saint. This may be the best hint of what ultimately moved Fogarty to action.

At the time of his death, Fogarty had become one of the most powerful and effective congressional leaders of the 20th century. He received more honors and awards, honorary doctoral degrees and acclamation from professional groups than any other member of Congress in history.

Shocked by the loss of their colleague and champion of public health legislation, Congress moved quickly to authorize funding for an international center at NIH to bear his name. Fogarty had repeatedly but unsuccessfully proposed the creation of an Institute of International Health Research to promote the study of global health problems. His untimely death would prove to be the catalyst that finally brought the Center—The John E. Fogarty International Center for Advanced Study in the Health Sciences—into existence.

James P. Crowley, MFD, FACP,
Professor of Medicine, Brown University
(with thanks to Matthew Smith,
Curator of the Fogarty papers at
Providence College and Susan Diggins and
Susan Dunn for their assistance)

1958

1968

1969

1975

1978

1981

1984

Milo Leavitt

Leon Jacobs

Claude Lenfant

Craig Wallace

IRF

IRF, SIR

IRF, SIR, SIF



AND HIS VISION

John Fogarty's years in Congress as the representative from Rhode Island's 2nd district were remarkable for his repeated urgings of the nation to support international health research. At the time, America was emerging from World War II and the NIH itself was a modest organization with a 1949 budget of \$37 million. Today, the world can all too readily acknowledge the truth of Fogarty's oft-quoted argument for global research, "because disease knows no national boundaries." But that was only one of several arguments that distinguish Fogarty as a man ahead of his times.

His appeals began with his appointment in 1947 to the Subcommittee for Appropriations for Labor, Health, Education, and Welfare, which was responsible for the NIH budget. When he was named chairman of the Subcommittee two years later, he would use that powerful position for the rest of his life to build NIH and to press for establishing an Institute at NIH dedicated to the support and conduct of international research and research training—stipulating as early as 1958 that it should have an annual budget of \$50 million.

Fifty years before phrases like "global village" became commonplace, Fogarty recognized that the nations of the earth constitute one world and one family of man whose members are morally bound by ties of mutual respect and caring. At the same time Fogarty, the politically astute legislator, was well aware of competing interests for federal funds, so he marshaled support for his vision by underscoring the political and economic benefits to be gained. He argued that a medical research-driven reduction in the burden of chronic disease would enlarge the labor force of active, productive American citizens who would contribute to a growth in GNP and tax revenues.

1988

1989

1992

1993

1994

1995

1996

Philip Schambra

AITRP

FIRCA, MIRT

Biodiversity

Environmental and
Occupational Health,
Population and Health

Emerging
Infectious
Diseases



“I submit that investment in medical research, aside from the unending humanitarian benefits, is an economical investment in life. ...Research is the only means we have for reducing the growing federal burden of medical care costs.”

Senator Lister Hill left, and Rep. John Fogarty right, flank President John F. Kennedy at the signing of the International Health Research Act.

Fogarty also used arguments that spoke to a nation preoccupied with the Cold War—and the fear that the war might heat up—even that weapons of mass destruction might be used. Decades before bioterrorism became a household word, Fogarty was arguing that medical research could yield protection against bacteriological and radiological warfare. Biomedical research could also improve the health of the nation’s youth, thus enhancing military preparedness. (Fogarty was well aware of the number of World War II recruits who had to be rejected for health reasons.) In the event of war, medical advances could also lead to better care and treatment of casualties. Alternatively, he reasoned that by extending the benefits of biomed-

1997

1998

1999

2000

2001

2002

2003

Gerald Keusch

MIM (malaria),
Human Frontier
Science Program

Medical
Informatics

Maternal and Child
Health, IRSDA, IMTRP

Ecology of Infectious
Diseases, Bioethics,
Health and Economic
Development, Tobacco,
Genetics

GRIP, ICOHRTA,
ICOHRTA(AIDS/TB)
Global Infectious
Disease, ICER

DCPP, Brain Disorders,
Health/Env/Eco
Development, Stigma

ical research to improve the health of people in developing nations, they and their governments might be persuaded to lean toward democracy and the West, rather than communism and the East.

More often, however, Fogarty's essential humanity and zeal to reduce the level of universal human suffering led him to emphasize the positive values of supporting international health research, rather than its use as an instrument of Cold War diplomacy.

"Time and again it has been demonstrated that the goal of better health has the capacity to demolish geographic and political boundaries and to enter the hearts and minds of men, women and children in the four corners of the earth...For pestilence and prolonged disability and premature death, wherever they may occur, are tragedies which strike a responsive chord in man and his governments."

"IN THE WAKE OF TECHNOLOGICAL ADVANCES, THE WORLD HAS SHRIVELED IN SIZE. THE MOST DISTANT PLACES ARE ONLY HOURS APART. WHEN A CHILD IN CALCUTTA FALLS VICTIM TO CHOLERA OR A WORKER IN MEXICO CONTRACTS SMALLPOX, THE MOTHERS OF PROVIDENCE AND KANSAS CITY AND LOS ANGELES MUST BE CONCERNED."

And he was prescient in seeing the economic benefits of improving the health and stability of poor countries.

"From an economic standpoint, we have had a major stake in a healthy world. Our country has billions of dollars in investments, private and governmental, throughout the world. American industry has expanded in many parts of the globe and many Americans are living and working abroad. Improving the level of health in the countries in which we have investments is definitely to our advantage. The stability of our own economy depends in large measure upon our trade with other nations. We have better markets for our products where widespread disease does not depress their national economy. By the same token, we must pay more for products and materials we import if the economy of the exporting country is weakened by disease and a low standard of living."

THE LEGISLATIVE HISTORY OF FIC

Fogarty's many friends and wide popularity in both the House and Senate ensured that his legislative proposals could count on multiple co-sponsors. In particular, he shared his vision with Lister Hill (D. Ala), who chaired the Labor HEW appropriations subcommittee on the Senate side. Between them, and with the support of colleagues like Hubert H. Humphrey, then the democratic senator from Minnesota, they proposed measures to enhance biomedical research and establish an international center at NIH:

1957. Fogarty sponsored a bill that provided federal funds for construction of public health education and research facilities (the *Health Education and Facilities Construction Act of 1957*) and other bills that increased funds for NIH training programs and increased salaries of NIH personnel.

1958: September. Lister Hill proposed Senate Joint Resolution 199, the "Health for Peace" bill, which Fogarty followed with an identical resolution, H.R. 698, in the House. The bill established an Institute for International Medical Research at NIH with a \$50 million annual budget and it vested power in the U.S. Surgeon General to chair a new National Advisory Council to guide International Medical Research. The bill was referred to the Committee on Labor and Public Welfare but no action was taken on the bill until the following year.

1959 May. The bill was re-introduced in the Senate as J.R. 41 and in the House as H.R. 370. In presenting it Fogarty proclaimed, "Let our second American revolution be a world war against disease." The bill passed in the Senate but was opposed by the Eisenhower Administration. It did not help that

the nation was now in recession and foreign aid was an easy target. A disappointed Fogarty summed up the opposition: It would cost too much money and a new institute at NIH was unnecessary. He acknowledged that the major sticking point was that the administration wanted international programs to be the province of the State Department and the International Cooperation Administration on a government-to-government basis and not on a scientist-to-scientist program administered through HEW. Broad authority in the field of international health research was deemed the role of the President, who could support research projects using foreign currencies or credits generated by the sale of surplus agricultural commodities abroad.

1960 June. The House subsequently drafted a weaker bill, retaining the concept of an International Institute as an objective, but not authorizing its establishment. The bill passed in the House and Senate and became Public Law 86-610, the *International Health Research Act of 1960*. The act granted the Secretary of HEW authority in some areas to advance health science in the United States through cooperative research

and research training endeavors with foreign countries, but states that authority to advance the international status of health science through international cooperative endeavors rests with the President.

1961 February. An **Office of International Research** was established in the Office of the Director, NIH. Among authorities delegated to it was the maintenance of several NIH offices overseas and the administration of an International Research Fellowship program, established at NIH in FY 1958, first under the Division of Research Grants and then under the Division of General Medical Sciences. (When the Fogarty Center was established, most of the functions of OIR were transferred to it.)

1963 September. Fogarty again introduced his concept for an Institute of International Health Research at NIH in a speech at the Third National Conference on World Health. He spoke of bringing "into being at Bethesda a great international center for research in biology and medicine and dedicated to international cooperation and collaboration in the interests of the health of mankind." Over the next few years

Fogarty continued to speak out for global cooperation in health research, for support of the World Health Organization, and for applying the results of research to improve clinical care in diagnosis, treatment, and prevention. He was an early advocate of worldwide eradication of polio, malaria, and smallpox.

1967 January 10. John Fogarty dies while working at his desk on the day before the opening session of Congress.

1967 January 18. Labor, HEW Subcommittee member Melvin Laird (R. WI) proposes establishing an **International Center for Advanced Study in the Health Sciences** at NIH in Fogarty's honor.

1967 February. President Lyndon Johnson delivers a health message to Congress asking for funds to establish the Center.

1967 August. \$500,000 in planning funds for the Fogarty International Center are included in the FY 1968 NIH appropriation and for scholarships and fellowships in the Center.

1968. The Fogarty International Center for Advanced Study in the Health Sciences is born.



REPLICATING THE MODEL

AITRP has become a model for a number of FIC research capacity-building programs in the developing world in such areas as maternal and child health, tropical diseases, emerging infectious diseases, environmental and occupational health, and population-related research (see pp. 19-21, 27-30). With its emphasis on training, however, the program shared a perspective that FIC had in its early years—albeit with a significant shift in approach from individual fellowships to institutional training grants that now emphasize institutional partnerships and networking. When the Center was established, several small programs were transferred to it from an existing Office of International Research (OIR), which had been situated in the Office of the Director, NIH since 1961. Milo D. Leavitt, Jr. who had served as OIR Director, became the first Director of FIC, a position he held for 10 years until his retirement in 1978. OIR activities transferred to FIC included the handling of the NIH portion of special foreign currency programs established after World War II; maintenance of four NIH overseas offices in Rio de Janeiro, Paris, Tokyo, and New Delhi; and the administration of an International Research Fellowship program begun in 1958. While personnel and budgetary constraints would shrink most of these programs (all overseas offices except New Delhi were closed by June 1970, for example), the International Research Fellowship program (IRF) flourished.



THE INTERNATIONAL RESEARCH FELLOWSHIP PROGRAM

When World War II ended in 1945 the nations of Europe were devastated, their economies destroyed, their cities in ruin, their populations starving. In a major effort at reconstruction, the U.S. implemented a section of the Foreign Assistance Act of 1948 called the European Recovery Program—popularly known as the “Marshall Plan”. The idea was to provide financial and material assistance to participating countries in Western Europe to aid them “through their own individual and concerted efforts, to become independent of extraordinary economic assistance within a certain period.”

A decade later, in 1958, under Shannon’s leadership and with the support of Fogarty and colleagues in Congress, NIH launched a kind of Marshall Plan of its own. The **International Research Fellowship (IRF)** program was designed to rebuild European capacity for biomedical research by developing a cadre of foreign investigators who would be trained in American academic institutions and return to take their places in Europe’s leading universities and research centers.

And so they did. Eligibility for the program came through nomination by committees in the countries of origin, with the prospective Fellows making direct contact with senior U.S. investigators to arrange sponsorship, and submitting evidence that a research position in a non-profit institution awaited their return after training. Over the next few decades, and with the addition of candidates from other parts of the world as Europe rebounded, the IRF program trained thousands of scientists in leading research universities in America. The majority of Fellows returned to their home countries to pursue careers in research, teaching, and administration, often keeping in close touch with their American colleagues. By 1988, 30 years after the program’s inception, over 2,500 Fellows from 55 countries in Europe, Asia and the Pacific, the Middle East, Africa, and Latin America, had been trained at a total cost of \$50 million.

The list of mentors for many of the Fellows in the early decades reads like a Who's Who of leading American scientists, a number of whom would go on to become Nobel laureates: Christian Anfinsen, Julius Axelrod, David Baltimore, Severo Ochoa, Arthur Kornberg, Werner Loewenstein, Bruce McEwen, Albert Lehninger, Dominick Purpura, Irwin Kopin, Vernon Mountcastle, Ira Pastan, Baruj Benacerraf, and Bernard Brodie. Likewise, the roster of sponsoring institutions represented the country's leading research centers then and now: Harvard, Yale, Johns Hopkins University, the University of California at San Francisco and the U.C. campuses in Los Angeles and San Diego, Stanford University, the Universities of Washington and Wisconsin, and the NIH itself.

In an independent assessment of the IRF program in 1988, which included a survey of over 1,600 former Fellows and an analysis of papers they published in the scientific literature, the evaluators concluded, "Based on their scientific achievements, Fellows from developing countries are likely to contribute significantly to the quantity of biomedical research and health care in their respective countries." In particular, they noted:

- On average, 4 out of 10 former Fellows reported introducing new equipment or technologies at home, including magnetic resonance imaging, computer-aided epidemiologic and clinical studies, various cell biology laboratory techniques, and thyroid chemical and radiological diagnostics.
- Research findings ranged from early Fellows' advances in understanding the mechanisms involved in virus attachment, synaptic transmission, and in the pathology associated with certain cancers, to later Fellows' work in immunology and genetics, such as developing monoclonal antibodies, sequencing hepatitis B virus genes, and cloning genes for several members of the cholinesterase family.
- Three out of every four Fellows reported continuing international collaborations in research, often with their "alma mater" institution, while half had become mentors themselves, supervising graduate or post-doctoral students in their home country.
- The number of papers published by Fellows in the international scientific literature and their citation rates (a measure of a paper's importance based on how often a given paper is cited in other papers published in well-recognized journals) was fully comparable to the number of papers and citations rates of other NIH grantees. (continued on page 22)

REPLICATING THE AIDS MODEL — FOGARTY TRAINING PROGRAMS

The launching of FIC's AIDS International Training and Research Program (AITRP) in FY 1988 inspired a succession of other similar FIC training programs, each designed to enhance research capacity in the developing world on particular topics. Each of these initiatives, which are intended to be long term, measured in decades, albeit re-competed at five-year intervals, provides research training at a U.S. academic institution for a succession of junior investigators from a foreign institution. The intent is two-fold, first, to promote greater equity in scientific capacity to support ongoing collaborations on research projects when the trainees return to their home countries, and second, to establish long-term collaborative research relationships. Each program singles out an area of critical importance to improving the health and living conditions of present and future generations of people in areas of the world undergoing rapid development and technological change.

ENVIRONMENTAL AND OCCUPATIONAL HEALTH

Child labor, sweatshops, grueling and hazardous working conditions in factories and mines, air and water pollution, exposure to pesticides and fertilizers on lands cleared for monoculture crops—in sum, all the sins of the 19th and 20th century industrial and agricultural revolutions in Europe and the U.S., are being visited on new generations of workers in the 21st century developing world. With it, degradation and pollution of the environment is seriously affecting the health of all who are exposed, and not just workers. The Fogarty International Center's program on International Training and Research in Environmental and Occupational Health (**ITREOH**), with the close support of the National Institute on Environmental Health Sciences and other partners, aims to prevent a legacy of morbidity and mortality and environmental devastation from building up in the developing world. It focuses on training local professionals in research on workplace and environmental protection and public health and safety, with emphasis on implementing interventions targeted to specific conditions in the home country. The program, begun in 1995 and now in its second round of 5-year awards, has engaged over a dozen American universities and faculty, staff, and students from institutions in 28 countries in Africa, Central and South America, Eastern Europe, India, and China.

As the program has matured, there is a movement towards the development of regional centers of excellence to address issues common to several contiguous countries. This would be an effective approach to multiply the impact of the program, and toward that end, current grantees are working together to address common interests to create such centers.



FIC international conferences are often the springboard for new initiatives.



Cement bagging operation evaluated during a dust-and-noise monitoring course in Zambia.

Among significant outcomes to date has been the publication of a text on environmental epidemiology, the result of collaboration between FIC grantees at the University of California at Los Angeles and trainees at the National Institute of Public Health in Cuernavaca, Mexico. The text, in Spanish, covers issues of special relevance in Latin America, including the relationship between the prevalence of bladder cancer and arsenic

exposure in Argentina, the association between birth defects and exposure to pesticides in Colombia, urban exposure to mercury in gold production in parts of Brazil, and the relationship between chronic respiratory illness and exposure to wood smoke in Mexican women. Another important ITREOH program concerns the 1986 nuclear power plant explosion in Chernobyl, Ukraine. It has been the focus of a collaboration between Ukrainian, Russian, and Belarussian trainees and scientists at the University of Illinois, Chicago. The collaborators developed a data management program and systems for the prospective management of a backlog of data from a cohort study of populations from these countries that details the relationship between exposure to radioactivity released at Chernobyl and the prevalence of thyroid cancer in children. At the present time, the National Cancer Institute, working with the Ukrainian Institute of Endocrinology and Metabolism in Kiev in a study funded by the U.S. Department of Energy, has requested that a data management center be established at the Metabolism Institute. FIC is helping to fund the center to allow continued support of the project as well as to enhance the research capacity of the Ukrainian scientists.

ITREOH partners with FIC: National Institute of Environmental Health Sciences, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, and the Agency for Toxic Substance and Disease Registry (ATSDR).

POPULATION AND HEALTH

The impetus for Fogarty's International Training and Research Program on Population and Health (**ITRPH**) has been the need for better epidemiologic and demographic data on populations in developing countries. Since FY 1995 the program has been supporting population-based research to improve collection and analysis of baseline and longitudinal data in developing countries, as well as factors affecting birth rates and aging. In the African Census Analysis Project, for example, researchers at the University of Pennsylvania (Philadelphia) have been working with the census bureaus of 20 African countries to enable more refined demographic analyses of census data. Such studies have explored provincial differences in mortality of young children in Kenya, geographic distribution of ethnic groups in Senegal, and patterns of fertility and marriage among the many ethnic subgroups in

South Africa. As well, the programs support basic biomedical and behavioral research on fertility and contraception. Studies of male contraception in experimental animal models are included in two ITRPH programs, one between scientists at University of Pennsylvania and colleagues in Latin America, and a second between University of Virginia scientists with partners in China and India.

The ITRPH programs are important in tracking the effects of changes in fertility and mortality that occur as developing countries become more technologically sophisticated. For example, University of Michigan researchers, working with Vietnamese trainees, have been studying the effects of declining fertility rates on the social support system of older adults. The study indicated that older adults who had had smaller families had no less support in their old age from their children, except in the case of a group of older adults in North Vietnam who had had no sons. This is a powerful message on the lack of correlation between family size and social support systems as this society develops.

ITRPH partners with FIC: National Institute of Child Health and Human Development, National Institute on Aging.



MATERNAL AND CHILD HEALTH

Lack of prenatal care, poor nutrition, and frequent pregnancies are common in developing countries, accounting for high rates of stillborn or premature low-birth-weight babies. To counter these problems FIC initiated an International Maternal and Child Health Research and Training program (**IMCHRT**) in FY 1999. Co-funded with the National Institute of Child Health and Human Development, the program trains developing country professionals on the health problems of pregnant mothers and their infants with an emphasis on preventing complications of pregnancy, such as preeclampsia and preterm labor, and protecting infants from diarrheal diseases and perinatal transmission of HIV/AIDS. Grantees at seven U.S. universities are currently collaborating in training and research projects with investigators in Latin America, Asia, and Africa. In addition to disease pathology and prevention research, several programs are collecting epidemiologic data on reproductive and perinatal health, studying child development, infant feeding and nutrition, and conducting basic research on neonatal host defenses. Of interest in relation to the research priorities of the Multilateral Initiative on Malaria, scientists at Georgetown University in Washington DC are collaborating with investigators in Cameroon to study malarial immunity in pregnant women, neonates, and children.

IMCHRT partner with FIC: the Global Network for Women's and Children's Health Research of the National Institute of Child Health and Human Development.

With the relatively rapid recovery of Western Europe's economy and its science and technology base after World War II, the IRF program increasingly targeted developing countries elsewhere in the world. By the 1970s IRF collaborations were established with Warsaw pact nations, helping to create a climate of intellectual freedom and cooperation in countries behind the Iron Curtain. Overtures to China led to the first Chinese fellow being named in 1984. By the time of the collapse of the Soviet Union in 1990 FIC was ready with a proposal for collaborations with the newly emerging independent states. New fellowship programs began with Russia, Bulgaria, and Czechoslovakia, and importantly, a new grant program was initiated in FY 1992: the "FIRCA" (Fogarty International Research Collaborative Award). In its early phase, these were small international collaborative research awards to an American investigator whose research would benefit from collaboration with a partner from Latin America or Eastern Europe. They served to test the waters of collaboration and were used to generate the pilot data needed to apply for larger grants. Today, the scope of this program has expanded to cover the developing regions of the world everywhere.



SCHOLARS IN RESIDENCE

While the IRF program had grown out of World War II and predated the Fogarty Center, a second fellowship program as well as the inauguration of a workshop and conference program were initiated in 1969, the first full year after FIC's establishment. If the Marshall plan demonstrated that it was in America's best interests to promote a stable economy in the West—with mutual benefits to be gained from international cooperation and communication—so too would these new programs, particularly the new **Scholars in Residence** or **SIR** program. As Milo Leavitt explained to Senator Warren Magnuson at the 1970 appropriations hearings, the new fellowships were set up "to enable the NIH to capitalize on the best thinking, the best brains in the world." The intent was to bring internationally renowned scientists—both American and foreign—to NIH for periods of up to a year or more. At any given time there would be half a dozen or more of these scholars in residence at Stone House on the NIH campus. During their stay, they would hold seminars and workshops, write books, and conduct research in collaboration with colleagues in other

NIH institutes. The scholars were selected by an advisory panel from nominations made by leading NIH intramural scientists. In addition to their formal activities, it was assumed that the informal discussions and daily exchanges among the scholars while at Stone House would themselves spark creative ideas and innovations.

The “SIR” program succeeded in bringing a pantheon of gifted scientists to NIH over the years—more than 200—including Margaret Mead and Albert Sabin, four Nobel prize winners: Daniel Bovet, Rita Levi-Montalcini, Sir Hans Krebs, and Ragnar Granit; a number of Lasker award winners, and others recognized as leaders in their fields. Albert Sabin brought to NIH his commitment to rid the world of polio using the Sabin oral vaccine (which had already debuted on the international scene having been tested in Russian schoolchildren). During his periodic stays at NIH in the early 1980s Sabin oversaw strategies that would lead to the complete elimination of polio in the western hemisphere by 1993. He worked with governments, international organizations such as Rotary International, and the World Health Organization to incorporate annual national vaccination programs with routine health services in developing countries. He also recognized early on the importance of working at the local level to enlist the support of community leaders and volunteers to encourage vaccination.

Among the earliest Scholars was Sir George Godber, the architect of the British National Health Service. Other notables over the years included Peter Perlmann, from the University of Stockholm, who developed the ELISA technique, widely used in research and diagnostics, for example, in blood tests for HIV and other pathogens; William Jarrett, whose work with feline leukemia virus paved the way for Robert Gallo’s later isolation of human leukemia viruses. Gallo has remarked that without the input of foreign nationals and investigators he would not have been able to make the progress he has, referring to his lab as a “rainbow coalition.” In 1990 Fogarty welcomed its first African scholar, Olufemi Williams from Nigeria, who completed a book while in residence detailing comparisons between AIDS in Africa and AIDS in the U.S. In 1992 Lev Bergelson arrived as the first scholar from Russia, noted for his studies of the role of lipids in heart disease and cancer.

The most recent Fogarty scholar, in residence at the FIC in the spring of 2003 and co-sponsored by FIC together with the National Institute of Diabetes, Digestive and Kidney Diseases, the National Human Genome Research Institute, and the National Institute of Environmental Health Sciences, is Sir David Weatherall, Regius Professor of Medicine Emeritus at Oxford University and the founding Director of the Weatherall Institute of Molecular Medicine at Oxford. Professor Weatherall is an internationally acclaimed molecular hematologist who has long worked on the inher-

ited hemoglobin disorders prevalent in developing countries. He is the author, among hundreds of peer-reviewed articles, of the recent WHO report, *Genomics and World Health*, which is oriented towards mitigating the growing global divide in the utilization of genomics and genetics information in health research to improve the quality and delivery of health to those in developing nations.



THE SENIOR INTERNATIONAL FELLOWSHIP

In contrast to the International Fellows and the Scholars programs, a third fellowship established during the Fogarty Center's first decade was specifically targeted to leading *American* investigators. The **Senior International Fellowship (SIF)** program begun in 1975, was, as one strong proponent in Congress put it, a kind of Lend-Lease program (or indeed, an IRF program) in reverse: Instead of bringing junior scientists from developing countries to America, the program enabled established U.S. investigators to travel abroad, perhaps during sabbatical years, to take advantage of outstanding research at other major centers or to have opportunities for studying unique patient populations or learning new techniques from international colleagues.

Thus for its first two decades the Fogarty International Center was primarily associated with a series of fellowship and conference programs. These were organized in several administrative branches of the Center: an International Research and Awards Branch for the IRF and SIF programs, and an Advanced Studies and an International Studies and Awards Branch for the SIR and conference programs. A fourth branch, International Coordination and Liaison, was responsible for promoting and/or implementing bilateral or multilateral agreements for scientist exchange programs and international research collaborations. FIC was also the official Reception Center for foreign scientists and was responsible for providing visa and immigration services for visiting scientists and guest workers invited to work in laboratories on the NIH campus. This "Foreign Scientist Assistance" branch was responsible for smoothing the bureaucratic path by which these visiting scientists, fully a third of the NIH intramural program who come from abroad, were able to work for extended periods of time in NIH laboratories.

SUCCESS/PROGRESS/CHANGE

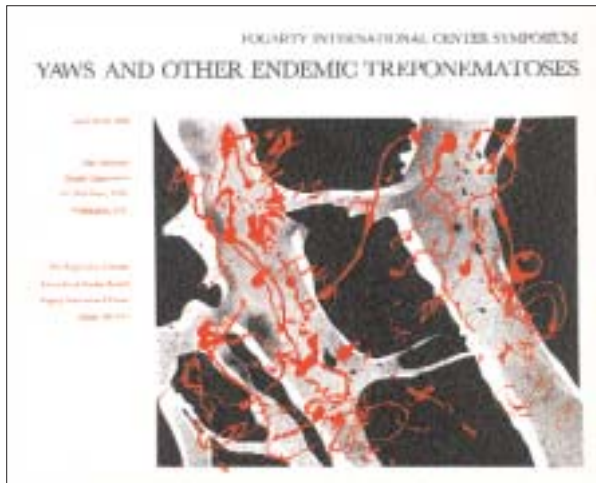
Fogarty's fellowship programs predated the revolutions in travel and in communications that are commonplace today. They also predated changes in biomedical science itself—changes in substance and style born of the revolution in genetics and molecular biology and the emergence of big, equipment-heavy laboratories and multidisciplinary teams of researchers. It was wonderful to nurture a new post-World War II generation of investigators. It was exhilarating to bring stellar scientists to NIH to act as catalysts for new ideas. And it could only add to the luster of established American investigators to have the opportunity of working abroad. So it can be said that each of the programs—the “IRF,” the “SIR,” and the “SIF”—truly succeeded in its goals. But change was in the air. By the 80s and 90s the population of world-class scientists in developed countries had grown substantially. Convenient jet travel made it easy for an American scientist to spend a few days abroad to attend a meeting or confer with colleagues—who could also be contacted by e-mail. Longer times away were becoming problematic given the responsibilities of a large lab to administer, graduate students to advise, and grant proposals to write.¹ With changing times and changing needs of scientists, FIC's programs and initiatives kept pace.



GLOBAL PROBLEMS, GLOBAL SOLUTIONS

These changes in science were occurring at the same time that the world was coming to grips with global health problems—problems that would need global solutions, exactly as John Fogarty had foretold in his lifetime. In the world of medical science, at NIH in general, and for the Fogarty Center in particular, AIDS was the watershed event that signaled a major change in direction. By 1988 FIC had initiated its AIDS institutional training and research program and was expanding its horizons. It was clear that there were other pressing global health and environmental problems that demanded attention. Whether in the form of a new infectious disease “that was only a jet plane away,” as the Nobel laureate Joshua Lederberg

had remarked, or in the form of re-emerging and antibiotic-resistant forms of old plagues like tuberculosis, global health and disease suddenly began to take center stage—at the White House, in Congress, and at the NIH itself.



Old and new plagues are an ever-present threat requiring vigilance.

Through the Center’s own program evaluations over the years, its strategic planning and policy documents, and its proposals to reduce disparities in global health, FIC had seen the importance of addressing the needs of the developing world—and within that world the need to attend to the effects of development itself. It was not only that so many in the developing world were burdened by poverty and disease, it was that development itself could profoundly affect health and well-being—and that health was essential for development. New industry and commerce, advances in transportation and communication, are transforming events, changing landscapes and lifestyles. Relocations from villages to larger towns and cities all too often result in disruptions in family life and customs, changes in diets and behaviors, and introduce yet other sources of disease or disease risk in the form of industrial waste, air pollution, and destruction of the natural habitat. (continued on page 31)

AT A TIME WHEN AMERICANS ARE INCREASINGLY AWARE OF OUR LIFE IN A GLOBAL COMMUNITY, THE FOGARTY CENTER SERVES AS A FOCUS OF NIH OUTREACH TO THE DEVELOPING WORLD. THE RECRUITMENT OF SCHOLARS TO STUDY IN THE U.S. AND RETURN TO THEIR NATIVE LANDS FORTIFIED WITH NEW INFORMATION AND TECHNOLOGY TO IMPROVE THE HEALTH OF THEIR PEOPLE IS A WORTHY ENDEAVOR, DESERVING EVER-INCREASING SUPPORT.

Samuel Katz
Professor of Pediatrics, Emeritus
Duke University School of Medicine

GLOBAL INFECTIOUS DISEASE

THE IMPORTANCE OF INFECTIOUS DISEASE AS A CAUSE OF WORLDWIDE DEATH AND DISABILITY CANNOT BE OVERSTATED. THE GLOBAL MORTALITY FIGURES FOR INFECTIOUS DISEASES IN 2000 EXCEEDED 17 MILLION MEN, WOMEN AND ESPECIALLY CHILDREN, OVER HALF OF WHICH WERE DUE TO JUST THREE CAUSES, HIV/AIDS, TUBERCULOSIS, AND MALARIA. USING THE WORLD HEALTH ORGANIZATION'S METRIC OF DISABILITY-ADJUSTED LIFE YEARS—DALYS—A TIME-BASED METRIC WHICH COMBINES MORTALITY AND NON-FATAL OUTCOMES TO REPRESENT THE HEALTH STATUS OF A POPULATION AS A SINGLE NUMBER, THE DALY MEASURES FOR AIDS, TB, AND MALARIA COMBINED ACCOUNTED FOR 11 PERCENT OF ALL DEATH AND DISABILITY IN THE WORLD IN 2000. TO BOTH SUSTAIN ITS FOCUS ON HIV/AIDS AND TO FACILITATE RESEARCH AND TRAINING ON ALL INFECTIOUS DISEASES IN DEVELOPING COUNTRIES, FIC IS MAINTAINING AND STRENGTHENING ITS HIV/AIDS INITIATIVES, AND HAS COMBINED INDEPENDENT TRAINING AND RESEARCH PROGRAMS FOR THREE SEPARATE PROGRAMS —ON EMERGING INFECTIOUS DISEASES, TUBERCULOSIS, AND MALARIA—INTO A SINGLE GLOBAL INFECTIOUS DISEASE RESEARCH TRAINING PROGRAM.



EMERGING INFECTIOUS DISEASES

West Nile, Ebola, and now SARS (severe acute respiratory syndrome) are part of a growing vocabulary of words that strike fear in millions across the globe for their association with new or newly introduced and deadly infectious diseases. Defined by the Institute of Medicine as “diseases of infectious origin whose incidence in humans has increased within the past two decades or threatens to increase in the near future,” emerging and re-emerging infections are reminders, too, that patterns of health and disease are never static. They can change as a result of seemingly random events, macroscopic changes in climate, weather, and terrain, or microscopic changes at the level of genes in cells. Contributing to this flux in disease patterns is human behavior. Such activities as the well-intentioned use of agents to control the spread of disease or destroy disease-causing organisms often leads to microbial resistance to the measures employed. Behavior can also include the malign intent to alarm and kill human populations through the use of bioterrorism agents. The six diseases on the Centers for Disease Control and Prevention Category A list (associated with the most lethal, most easily disseminated bioterrorism agents) are all dreaded infections: smallpox, anthrax, plague, botulism, tularemia, and hemorrhagic fever (e.g., Ebola).

It is hardly surprising that FIC was involved early on in addressing the broad new field of Emerging Infectious Diseases, working closely with NIAID. FIC's initial steps included assembling meetings of experts to discuss research gaps and opportunities, publishing reports, and initiating programs to expand research and training on re-emerging and emerging diseases. For example, a current FIC staff member who witnessed the original 1976 Ebola outbreak in Zaire, now called the Democratic Republic of the Congo, helped organize a critical meeting on the disease at Stone House in 1995, shortly after the second large outbreak of the disease occurred in the same country. This meeting called attention to the disease (which had also affected experimental monkeys in Reston, Virginia in 1989, popularized in the book *The Hot Zone* by Richard Preston), laying the groundwork for a larger international meeting on Ebola in Antwerp, Belgium in 1996. Another current FIC staff member initiated and co-chaired with NIAID a trans-NIH group to take stock of NIH programs in the field of emerging diseases and to serve as an advisory group to those involved in development of U.S. policies to address the new challenges they posed.

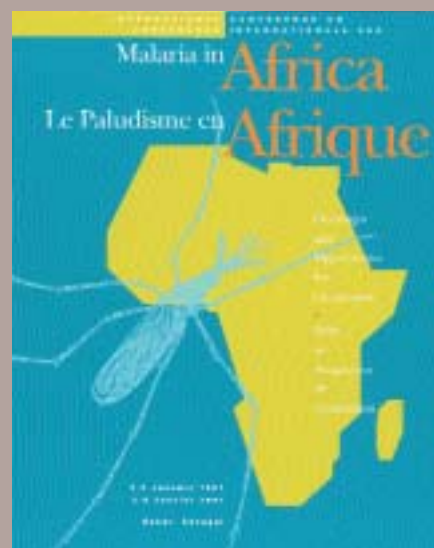
In 1997, FIC initiated its International Training and Research Program in Emerging Infectious Diseases (**ITREID**), aimed at enhancing the ability of developing country health professionals to understand, control, and prevent outbreaks of emerging infectious diseases through research training and collaborations with U.S. scientists. Malaria and tuberculosis rank high as areas of study in ITREID programs, because of their prevalence, resurgence, and resistance to treatment, but local and regional health concerns in low- and high-income countries dictate that a wide range of bacterial, fungal, viral, rickettsial, and parasitic diseases be studied. Given the need to mobilize quickly to identify, contain, and control an emerging infection, the programs emphasize epidemiologic surveillance and development of rapid, reliable—and in resource-poor countries—inexpensive diagnostic tests, in addition to improved means of treatment and prevention. Training often includes the introduction of the high-tech tools of genetics and molecular medicine, such as polymerase chain reaction (PCR) technology, microarrays, and pulsed field gel electrophoresis. The 13 ITREID awardees (at 12 American universities and one state health department) are currently collaborating on projects in over 30 countries and report some notable accomplishments:

- Development of a simple sputum test to diagnose and determine treatment susceptibility of *Mycobacterium tuberculosis* (Peru).
- Discovery of a master gene—controlling the function of over 30 other genes and influencing many more—that may be responsible for activation of the latent tuberculosis bacterium to cause overt disease. The gene is involved in tissue damage to the lung and appears to confer protection of the pathogen from heat, oxidation, and other stressors.

- Demonstration of an association between El Niño weather changes (related to temperature increases) and marked increases in diarrhea cases (Peru).
- Association of outbreaks of mosquito-borne dengue fever in Brazil with relaxation of vector monitoring activities and control of mosquito breeding sites.
- Use of a rapid immunoassay to diagnose leptospirosis and distinguish it from dengue fever (Brazil).
- Effectiveness of a simple, restriction site-specific PCR technique to reliably detect subtypes of hepatitis C virus (HCV) from blood samples, replacing costly and labor-intensive methods (Czech Republic). The tests will enable studies of the comparative distribution and virulence of subtypes of HCV—a major emerging disease estimated to infect 170 million people worldwide.
- High clusters of NOMA (severe ulcerations and lesions of the orofacial cavity) in Niger associated with nomadic lifestyle and close contact with livestock, including sharing of water supply (one source of the causative anaerobic bacteria).

FIC partners: National Institute of Allergy and Infectious Diseases, National Institute of Dental and Craniofacial Research, National Center on Minority Health and Health Disparities, and the Centers for Disease Control and Prevention.

Malaria. An important finding in the International Malaria Research Training (IMRT) program, which has funded five collaborations in Africa since FY 1999, concerns the great contemporary dilemma, effective and affordable therapy. In the face of resistance to chloroquine, the mainstay anti-malarial drug, University of California, San Francisco investigators, in collaboration with trainees at Makerere University in Uganda have found that a combination of three existing drugs, amodiaquine, sulfadoxine, and pyrimethamine was safe to administer and more effective than each of these drugs used separately. Use of a combination of drugs is also likely to lower the probability of resistance. Moreover, because the drug regimen led to impressive reductions in blood levels of the infectious form of the plasmodium, the risk of uninfected mosquitoes acquiring the malaria parasite while biting a patient and subsequently spreading disease by biting uninfected persons is also reduced.



Dakar, Senegal was the site of the conference that launched the Multilateral Initiative on Malaria.

Tuberculosis. Since FY 1998 the Tuberculosis International Training and Research Program (**TBITRP**) has supported 7 programs engaging collaborators in Eastern Europe, Asia, Africa, and Latin America. Because tuberculosis is actually the leading cause of death of HIV-infected persons in developing countries, a number of research studies have focused on preventing activation of latent TB infection in HIV-positive adults. A study in Uganda showed that six-month treatment with the standard TB drug isoniazid provided short-term protection against reactivation of the disease in persons with latent infection, while a combination of three anti-tubercular drugs for three months conferred protection for up to 3 years.

ACTIONS TO BUILD CAPACITY

Contributing to the Fogarty Center's infectious disease activities is a special Actions for Building Capacity or **ABC** program, begun in FY 1999. The program adds a research training component to an NIAID program on tropical diseases known as the International Collaborations in Infectious Disease Research (**ICIDR**), which is the foundation for NIAID's network of International Centers for Tropical Disease Research. Only ICIDR grantees are eligible for the FIC ABC awards, which currently support investigators in 10 U.S. universities and hospitals. Research and training activities are conducted primarily in-country at 18 ICIDR sites in Africa (Egypt, Kenya, and South Africa), Asia (Bangladesh), with the remainder in Latin America. As with FIC's emerging disease initiative, the aims of the ABC program are to increase the knowledge and technical skills of scientists and health care workers in developing countries enabling them to conduct surveillance, understand the causative organisms and vectors, develop reliable diagnostic tests, and improve treatment and prevention for a range of tropical diseases including malaria, dengue fever, cholera, diarrheal diseases, hantaviruses, and hepatitis.

Note: FIC also supports an initiative on the Ecology of Infectious Diseases (see page 44).

THE FOGARTY CENTER HAS MADE EXTRAORDINARY CONTRIBUTIONS TO ENSURE THAT THE LIFE-SAVING INTERVENTIONS WE TAKE FOR GRANTED IN THE U.S. CAN BE MOBILIZED FOR THE POOREST PEOPLE IN THE DEVELOPING WORLD. BY INVESTING SO SUCCESSFULLY IN HUMAN RESEARCH CAPACITY IN DEVELOPING COUNTRIES, AND TO THE DEVELOPMENT OF INDEPENDENT RESEARCH CAREERS BY SCIENTISTS FROM THESE COUNTRIES, THE CENTER HAS BEEN ABLE TO LEVERAGE U.S. KNOW-HOW TO IMPROVE GLOBAL HEALTH AND THE CAPACITY OF DEVELOPING COUNTRIES TO ADDRESS THEIR OWN PROBLEMS.

Sally Stansfield
Bill & Melinda Gates Foundation



THE FOUNDATION OF THE HOUSE

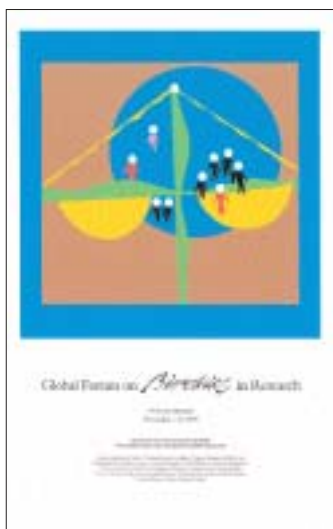
Clearly there is no dearth of health problems in the developing world, but where to begin? Here FIC has been guided by a decision-making process emphasizing global needs and scientific opportunities, combined with a pragmatism that any proposed program be feasible and of broad enough importance and potential to build partnerships to maximize the effort. These principles are embodied in four programs described in the Center's 2000-2003 Strategic Plan² that form the basis for FIC's continuing growth and expansion. Gerald Keusch, FIC's Director since 1998, considers the four programs—in bioethics, clinical research, medical informatics, and genetics—the foundation of the house that FIC is building on.

These cross-cutting areas owe their prominence in planning to the astonishing pace of progress in biomedical science and technology—not least the mapping of the human and other genomes—and the zeal to move findings to clinical applications in biotechnology, drug development, diagnostics, and therapeutics. Thus, by the time of the 50th anniversary of the elucidation of the double helix structure of DNA in April 2003 researchers had completed the sequencing of the human genome, the most important malaria parasite, and the most efficient mosquito vector transmitting malaria, paving the way for innovative research to identify new targets for the generation of new drugs, vaccines, and insecticides to control malaria around the world. These developments are also placing new demands on the education and training of researchers and care providers. Health professionals in both the developed and developing world must be sensitive to the social, ethical, and legal issues involved in human subject research. They need a thorough grounding in the design, conduct, and interpretation of clinical studies and trials. Their skills must include the ability to build and/or access the databases, computer systems, and tools necessary for the storage and analysis of experimental and clinical data. Finally, researchers, health providers, and the public at large need to understand that, with the exception of injury, all diseases and disorders involve a genetic component, whereby the interactions of genes with environmental factors affect an individual's susceptibility to disease, and even the body's response to injury and repair is likely to be modulated by genetic controls. FIC's four foundation programs are designed to build research competence and

capacity in these areas in the developing world. To encourage the active participation of low- to middle-income countries, extensive consultation with developing country scientists has preceded the call for applications in each new program area, and the programs have been designed to permit one- to two-year competitive peer-reviewed planning grants to institutions in developing countries to develop their research and training plans. During this time the developing country team can organize a program geared to their needs and interests, and seek a collaborating partner in the developed world to complement/supplement those needs. Once the partnership is in place applicants can apply for full grant support in response to a Request for Applications issued by FIC and its co-funding partners.

BIOETHICS

The **International Bioethics Education and Career Development Award** is a capacity-building training program that supports curricular development in U.S. and other developed and developing country institutions to enhance teaching and research on bioethics for trainees from developing countries, with special attention to the conduct of clinical research. Bioethics training is provided at a sufficiently advanced level to allow developing country professionals not only to assume responsibilities for the ethical review of clinical investigations when they return home, but perhaps even more critical for the long term, by becoming bioethicists who understand the research environment and can create a climate of ethical debate and conduct within their country. The program also provides short-term training courses for home-based investigators who are directly involved in ethical



The Bioethics Program was an immediate outcome of the 1999 Global Forum on Bioethics organized by FIC.

review of human subjects' research and clinical trials. The program, announced in 2000, was an immediate outcome of the 1999 Global Forum for Bioethics in Research, organized by FIC and the first in an ongoing series of international conferences. These meetings, held at international sites and sponsored by a rotating group of international organizations and FIC and its NIH partners, bring scientists and ethicists from the developing and developed worlds together to discuss the complex issues of conducting clinical research in developing countries.

IN THE AREAS OF GLOBAL HEALTH AND BIOETHICS, PUNDITS HAD BEEN HAVING ENDLESS DISCUSSIONS IN MATTERS OF SEMANTICS FOR YEARS...FOGARTY INVESTED IN CREATING NETWORKS AND TRAINING PROGRAMS ON BIOETHICS AND GLOBAL HEALTH — AND IT WAS THE FIRST ORGANIZATION TO DO SO.

Peter Singer
University of Toronto Joint Centre for Bioethics

Among the issues the bioethics initiative addresses are concerns that have been raised about the ethics of testing drugs or vaccines in resource-poor countries where there is little in the way of available “standard” treatment to offer control subjects, when the nature of benefits to the participants once the research is over is not clear, or where the use of a placebo control has been questioned. The nature of informed consent, the rights/abilities of women or children to participate in studies, and how clinical trials are explained to volunteers, are some of the other issues that have been debated. Developing an ethics training program based on the inputs from the first Global Forum on Bioethics in Research, FIC and three NIH partners have established the network that now includes 7 training sites in the U.S., one in Canada, and 6 in developing countries in Africa, Asia, and Latin America. With 40 trainees per year coming through these programs the increasing expertise in bioethics in developing countries will soon begin to make a difference in practice.

SHORTAGES OF TRAINED RESEARCHERS AND HEALTH CARE WORKERS, USE OF INAPPROPRIATE THERAPIES, AND LACK OF EFFECTIVE TREATMENTS CURRENTLY LEAD TO NEGLECT OF HEALTH CRISES SUCH AS DEPRESSION, SUICIDE, SUBSTANCE ABUSE, VIOLENCE, BREAKDOWN OF THE FAMILY, DISINTEGRATION OF COMMUNITIES AND STIGMATIZATION OF THE AFFLICTED.

Gerald Keusch
FIC Director

CLINICAL RESEARCH

Two clinically oriented FIC training programs more broadly address the need to increase the pool of professional personnel able to translate research advances into effective health care service and delivery programs. The programs, which apply to the developing world as well as to countries in Eastern Europe, Russia, and the independent states of the former Soviet Union support multidisciplinary education and training for foreign scientists, clinicians, medical sociologists, mental health and other health services researchers, among others. The objective is to support training in the design and conduct of clinical research protocols, on small and large scales, in order to speed the translation of new scientific knowledge into health care policy and practice.

The programs, known as International Clinical, Operational, and Health Services Research and Training Awards (**ICOHRTAs**), are currently made in two areas: behavioral sciences and mental health (ICOHRTA-I), co funded with 5 NIH partners, and AIDS and tuberculosis (ICOHRTA-II), co-funded with 10 NIH partners and the Centers for Disease Control and Prevention. Among the 14 awards made in the non-communicable disease program are collaborations between US universities and international centers addressing suicide prevention (China), substance abuse prevention (Peru), developmental disorders and children's mental health (Turkey), alcoholism (Poland), coronary heart disease (India), and health care for the elderly (China). The AIDS/TB ICOHRTA program differs from ICOHRTA I in being issued as a program announcement, which accepts planning grant applications each year, rather than at 4-5 year intervals. Secondly, the program allows developing country applicants to choose their collaborating partners, rather than the other way around. Thirdly, the program funds each of the partners directly, following the development and submission of separate but integrated applications detailing the role and responsibility of each. This is clearly a paradigm for the future, to be emulated and expanded to the greatest extent possible.

MEDICAL INFORMATICS.

The impetus for FIC's **International Training in Medical Informatics (ITMI)** program is the digital gap separating the developed from the developing world. The lack of computer systems and technology is a major impediment to the ability of health professionals to communicate and share information with colleagues via the Internet or stay abreast of developments in health research by accessing Medline or professional journals online. But it is in the conduct of research itself that the digital gap poses the most serious barrier. Health professionals need to be able to store and/or access data collected and maintained in databases assembled for research or for public health needs (such as the collection of epidemiological and surveillance data that might signal a country-wide disease threat). And they need to communicate with one another and exchange data for analysis. The ITMI program, begun in FY 1998 in partnership with NIAID and the National Library of Medicine, has the characteristic features of all FIC research and training programs: it aims to build a broad informatics research capacity in the developing country by training developing world researchers in the U.S. or at home institutions. At the same time, the program also provides targeted short-term and locally adapted informatics training to promote the development and broader dissemination of informatics technologies in the home country. Overall, the program aims to enhance research collaborations between U.S. and developing country investigators using medical informatics to facilitate studies of diseases and disorders that may be more prevalent or endemic in developing countries. Scientists from four sub-Saharan countries received training in the first round of competition

for ITMI awards and subsequent rounds have added other countries in Africa as well as in Latin America. In the future this program will expand to all regions where there is need.

GENETICS

The successful complete mapping and sequencing of the human genome, announced at the NIH's 50-year celebration of the April 1953 report of the structure of DNA by James Watson and Francis Crick, was dependent on the huge investments in research using automated DNA sequencing equipment and computer software programs that are possible in high resource, high-tech countries like the US and its major UK partner, and other genome project centers in France, Germany, Japan, and China. The rewards of such research—the potential, for example, of using genomics to identify genes whose mutations are associated with heightened risk for debilitating diseases and following up with ways to prevent or mitigate the disease in question—are among the highest hopes of 21st century biomedical research. In one of its most innovative programs the Fogarty Center, with the World Health Organization and seven NIH partners, has worked to see that those hopes are not denied to developing countries. The new **International Collaborative Genetics Research Training Program**, which was developed in consultation with scientists from developing countries at every step of the way, will provide Master's and Ph.D. level training at U.S. institutions for developing country investigators to enable them to conduct post-genome genetic studies relevant to their country's needs when they return home. Hand in hand with their learning technical skills, the trainees' education includes a focus on the ethical, legal, and social implications of genetic research. To ensure that returning investigators will not lack the wherewithal for conducting genetic research at the home site, the first awards in the program have been made to U.S. institutions already collaborating in human genetic studies with institutions in developing countries with a level of genetic infrastructure already in place. The six awards made in 2002 include collaborations with Costa Rica on psychiatric genetic studies, Thailand on the genetics of drug dependence, Venezuela on heritable neurodegenerative diseases, China on orofacial clefting syndromes, and with institutions at two sites in India studying psychiatric disorders and genetic epidemiology, respectively. (continued on page 43)

1 FIC has recently reconfigured the SIF program to encourage junior investigators to pursue careers in international health research. The International Research Scientist Development Award (IRSDA) provides a mentored research experience for U.S. postdoctoral students at an internationally recognized developing country institution already in collaboration with a U.S. counterpart (who would sponsor the candidate). FIC also offers a Minority International Research and Training (MIRT) program, soon to transfer to the new Center on Minority Health and Health Disparities, to encourage underrepresented minorities, from college to predoctoral level, to extend research training to foreign sites.

2 www.fic.nih.gov/about/plan.html



FOGARTY INTERNATIONAL CENTER: IN THE DIPLOMATIC MODE

With its commitment to advance science for global health coupled with its practical knowledge of U.S. diplomatic channels and foreign science agency infrastructure, the Fogarty International Center is well positioned to serve as a bellwether for NIH and other agencies, advising on global health issues and identifying and developing initiatives to expand international science collaborations. Toward that end, Fogarty staff, and in particular, its mini-State Department, the Division of International Relations (formerly the International Coordination and Liaison Branch), contribute on behalf of the Center and NIH to a range of intergovernmental negotiations and countless informal discussions among potential partner agencies around the globe.

Working closely with the State Department and the Department of Health and Human Services, FIC has brokered hundreds of formal agreements, including Memoranda of Understanding (MOUs) and many more hundreds of less formal agreements, including Letters of Intent, with foreign agencies. Today, FIC administers on behalf of NIH over 90 formal agreements, including those with China on AIDS, with India and with Russia in broad areas of science and technology, and with Brazil and Mexico on a range of health priorities of mutual interest. These agreements provide a foundation upon which joint activities are built and supported by both sides.

THE FOGARTY CENTER IS ONE OF THE BEST INVESTMENTS THE AMERICAN TAXPAYER MAKES, LEVERAGING OTHER GOVERNMENT INVESTMENTS TO PAY MULTIPLE SCIENTIFIC DIVIDENDS. PERSONS TRAINED THROUGH CENTER GRANTS ACT AS SCIENTIFIC AMBASSADORS FOR IMPROVING THE QUALITY OF GLOBAL RESEARCH AND CONTRIBUTING TO GLOBAL HEALTH.

Ward Cates, President
Family Health International

The Center also serves as the hub of activity for NIH engagement with international organizations of the United Nations, including UNICEF, PAHO and the World Health Organization. One of FIC's chief roles in this area is to coordinate broad NIH input on health issues under debate in formal intergovernmental discussions, taking stock of major areas of interest of each IC and the NIH Director. Position papers produced through this process ensure that the best scientific evidence is made available to NIH and DHHS leadership as well as State Department officials involved in the negotiations. In recent years, FIC has begun to work with a broader array of international organizations to ensure that health research is considered fully in discussions on sustainable economic development and on environmental issues. The World Bank and the InterAmerican Development Bank, as examples, are partners with FIC and NIH in efforts to build research capacity in poor countries and to link health research efforts more closely with health care delivery programs.

FIC seizes the opportunity to forge international links occasioned by changes in the political climate, such as the end of the Cold War, or by the exigencies of global health needs, such as the AIDS pandemic. Indeed, the Center is often the driving force for expanding research boundaries, bringing experts together to explore new horizons for health or to address emerging threats. Thus in 1980, buoyed by the WHO declaration that same year that smallpox had been eradicated from the world, an international meeting was held at Stone House to discuss the feasibility of global eradication of polio, measles, yaws, and several other notorious infectious diseases. As the Center now elaborates initiatives that explore how health and environment interact with the economies of developing countries, it will reach out to provide results of these studies to ministers of finance, commerce, and development, as well as to health ministers.

The thread that ties all of FIC's initiatives together in the diplomatic arena is its singular focus on identifying the most effective mechanisms to support international cooperation that will lead to health benefits for U.S. and foreign partners. The routine behind-the-scenes efforts of FIC staff are critical in identifying and supporting such mechanisms, including overcoming obstacles in international cooperation. Day-to-day efforts to establish scientist-to-scientist dialogue, address visa issues and logistics issues for movement of reagents and equipment across borders, and work with counterparts at the State Department to ensure that NIH-supported foreign projects are brought to the attention of the Ambassador and scientific staff at U.S. embassies are all critical elements in a broad program of international research support. Working with one scientist—or one foreign delegation—at a time, FIC is unwavering in its support for the identification and fostering of excellence in international health research.

A sample among FIC achievements over the decades includes the following:

- Following initiatives of the State department in the 1970s and 1980s to set aside funds to support international cooperation with key countries, FIC worked on behalf of NIH to identify funds to support bilateral health research projects, and ultimately administered on behalf of NIH, several major State Department-funded research programs with governments such as India, Poland, and Hungary. The research supported through these programs led to new knowledge in key fields, most striking in infectious diseases and the neurosciences, the strengthening of research capacity abroad, and furthering U.S. ties with the cooperating nations. Additionally, FIC was able to broker a funding relationship between the National Cancer Institute and USAID in the early phase of development of the Middle East Cancer Consortium (MECC), arguably one of the most successful regional initiatives on health and research. USAID initial support for the MECC was critical in its launch.
- In 1986, President Ronald Reagan and India's Premier Rajiv Ghandi met to determine areas of cooperation to strengthen an already mature relationship. As formulated by FIC and NIAID scientists, President Reagan proposed a Vaccine Action Program (VAP), by which Indian and U.S. investigators would collaborate on vaccine research. The VAP initiative is particularly credited with accelerating development of a new vaccine against rotavirus—the cause of diarrhea so severe that it has long been one of the leading cause of death in infants and young children in the developing world.
- With the end of the Cold War, FIC launched an Eastern European Initiative to strengthen international collaborations and identify new opportunities to advance key areas of science. U.S. scientists responded enthusiastically to the new opportunities to work with counterparts in Hungary, Poland, and other countries, resulting in advances in understanding of risk factors and pathogenesis of chronic obstructive pulmonary disease and other chronic diseases in areas of high prevalence, due to unusual levels of environmental pollution. Over time, the program expanded to include all nations in low- and middle-income countries, and served as the model for other science-funding agency efforts in poorer countries, including those of the Howard Hughes Medical Institute.

- As U.S.-Mexico economic cooperation increased in the early 90's, FIC saw that much could be done to unite U.S. and Mexican scientists on scientific issues of common concern. Focusing initially on training young scientists, FIC led the way with its counterpart Mexican agency, CONACYT, in the development of the Pan American Fellowship Program. To date more than 30 young Mexican scientists have come to the NIH for post-doctoral training, supported both by CONACYT and NIH. The addition of reentry grants provided by the Mexican agency also provides an incentive for the newly trained scientists to return home. The program has now been replicated with Venezuela, Chile, Argentina, Brazil, Costa Rica, and the Pan American Health Organization, on behalf of the poorer countries of the region.
- Recognizing that the collapse of the Argentinean economy threatened the survival of its highly productive health research system, FIC organized a pragmatic response from NIH. This included support of Argentinean post-doctoral trainees through the NIH intramural visiting program, extending eligibility for the Fogarty re-entry grant program to Argentinean trainees in the U.S., and lab-to-lab collaborations, which could also assist in supplying reagents and surplus equipment. Through visits to key labs and communications with Argentinean scientists, FIC has ensured the Argentinean scientific community that it is neither isolated nor forgotten.
- In the mid-90's, as the U.S. awareness of the threats posed by new and emerging infectious diseases increased, FIC and NIAID initiated and led a trans-NIH group to explore research gaps and opportunities. When the White House established a cross-government group to examine the same issues, the NIH was well prepared to contribute to the broader U.S. effort. As policies were developed and implemented, support for research and related training on new and emerging diseases was included among the highest priorities. In other forums, such as preparatory meetings for G8 Summits, annual deliberations of working groups under the U.S.-European Union Transatlantic Agenda, and the U.S.-Japan Common Agenda, FIC, working closely with NIAID, promoted research on emerging infectious diseases among its highest priorities for new intergovernmental cooperative efforts.

FIC'S INVESTMENT IN DEVELOPING THE CAPACITY OF SCIENTISTS IN SOUTH AFRICA HAS BEEN INVALUABLE IN A COUNTRY EXPERIENCING ONE OF THE WORST AIDS EPIDEMICS IN THE WORLD. IT IS A MODEL OF HOW TO MOVE A DEVELOPING COUNTRY BEYOND SERVING AS A FIELD SITE TO BECOMING A FULL RESEARCH PARTNER CONTRIBUTING TO GLOBAL SOLUTIONS TO THE AIDS EPIDEMIC.

Salim S. Abdool Karim
University of Natal, Durban, South Africa



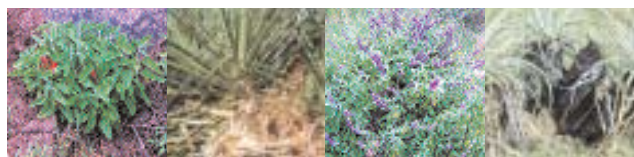
BIOPROSPECTING: A BETTER WAY IN SEARCH OF NATURE'S TREASURES



A century ago doctors had only a handful of drugs to treat disease—morphine, quinine, digitalis, aspirin—derived respectively from the opium poppy, cinchona bark, foxglove, and willow bark—nature's gifts to the medical armamentarium. Not much was added to the doctor's black bag until after World War I when the chemical synthesis of "magic bullets" to treat infection, and later, the discovery of penicillin from a mold, ushered in the antibiotic era. Today, approximately 50 percent of the several thousand prescription and over-the-counter drugs available are synthesized or materially derived from plants, animals, or microorganisms found in the wild. Unfortunately the world's wild places are rapidly dwindling. The global population explosion has turned virgin lands and forests into settlements and sprawls, while agricultural development, industry, mining, transportation, and commerce have not only changed the face of the landscape and resulted in the loss of untold numbers of species of flora and fauna—at a rate of a quarter of one percent a year of all species according to some experts—but also affected the quality of the atmosphere, with all that that portends in effects on weather, climate, and health.

Needless to say development has brought advances in the standard of living for many, and added quality as well as length to the average life span of many of the world's peoples. But there is a *better* way to achieve development: It is by

promoting sustainable patterns of growth so that 1) earth's biodiversity can be preserved, 2) species in natural habitats can be studied for what they may contribute to human and animal health and agriculture, and 3) local communities and the larger economy of developing countries can profit from research and training to build and conserve their natural resources. Such a win-win situation was envisioned at an NIH conference organized by the Fogarty Center in 1991 in collaboration with other parts of the NIH, the National Science Foundation, and the U.S. Agency for International Development. A year later the Fogarty Center, with five NIH partners', the NSF, and USAID launched a program of **International Cooperative Biodiversity Groups (ICBG)**. Grant applicants were invited to form international bioprospecting teams led by an investigator either in the U.S. or in a developing country with habitats of interest. The goals could include surveying, collecting, and testing plant, insect, or fungal specimens of potential therapeutic interest, while simultaneously promoting conservation and sustainable use of these natural resources. Five awards were made in 1993 and 1994 to multidisciplinary teams from universities, pharmaceutical firms, foundations, environmental organizations, and museums, with three new projects added over the decade. Field studies ranged from sites in Panama, Peru, Mexico, Costa Rica, Suriname, Chile, and Argentina in the New World, to Madagascar, Cameroon, and Nigeria in Africa, and Laos and Vietnam in Asia. For the current (third) round of competitive awards, investigators have been invited to spread the bioprospecting net wider to include marine organisms as well as unstudied microorganisms in soil. Significantly, applicants are also urged to develop strategies for compiling a centralized data base that would consolidate key findings from all the programs, with public and restricted access to balance public and proprietary interests.



ACCOMPLISHMENTS

All ICBG programs have shared medicinal goals, such as seeking new therapies for malaria, cancer, heart disease, AIDS, TB, and other infectious diseases; a few have included studies related to veterinary medicine and pest control. The range and variety of projects have been extensive, as have been the gains in knowledge, research capacity building, and rewards for the cooperating partners at home and abroad:

- Over 250 novel bioactive compounds discovered.
- 12 compounds now identified as promising agents for treating malaria, leishmaniasis, tuberculosis, HIV, bacteria, and mental disorders. Examples include a potentially important anti-tubercular drug derived from a brown alga found in Chile and an anti-leishmaniasis and other anti-trypanosome agents from Nigerian plants.
- New species of plants, fungi, and insects identified.
- 12 countries now have increased laboratory and field research capacity.
- 4,000 people trained in technical and social science techniques. Supplies and materials for preserving and storing specimens and the construction of greenhouses and field stations have strengthened infrastructure in the U.S. and abroad.
- New and enhanced local databases on biodiversity distribution.
- Publications in chemistry, biodiversity, and policy journals.
- Contributions to the establishment and strengthening of biodiversity reserves. [Initiatives on establishing biodiversity reserves stimulated.]
- Investments leveraged from corporations, foundations, universities, and government sources.
- Socioeconomic status of local communities improved.
- New models of intellectual property rights and benefits sharing developed.
- National policies on bioprospecting informed and advised.

Overall, the success of the ICBG programs has provided a model of collaborative international research that demonstrates that projects involving multiple government, private, and academic partners can work to the benefit of all parties. The rich and varied experience of the researchers themselves also serves as a valuable resource to guide future governmental research and conservation policies. Indeed, each of the ICBG programs established contractual arrangements and benefit-sharing principles at the outset of the collaboration to ensure that the rights of source countries and traditional groups would be protected. The principles involved—of conservation, sustainable use, and equitable sharing of benefits for commercial use—are the same as those adopted in the UN Convention on Biological Diversity that emerged from the United Nations conference in Rio de Janeiro in 1992 – the year that the Fogarty Center initiated the ICBG program.

¹ The National Cancer Institute, National Institute of Allergy and Infectious Diseases, National Heart, Lung and Blood Institute, National Institute of Mental Health, and National Institute on Drug Abuse



BUILDING THE HOUSE OF THE FUTURE

With the turn of the century the Fogarty Center has embarked on an ambitious program to build on the foundation of its cross-cutting programs in genetics, informatics, clinical research, and bioethics. The intent of this 21st century agenda is to equip low- and middle-income countries with knowledge about the root causes of the diseases that are now prevalent or endemic in their countries and what changes they may expect in the future. The “root” studies as well as forecasts of patterns-of-diseases-to-come are not restricted to the developing world, but are global in nature, and they carry with them the admonition to act now. Using the findings from such research, a nation’s governing bodies can make informed health policy decisions and put in place cost-effective programs to reduce the burden of disease and enhance public health and safety. The benefits to be gained are not only improvements in health and well-being, but in the strengthening of stable and productive societies.

ECONOMY AND ECOLOGY

Knowledge about the underlying causes of disease in individuals and in populations depends on an understanding of the several variables defined as the determinants of health and how they interact. These variables include biological characteristics, the environment, sociocultural factors, behavior, and systems of health care. Two of FIC’s new programs are looking specifically at how the interactions of selected determinants affect not just the health of an individual, but the wealth of society—its economy. In the case of the International Studies on Health and Economic Development (**ISHED**) program, researchers are studying some of the very issues raised by John Fogarty 40 years ago. He observed that the productivity of the labor force, and in turn the economy and political stability of a country, falter when the majority of its people are in poor health. The truth of that observation is only too apparent today in the sub-Saharan countries devastated by HIV/AIDS.

The ISHED program emphasizes the need for longitudinal databases of populations to track the relationship between health variables and economic development. The research grant program, begun in 2000, has made six full five-year awards and five three-year planning awards to grantees poised to answer such questions as: How does malnutrition in infancy affect school performance and future earnings? How does health status over the lifespan affect the kinds of work people do, how much they earn, and what they buy or save? What is the impact of malaria, tuberculosis, and HIV/AIDS on agricultural labor, small business, and other economic development in various parts of Africa? The intent is not only to collect impact data, but also to test whether interventions, e.g., programs to enhance prenatal and early childhood nutrition, can make a difference in adult achievements and well-being, and ultimately in the nation's economy.

In 2002 FIC considered an additional determinant in the study of health and economic development: changes in the environment of a developing country. The Health, Environment and Economic Development (**HEED**) program is designed to support pilot or developmental studies to probe how environmental changes, primarily due to human alterations, affect health and economic development. A dramatic example of a human behavior/environmental event with long-lasting health and economic consequences was the 1986 explosion of the nuclear reactor at Chernobyl, Ukraine, which released 30 to 40 times the amount of radioactivity of the bombs dropped on Hiroshima and Nagasaki. Entire cities and settlements in Ukraine, Russia, and Belarus had to be abandoned, and there may yet be as many as 3 million people living in contaminated areas, at high risk for thyroid cancer and other deadly cancers and diseases that have already taken a huge toll.

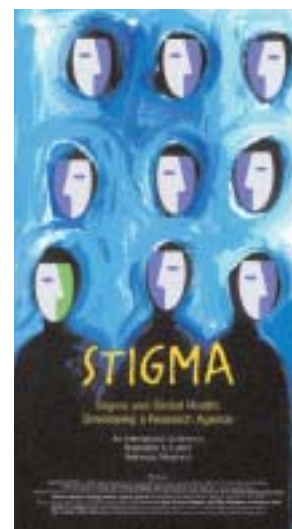
A third initiative that looks at the complex interactions among health determinants is studying when and how outbreaks of infectious disease occur, and how this knowledge can be used to prevent or identify a future epidemic at the earliest stages. Grantees conducting research under the **Ecology of Infectious Diseases** program, begun in 2000, look at natural events, such as changes in climate and the environment, as well as the impact of human behavior, that together may alter the local ecology to create a niche for the emergence or reemergence of pathogens and vectors of infectious disease. FIC is leading this initiative in partnership with NIAID, NIEHS, and the National Science Foundation. Awards have been made to investigators at 12 U.S. universities, who are collaborating in global research projects that include studies of environmental determinants of malaria in Belize, the ecology of the encephalitis virus in the southeastern United States, studies of bat colonies in Colorado (as vectors of rabies), and a number of animal studies, including the effects of changing land use on the dynamics of prion disease in wildlife.

EPIDEMICS AND BIOTERRORISM

FIC scientists in a new **Division of International Epidemiology and Population Studies (EPS)** are studying the ecology of infectious diseases using computer programs to model an epidemic. Beginning with modeling work on vaccine preventable diseases, malaria, and global cycles of influenza transmission, EPS was in a position to quickly model potential scenarios and develop tools to help policy-makers plan and respond to a potential bioweapon attack. Since then the EPS group has been the hub of a modeling effort, including both government and academic scientists, assisting the Department of Health and Human Services, the National Science Foundation, the Department of Defense, National security agencies, and the international community, to identify research gaps and better address critical questions that might occur in the event of rapidly disseminating infectious agents. Most recently, it has developed a model to address the role of international transportation networks in the potential spread of SARS. This work has demonstrated the value of a small group focused on the epidemiology of infectious diseases of global epidemic potential, and EPS is expected to continue to grow and develop to meet the needs.

STIGMA AND GLOBAL HEALTH

An International Conference on Stigma and Global Health organized by the Fogarty Center in September 2001 called attention to yet another negative influence on health: stigma. Patients with diseases or disorders that a given society stigmatizes—for whatever reasons—can experience a worsening of signs and symptoms or be severely abused—even leading to death. Indeed, as a sociocultural determinant of health, stigma is surely one of the highest risk factors for making a serious disease worse. The conference provided numerous examples in both developed and developing countries of how stigma operates in relation to HIV/AIDS, epilepsy, leprosy, mental illness, birth defects, alcoholism, drug abuse, and sexual abuse and violence—examples chosen to represent major categories of stigmatized diseases and disorders that lead societies to punish patients and their families and friends. The punishment can take the form of overt physical and mental abuse, isolation, refusal to treat, and legal proscriptions—in sum, a denial of fundamental human rights. Because the consequences of stigma are so severe, patients themselves often deny symptoms or avoid seeking treatment, risking a further exacerbation or progression of disease to a point of no return. As with many other FIC-organized meetings, the conference was a turning point—the stimulus to move beyond the stage of talking about a problem to doing something about it. The recommendations attendees developed for new research on stigma: how and why it develops, what epidemiology research can tell us about its prevalence, what can be done to prevent or reverse the effects of stigma, have now been incorporated into a Request for



The FIC conference on Stigma and Global Health called attention to the negative influence of stigma on health.

Applications for a new **Stigma and Global Health** research grant program, co-funded with many NIH partners, with awards to be made in late 2003.

DISEASE CONTROL PRIORITIES IN DEVELOPING COUNTRIES

Human behavior, whether in the form of stigmatizing disease, or in effecting environmental and ecological changes that have negative consequences on health, is, as noted, a part of the larger set of factors that determine the patterns of health and disease in individuals and communities. Now a major effort is underway to assess and update epidemiologic data and clinical evidence on disease and risk factors—negative determinants of health—and balance that information with the positive life-saving and life-extending interventions generated in recent years by biomedical and behavioral research, to predict future patterns of disease and prioritize interventions in developing countries. This three-year **Disease Control Priorities Project (DCPP)** begun in September 2002, is a joint effort of the Fogarty Center, the World Bank and WHO, funded in part by a \$3.5 million grant from the Bill & Melinda Gates Foundation. FIC is acting as the Project Secretariat, coordinating operations under the guidance of a global advisory board and a board of editors that includes leaders of FIC, PAHO, the World Bank, WHO, and universities in the U.S., Canada, and the U.K.

The aim of the project is to publish, in 2005, an expanded, updated second edition of the 1993 WHO publication, *Disease Control Priorities in Developing Countries*, a landmark volume which listed 25 health conditions for which priorities had been established, based on their public health significance and the cost-effectiveness of measures to prevent or manage them. The volume was published in tandem with *Investing in Health*, a 1993 World Development Report by the World Bank. The second edition (DCP2) will be generated from workshops, working papers, and draft chapters circulated to advisors and posted on the project web site, and their subsequent debate, discussion, and refinement. The draft papers have been elicited by the editors from world authorities. The prevalence and cost data used will reference the work of demographers, epidemiologists, economists, and other health scholars who calculate the burden of disease using the “DALYs” construct, which attempts to quantify the mortality (years of life lost) and years of morbidity experienced due to the consequences of specific conditions and risk factors. In turn, studies of methods of prevention and treatment will provide information on what may be the most cost-effective health measures to implement in resource-poor countries. Summary data will be provided for the world as well as for geographic regions, so that policy-makers in developing countries can more readily adapt the information to their populations, developing their own set of priorities and programs of prevention and control. In a bold departure from the previous study, DCP2 will also assess the potential for new and expanded existing research to generate new tools for disease

control in the next decade. These assessments will help to guide resource allocations among nations with limited reserves but with research capacity and the will to address these global health priorities.

The first working paper, with the provocative title, *At Least One-Third of Poor Countries' Disease Burden is Due to Malnutrition*, appeared in March 2003. The authors have incorporated new studies and have honed their analysis to include the role of micronutrients (e.g., iron, iodine) to calculate the degree to which malnutrition contributes to morbidity and mortality, with particular reference to women of childbearing age and infant children. Because they confined their analysis to the effects of malnutrition on communicable diseases, they caution that their estimates are conservative.

I CREDIT THE FOGARTY INTERNATIONAL CENTER WITH DEVELOPING NIH SUPPORT FOR GLOBAL RESEARCH ON SOCIAL AND MENTAL HEALTH ISSUES, ENHANCING UNDERSTANDING OF WHY GLOBAL HEALTH REQUIRES THE INTEGRATION OF BIOMEDICAL SCIENCE, SOCIAL SCIENCE AND PUBLIC HEALTH APPROACHES.

Arthur Kleinman
Harvard University and Harvard Medical School

What makes the DCPD particularly compelling today is the extent to which disease priorities and risk factors have changed over the last decade. In 1990 deaths from HIV were in 31st place and now have moved to 4th place in the world. Perinatal deaths remain high in the developing world, but infant mortality has declined, as have the deaths from diarrheal diseases. Turning to risk factors for mortality, the data are pointing toward a convergence of developed and developing world on factors such as high blood pressure, high cholesterol, and tobacco use. By the year 2000 the 10 conditions with the highest DALYs for the world included depressive disorders and heart and cerebrovascular disease—all of which are predicted to worsen in the developing world, as will deaths from intentional and unintentional injuries.

Concern over the new patterns of disease and risk factors evolving in the developing world has prompted the Fogarty Center to mount two new programs to address these problems. The **International Tobacco and Health Research and Capacity Building Program**, is a research grant (RO1) program to enable developing countries to study the implications of tobacco use and develop interventions for tobacco cessation. In contrast to the control measures in place in the U.S. to discourage tobacco use, addiction is easily acquired in the developing world because cigarettes are cheap (many are smuggled across borders and so avoid paying tariffs and taxes); they can be bought one at a time; and there are no warning labels or proscriptions of sales to children. Furthermore, tobacco use in many countries is the cultural norm, with over half of adult males

smoking—including physicians. As women become freer to leave traditional roles in the home, it is expected that they, too, will swell the ranks of tobacco users.

The situation with regard to growing mental illness and neurological diseases in the developing world has been the impetus for the development of a second new collaborative research program, which addresses **Brain Disorders in the Developing World: Research Across the Lifespan**. FIC convened a panel of experts led by Nobel laureate Torsten Wiesel to advise the Center on the research needs and training opportunities in the area. These have now been spelled out in a Request for Applications for planning grants to initiate programs of research and capacity building in the developing world on brain disorders that range from the developmental disorders of childhood, such as cerebral palsy and epilepsy, the mental illnesses such as chronic depression and schizophrenia that emerge in adolescence and adulthood, and the debilitating and degenerative disorders associated with aging, such as stroke and dementing diseases.

These new programs are first steps. As the Disease Control Priorities Project matures, and as the Fogarty Center continues its avant garde leadership in identifying the issues and themes that will dominate the health agenda of the developing and developed world in the 21st century, more innovations in FIC plans and programs will follow. In so doing the Center strives to fulfill the dream enunciated by John E. Fogarty a generation ago: “I am personally of the conviction that through leadership in international research and research training activities, the United States can contribute in a particularly meaningful way to the solution of health problems specifically, and the cause of peace generally. I visualize the Center, associated with the great facilities of the National Institutes of Health and the National Library of Medicine, as representing the visible and tangible embodiment of the Nation’s devotion to the use of science for peaceful purposes and the good of mankind.”

DESPITE STUDIES OF DISEASE BURDEN THAT HIGHLIGHT THE ENORMOUS IMPACT OF MENTAL ILLNESS ON DEVELOPING AND DEVELOPED COUNTRIES ALIKE, STIGMA AND IGNORANCE HAVE INHIBITED BOTH SCIENTIFIC INVESTIGATION AND THE ADOPTION OF EFFECTIVE TREATMENTS. WITH ITS CONFERENCE ON STIGMA, ITS SUPPORT OF AN INSTITUTE OF MEDICINE STUDY ON BRAIN DISORDERS IN THE DEVELOPING WORLD, AND ITS COLLABORATION WITH NIMH, THE FOGARTY CENTER HAS MADE SIGNIFICANT CONTRIBUTIONS THAT WILL HELP TO TURN THE TIDE.

Steven Hyman, Provost
Harvard University

COMBATING MALARIA

The story of the birth of the Multilateral Initiative on Malaria (MIM) illustrates how FIC, with the support of the leadership at NIH, worked to overcome political and bureaucratic barriers to international cooperation to create an international consortium to combat one of the world's oldest and deadliest scourges—malaria.

NO ONE FUNDING AGENCY CAN RESOLVE THE HEALTH PROBLEMS ENDEMIC IN DEVELOPING COUNTRIES—BUT BRINGING AGENCIES TOGETHER TO FOCUS ON A MAJOR THREAT LIKE MALARIA CAN MAKE ALL THE DIFFERENCE.

Philip Schambra, FIC Director 1988-1998



The data on malaria are stark: From 300 to 500 million new infections or more occur every year with estimates ranging up to nearly 3 million deaths—the majority in young children in sub-Saharan Africa...ongoing problems of mosquito resistance to pesticides; parasite resistance to anti-malarial drugs... potential for malaria-carrying mosquitoes spreading to new areas as a result of global warming, changes in patterns of land use (road-building; deforestation) creating new mosquito breeding sites, and growing urbanization accompanied by weakened public health and environmental infrastructure...

...Not that there haven't been dedicated malaria researchers, clinicians, and health care workers over the years. Ever since Sir Ronald Ross' discovery in the late 1890s that it was not bad air (mal-aria) that caused deadly bouts of intense fever and malaise, but a mosquito-borne parasite, investigators have sought interventions to prevent or control malaria. The result has been a see-saw of successes and failures as vectors and pathogens succumbed, but then developed resistance to the intervention. To mount a major effort to combat malaria—especially to take advantage of the promise of genetics research and molecular technology—more would be needed. The impetus for creating that “more” came about through a series of meet-

ings organized by the Fogarty International Center at Stone House in the mid-1990s. The initial meeting was chaired by then FIC Director Philip Schambra, with the participation and support of then NIH Director Harold Varmus. The meeting brought together interested international parties to review results of a FIC study on the scope of biomedical research in Africa being supported by the British, French, and American governments. At a follow-up meeting in 1995 with the Americans and Europeans joined by African scientists, the group concluded that there could be major gains in health for African populations if national and international agencies could unite to target a specific disease area. The clear choice was malaria.

Not so clear was how to bring funding agencies and scientists together to determine the best way forward. FIC worked closely with the National Institute of



Traditional birth attendants in Cameroon receiving training in malaria in pregnancy.

Allergy and Infectious Disease, the National Library of Medicine and the NIH Director as well as with major international partners to plan an international conference on malaria ultimately held in January 1997 in Dakar, Senegal. This first Pan-African Conference on Malaria brought funding agency representatives together with malariologists from around the world to develop a research agenda, specifying needs and priorities in areas ranging from epidemiology and pathogene-

sis, to vaccines and vector control. This out-of-Africa meeting marked the birth of a new global anti-malaria program and gave it its name: the **Multilateral Initiative on Malaria (MIM)**.

The Dakar agenda established clear priorities for research, training, and research capacity building in sub-Saharan Africa. Furthermore, for each of the major areas of research, such as epidemiology or immunology, the working groups emphasized the need for trans-national networking and sharing of data, which, to assure comparability and reliability, would need to be collected using standardized research techniques and reagents. There remained knotty questions of how such an unprecedented global effort could be administered. Who would manage and dispense research funds supplied to MIM? Who would be responsible for coordination, communication, planning, and feedback to researchers and funding agencies? Resolution of these and other issues turned to an existing resource—and created new ones. The Geneva-based World Health Organization's Special Programme in Tropical Disease Research was well-positioned to be the repository for research funds and to conduct peer review of research proposals from African scientists; it became the research arm of MIM—**MIM/TDR**. To improve communication and access to information, the NIH National Library of Medicine developed **MIMCom**, and invested in creating a malaria research electronic network that would allow African researchers to communicate with each other and with malaria researchers around the world, and access medical literature using the Internet. To address the need for a standardized research and reagent resource, the National Institute of

Allergy and Infectious Diseases, the lead U.S. agency funding malaria research, organized a meeting in November 1997 that led to the creation of the Malaria Research and Reference Reagent Resource—**MR4**—in 1998. This arm of MIM, located at the American Type Culture Collection in Manassas, Virginia, develops and distributes standard research protocols and reagents and provides training free to MIM researchers in Africa and elsewhere around the world. Finally, Britain's Wellcome Trust¹ proposed that it support MIM by acting as **Secretariat**. For a term of two to three years it would be responsible for coordination and communication among MIM members, and for such activities as planning future Pan-African Malaria Conferences. So it was that by 1998—within a year of Dakar—the four limbs of MIM were in place and operational. A year later, the Wellcome Trust organized the second Pan-African Malaria Conference in Durban, South Africa, at which time Secretariat responsibilities passed to the Fogarty International Center, at the request of the African malaria community and with the concurrence of the MIM partners.

FIC AS SECRETARIAT

During its time as MIM Secretariat, FIC developed a work plan based on the input of African malaria researchers. The Secretariat organized workshops on insecticide resistance and on several less-studied areas, highlighting the need for research on malaria anemia, malaria in pregnancy, and malaria caused by *Plasmodium vivax*—the species of parasite estimated to cause over half the cases of malaria occurring outside Africa (where the dominant species is *Plasmodium falciparum*). FIC also held workshops to enhance African researchers' skills in writing grant applications and in presenting and publishing their research. For more mature investigators, the Secretariat offered programs in research management, with an eye to ensuring that as African nations build research infrastructure and develop trained malaria researchers, there will be a cadre of research administrators with the skills to guide research efforts wisely and well. The Center also developed a transparent and democratic procedure by which to identify future MIM Secretariat sites, including all stakeholders in the process.

FIC organized a symposium that emphasized the need for more reliable data on the epidemiology and impact of malaria. This “new look at the numbers” noted in particular the long-term burden of malaria in its effects on infant development and ultimately on the productivity and economic viability of malaria-endemic countries—themes echoed in several recent FIC research programs². In the last year of its tenure, FIC organized the third and largest Pan-African Conference on Malaria, indeed the largest malaria conference ever anywhere in the world, working with the National Institute of Medical Research of Tanzania, the host nation. Over 1,200 attended the Arusha, Tanzania meeting in November 2002. Following a vote by the MIM partners, three Swedish institutions were elected to comprise the new

Secretariat: Stockholm University, the Karolinska Institute, and the Swedish Institute of Infectious Disease Control beginning in January 2003.

The Tanzania meeting served to tally the accomplishments of each of the four MIM components, counting the numbers of investigators trained, labs enhanced, and countries collaborating in research projects, both in Africa and between African and U.S. or European institutions. MIM noted the establishment of trans-African networks of multi-disciplinary research teams working in key areas: mapping risk of malaria; immunology and pathophysiology; vector biology and insecticide resistance; natural products and anti-malarial drug development; resistance of parasites to existing drugs; anti-malarial drug policy and chemotherapy; and malaria transmission intensity and mortality burden across Africa. Other research and training projects have been aimed at improving home management of malaria or enabling researchers to conduct molecular biology research on anti-malarial drug resistance. All have significantly addressed a critical need, increasing the number and capability of African researchers to contribute to the solution of the problems of Africa.

A GROWING GLOBAL CONSCIOUSNESS

It is gratifying to report that membership in MIM³ has grown as have other anti-malarial efforts. FIC has complemented its MIM activities by establishing an international malaria research training program (IMRT), linking closely to malaria research projects in Africa funded by NIAID. Both the World Health Organization with its “Roll Back Malaria” program, and the United Nations Global Fund to Fight AIDS, TB and Malaria, are supporting activities aimed at applying research to improve care, treatment, and prevention of disease in the countries most impacted. Indeed, the WHO and UN programs could be said to follow the example of MIM by creating consortia of nations targeted to fight major global health problems. So, too, is the Medicines for Malaria Venture—a public-private partnership to develop and distribute anti-malarial drugs in poor countries. Adding to the prospects for significant gains in the fight against malaria has been the recent mapping and sequencing of the human genome and the genomes of the malaria-carrying *Anopheles* mosquito, as well as of the parasite *Plasmodium falciparum*—opening a world of opportunities for developing safe and effective vaccines, new drugs, and innovative vector control methods.

1 Initial members of MIM included NIH, the Wellcome Trust, the World Bank, the World Health Organization's African Regional Office (WHO/AFRO), the government of Norway, TDR, and the Rockefeller Foundation.

2 Examples include FIC's ISHED (International Studies on Health and Economic Development) and HEED (Health, Environment and Economic Development) programs.

3 Current MIM members include components of NIH (FIC, NIAID, NLM, NIEHS), WHO/AFRO, WHO/TDR, Roll Back Malaria (WHO), Rockefeller Foundation, the Government of Japan, the World Bank, USAID, Bayer Environmental Science (South Africa), Bill & Melinda Gates Foundation, Burroughs Wellcome Fund, Calouste Gulbenkian Foundation (Portugal), Danish International Development Agency, Federal Ministry of Education and Research (Germany), GlaxoSmithKline (Belgium), Howard Hughes Medical Institute, Malaria Foundation International (USA), Malaria Vaccine Initiative (USA), Medical Research Council (UK), Netherlands Organization for Scientific Research, Sanofi-Synthelabo (France), Swedish International Development Agency, Swiss Development Corporation, Syngenta (Zimbabwe), and Wellcome Trust (UK).



DOING MORE WITH LESS

“Doing more with less” could be the motto of Fogarty International Center, which has leveraged its modest budgets over the years through programs that attract collaborators at NIH and other government agencies, as well as organizations in the private sector. To be accurate, however, a grand concept for FIC was introduced in the Congress in 1958 by John E. Fogarty, Representative from Rhode Island, who envisioned the creation of a National Institute for International Health Research with an initial budget of \$50 million. By the time it was established a decade later by Fogarty’s friends on the Hill and President Lyndon Johnson to honor his memory, the year after his untimely death, the Center was a much more modest entity. Thus, while Daniel Flood, chairman of the House Health Appropriations Subcommittee at the time called the Center the Committee’s “brainchild” and promised careful nurturance, instead of a \$50 million appropriation the first year budget for FIC was \$500,000. The major portion of these funds were used to renovate existing property on the NIH campus—the Peter family mansion that had been acquired by the government—and in planning for an additional building...

...which was never built. Instead, there was a modest \$100,000 increase in the 1969 budget allowing renovations to the mansion to be completed and enabling the fledgling center to get two new programs off to a fine start by 1970. One program would enable FIC to hold a series of international conferences and seminars to address global issues; the other was the Scholars-in-Residence fellowship program that would bring renowned scientists to live and work at NIH for upwards of a year or more.

In 1970 FIC’s budget increased sharply to \$2,954,000 but only because funds for the programs that had been transferred to it from the previous Office of International Research were now included, where previously they had shown up elsewhere in the NIH appropriation. The budget increased again by \$500,000 in 1971, the additional funds to be used for maintaining operations at the Gorgas Memorial Laboratory (GML) in Panama, which conducted research on tropical diseases. The Panama lab had come into existence in the late 1920’s, named in honor of William Gorgas, the government physician and later U.S. Surgeon General, whose work to combat yellow fever during the building of the Panama Canal had done much to spare the lives of the canal workers. The Gorgas Laboratory operated

independently of FIC and NIH; Congress simply used the Fogarty Center appropriation as a means to fund the Lab, with incremental increases from time to time. The practice continued until 1988 when Congress transferred the sums for Gorgas to the National Institute of Allergy and Infectious Diseases and invited GML and others to compete for funds under a new program in tropical medicine within NIAID.

The Fogarty Center's budget continued to grow modestly over its first two decades, but by no means did this represent the Center's actual support for international research and research training. To determine that requires a reading between the lines, for the overall budget included support for the visa services run by FIC in behalf of the NIH, staff salaries, consultations and meetings in support of program development and other administrative costs. It is important as well to recognize that FIC spending on international research and training does not capture all of the expenditures for international activities at the NIH. In fact, each of the categorical institutes can and many do make international research awards in great excess of the amounts expended by FIC. Over the past several years that amount represented under 2% of the total NIH budget—a percentage that has remained relatively consistent over time until most recently. Of course, even that must be examined more closely, for these funds include the costs of supporting the visiting program of research trainees and research scientists from other nations who spend one or several years engaged in the intramural research programs of the institutes, and for research grants to developed country institutions in Canada, the UK, France and others. These aspects of research and training support abroad are among the unique attributes of the NIH, and why NIH is such a global resource. NIH in general, and FIC in particular, are the embodiment of the notion that science is inherently international and that the free and open exchange of information among scientists of the world is its essential nature, as Fogarty himself recognized.

It must be said that even at those modest amounts and percentages the Fogarty Center and NIH have been subject to critics from time to time who ask: Why should US tax dollars be spent abroad? Are we going to shortchange our own researchers? These sentiments have not entirely abated, especially when budgets are tight, but by the 1980s, when a new and deadly disease was sweeping the world, mindsets began to change. The advent of the AIDS pandemic made it clear that no country could go it alone, even one as wealthy and as well resourced as the United States. Threats to the health and stability of any one nation could threaten all, and all who traveled were at potential risk of exposure. The Fogarty Center took that message to heart with its first international research and training program for AIDS, which presciently was oriented towards training of scientists in affected developing countries, through collaborations with U.S. academic centers. Since then, FIC has devoted the great majority of its funding to support

research and training in low- and middle-income countries. In fact, academic centers in the U.S. value these programs because they contribute so much to building the relationships necessary to carry out collaborative research, and competition for FIC grants is strong and challenging.

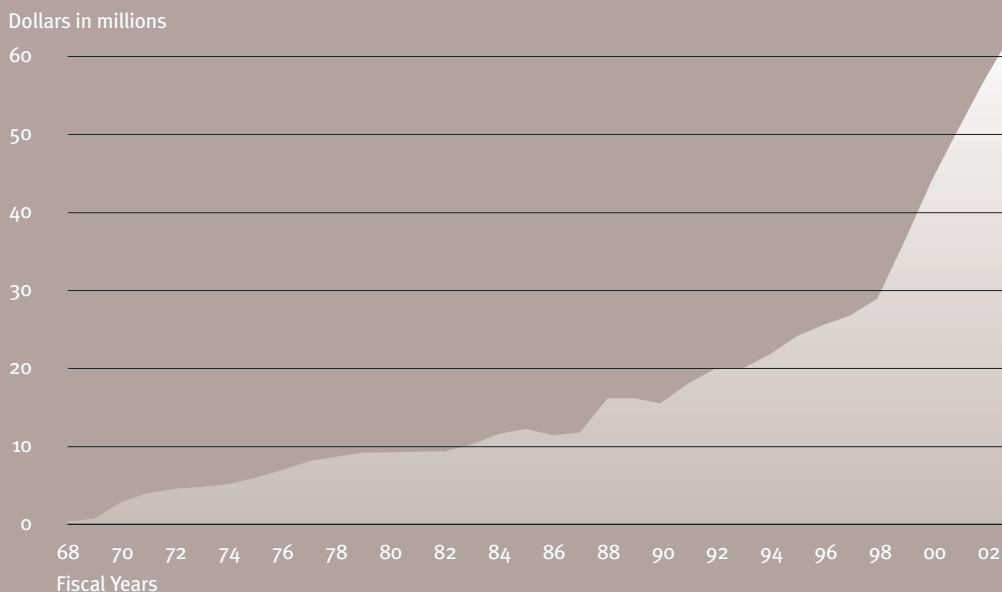
Remarkably, the initial and modest budget that FIC proposed for the AIDS International Training and Research program (generally referred to by the acronym AITRP) was increased by staff at the Office of Management and Budget (who review and make adjustments to the budget put forward by NIH), and was even further increased by Congress. Thus charting of the FIC budget reveals a distinct jump in FY 1988 because of the initiation of the AITRP, which continues to represent a significant percent of the Center's extramural budget.

More than that, the AIDS program made concrete an approach to global health issues that had been developing at the Fogarty Center for some time: the idea that the most productive use of the Center's staff and funding would be to focus on the developing world, beginning with programs to build research capacity. Initially this took the form of fellowships for foreign nationals to come to the U.S. for research training at a university awarded a FIC institutional training grant in specific targeted areas, such as AIDS. Later, the Fogarty Center developed a small grant program, which enabled U.S. researchers to apply for small collaborative research grants in partnership with non-U.S. investigators (originally \$20,000 and now \$32,000 per year) so that they could conduct research of mutual interest in the foreign country and generate pilot data for larger research grants they might later apply for. More recently, a regular research grant program was also initiated (employing the prototypical NIH investigator-initiated R01 grant mechanism), albeit focused on low- and middle-income country research priorities. Even more recently, trainees from low- and middle-income countries training at NIH or in academic centers under FIC training grants have been eligible to apply for "re-entry" RO1 grants, to return home and conduct research on major health problems. As these changes in directions for the Fogarty Center evolved in the 1990s, the old fellowship programs were phased out or modified, so that today, two types of awards—training grants to US universities focusing on selected global health issues, supplemented by a competitive small-grant research program for which returning trainees are eligible—and a regular research grant program, supplemented by the small collaborative grants program — now dominate the Fogarty Center budget.

PLANNING FOR THE FUTURE NOW

What is interesting is how broad and future-oriented the scope of research that FIC supports has become. Current programs continue to target infectious diseases like AIDS, tuberculosis, and malaria that are highly prevalent in the developing world, as well as emerging infectious diseases, increasingly taking an ecological, environmental and population biology approach to generating new insights into transmission and disease dynamics. The portfolio has also expanded to include studies of health and behavior in relation to population, occupational health, the environment, and economic development. Most recently, it had added a program of research on stigma and what can be done to ameliorate its destructive effects in association with a wide range of diseases and disorders. But it is in initiating programs that reflect the newest opportunities in science and what demographers and epidemiologists predict will be the major global health problems in both the developing and the developed world in coming decades that the Fogarty Center has been particularly noteworthy. These new programs focus on chronic diseases, genetics, diseases of aging, mental health, brain disorders—and as a major risk factor—initiation and cessation of tobacco use. As well, in each case FIC has been able to multiply the funds available via its own budget through partnerships across the NIH and beyond. A case in point is the recent announcement of an initiative to assess disease control priorities in developing countries. This joint project of FIC, the World Health Organization, and the World Bank is funded by a \$3.5 million grant by the Bill & Melinda Gates Foundation that will lead to the publication of the second edition of *Disease Control Priorities in Developing Countries* in 2005.

FIC CONGRESSIONAL APPROPRIATIONS HISTORY 1968-2003



GLOSSARY

ATSDR	Agency for Toxic Substance and Disease Registry
CDC	Centers for Disease Control and Prevention
CIHR	Canadian Institutes of Health Research
CONACYT	Consejo Nacional de Ciencia y Tecnologia (Mexico)
NIA	National Institute on Aging
NIAID	National Institute of Allergy and Infectious Diseases
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases
NCI	National Cancer Institute
NICHD	National Institute of Child Health and Human Development
NIDCR	National Institute of Dental and Craniofacial Research
NIEHS	National Institute of Environmental Health Sciences
NEI	National Eye Institute
NIGMS	National Institute of General Medical Sciences
NHLBI	National Heart, Lung and Blood Institute
NINDS	National Institute of Neurological Disorders and Stroke
NLM	National Library of Medicine
NHGRI	National Human Genome Research Institute
NINR	National Institute of Nursing Research
FIC	Fogarty International Center
NIMH	National Institute of Mental Health
NIAAA	National Institute of Alcohol Abuse and Alcoholism
NIDA	National Institute on Drug Abuse
NIOSH	National Institute for Occupational Safety and Health
NCCAM	National Center for Complementary and Alternative Medicine
NCMHD	National Center on Minority Health and Health Disparities
NSF	National Science Foundation
OAR	Office of AIDS Research
OBSSR	Office of Behavioral and Social Sciences Research
ODS	Office of Dietary Supplements
ORWH	Office of Research on Women's Health
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
WHO	World Health Organization

FOGARTY INTERNATIONAL CENTER PROGRAMS & PARTNERS

TRAINING GRANTS

ABC Actions for Building Capacity: a FIC training component in an NIAID program: International Collaborations on Infectious Disease Research.

AITRP AIDS International Training and Research Program, with NCI, NIDCR, NIDA, NIMH, NHLBI, and NINR.

GIDRTP Global Infectious Disease Research Training Program (incorporates ITREID, IMTRP and TBTRP), with NIAID, NIDCR, and CDC.

IBECDA International Bioethics Education and Career Development Award, with NHLBI, NIAID, NIAMS, NICHD, NIDA, NIDCR, NIEHS, NIGMS, NINR, and NCCAM.

ICER International Centers for Excellence in Research, Clinical Research and Management Training award, with NIAID (supports training at FIC- and NIAID-supported sites in developing countries).

ICOHRTA-I International Clinical, Operational, and Health Services Research and Training Award, with NIMH, NIDA, NIA, NCCAM, and NIDCR.

ICOHRTA-II (AIDS/TB) International Clinical, Operational, and Health Services Research and Training Award for AIDS/TB, with NIAID, NIAAA, NCI, NICHD, NIDA, NIMH, NINDS, OAR, OBSRR, ORWH, and CDC.

ICGRTP International Collaborative Genetics Research Training Program, with NHGRI, NIMH, NIA, NIEHS, NIDA, NIAAA, NINDS, and WHO.

IMRT International Malaria Research Training Program (now incorporated into GIDRTP).

IMCHRT International Maternal and Child Health Research and Training Program, with NICHD and CDC.

ITREID International Training and Research Program in Emerging Infectious Diseases, with NIAID, NIDCR, NCMHD, and CDC (now incorporated into GIDRTP).

ITREOH International Training and Research Program in Environmental and Occupational Health, with NIEHS, NIOSH, CDC, and ATSDR.

ITRPH International Training and Research Program in Population and Health, with NICHD and NIA.

ITMI International Training in Medical Informatics, with NIAID and NLM.

MIRT Minority International Research Training Grant, with NCMHD.

TBITRP Tuberculosis International Training and Research Program, with NIAID and USAID (now incorporated into GIDRTP).

RESEARCH GRANT PROGRAMS

Brain Disorders in the Developing World: Research Across the Lifespan with NIA, NIAAA, NICHD, NIDA, NIEHS, NEI, NIMH, NINDS, ODS, and the Institute of Neurosciences, Mental Health and Addiction of the Canadian Institutes of Health Research and Consejo Nacional de Ciencia y Tecnologia (CONACYT) of Mexico.

Ecology of Infectious Diseases, with NIAID, NIEHS, and NSF.

FIRCA Fogarty International Research Collaboration Award (R03) (provides funds for infrastructure and travel for a foreign scientist collaborating with a U.S. investigator who holds an NIH grant).

AIDS-FIRCA HIV-AIDS and Related Illnesses Collaboration Award (U.S. scientists who have an eligible AIDS-related NIH grant may apply).

GRIP Global Health Research Initiative Program for New Foreign Investigators. A re-entry R01 grant program providing research support and partial salary to an FIC-trained foreign scientist returning home to conduct research.

HEED Health, Environment and Economic Development Program, with NIEHS, NICHD, NIDA, OBSRR, and the U.S. Geological Survey.

ICBG International Cooperative Biodiversity Groups, with NCI, NIAID, NHLBI, NIMH, NIDA, NSF, USAID, and USDA Foreign Agricultural Service.

ISHED International Studies in Health and Economic Development, with NIA, NICHD, NIMH, OBSRR, and the Global Network of the World Bank.

International Tobacco and Health Research and Capacity Building Program, with NCI, NHLBI, NICHD, NIDA, NINR, CDC, CIHR, and WHO-Tobacco Free Initiative.

Stigma and Global Health Research Program, with NCMHD, NHGRI, NIAAA, NIAID, NIDCR, NIDA, NIMH, NINDS, OAR, OBSRR, and ORWH.

IRSDA International Research Scientist Development Award for U.S. Postdoctoral Scientists—a fellowship program providing mentored research at a foreign research institution in collaboration with a U.S. research institution.

FIC DOES ITS WORK QUIETLY AND WITHOUT FANFARE. WHEN IT INVESTS IN THE STRENGTHENING OF AN INSTITUTION, IT DOES SO STRATEGICALLY, WITH A RANGE OF SHORT, MEDIUM AND LONGER TRAINING PROGRAMS. IT IS THE BEST-KEPT SECRET AT NIH.

Michael Merson, Dean
Yale University School of Public Health



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The NIH Almanac – Organization

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National Center for Complementary and Alternative Medicine

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Mission

The National Center for Complementary and Alternative Medicine (NCCAM) is dedicated to exploring complementary and alternative healing practices in the context of rigorous science; training complementary and alternative medicine (CAM) researchers; and disseminating authoritative information to the public and professionals.

To fulfill its mission, the NCCAM supports a broad-based portfolio of research, research training, and educational grants and contracts, as well as various outreach mechanisms to disseminate information.

Research

NCCAM's primary responsibility is the conduct and support of basic and clinical research studies, using well-established tools of rigorous scientific design, conduct and oversight. These studies involve investigator-initiated projects as well as NCCAM-solicited applications. Examples include large, multi-center clinical trials; CAM Specialty Centers of Research; studies of therapies from whole medical systems (e.g., Ayurvedic medicine and traditional Chinese medicine); and studies in the four domains of CAM: manipulative and body-based therapies, biologically based practices, mind-body medicine, and energy medicine. The Center carries out these activities independently and in collaboration with other NIH Institutes and Centers, other government agencies, domestic and international research institutions, and industry.

Training

The NCCAM supports a full spectrum of predoctoral, postdoctoral, and career awards to develop a cadre of skilled investigators from both the CAM and conventional communities. The goal is to train individuals to apply the tools of exacting science to CAM systems and modalities. Institutional awards are available to support research fellows. Mentored Research Career Development Awards provide opportunities to clinicians and research scientists to develop skills for conducting rigorous research and to pursue careers as investigators. Limited support is also provided for research conferences.

Information Dissemination

Distributing scientifically based information on CAM research, practices, and findings is central to the NCCAM mission. This is accomplished through:

- Operating the NCCAM Information Clearinghouse
- Producing publications, such as fact sheets, a newsletter, and an e-bulletin;

- Offering a Web site at nccam.nih.gov
- Sponsoring lectures, conferences, an online continuing education program, and other outreach activities
- Exhibiting at events around the United States and the world
- Co-sponsoring, with the National Library of Medicine, the *CAM on PubMed* database, at nlm.nih.gov/nccam/camonpubmed.html
- Maintaining the Complementary and Alternative Medicine subfile of the *Combined Health Information Database (CHID)* at chid.nih.gov

Important Events in NCCAM History

October 1991 – The U.S. Congress passes legislation (P.L.102-170) that provides \$2 million in funding for fiscal year 1992 to establish an office within the National Institutes of Health (NIH) to investigate and evaluate promising unconventional medical practices. Stephen C. Groft, Pharm.D., is appointed Acting Director of the new Office of Alternative Medicine (OAM).

September 1992 – A Workshop on Alternative Medicine is convened in Chantilly, Virginia, to discuss the state-of-the-art of major areas of alternative medicine and to direct attention to priority areas for future research activities.

October 1992 – Joseph J. Jacobs, M.D., M.B.A., is appointed first Director of the OAM.

June 1993 – The National Institutes of Health Revitalization Act of 1993 (P.L.103-43) formally establishes the OAM within the Office of the Director, NIH, to facilitate study and evaluation of complementary and alternative medical practices and to disseminate the resulting information to the public.

September 1993 – The first OAM research project grants are funded through the National Center for Research Resources.

December 1993 – The Alternative Medicine Program Advisory Council is established.

September 1994 – Alan I. Trachtenberg, M.D., M.P.H., is appointed Acting Director of the OAM.

January 1995 – Wayne B. Jonas, M.D., is appointed the second Director of the OAM.

October 1995 – A Research Centers Program is established to provide a nationwide focus for interdisciplinary CAM research in academic institutions.

October 1996 – A Public Information Clearinghouse is established.

November 1996 – The OAM is designated a World Health Organization Collaborating Center in Traditional Medicine.

September 1997 – The first Phase III clinical trial is funded, a study of St. John's wort for major depression. The trial is co-sponsored by OAM, the National Institute of Mental Health, and the NIH Office of Dietary Supplements.

October 1998 – NCCAM is established by Congress under Title VI, Section 601 of the Omnibus

Appropriations Act of 1999 (P.L. 105-277). This bill amends Title IV of the Public Health Service Act and elevates the status of the OAM to an NIH Center.

January 1999 – William R. Harlan, M.D., is named Acting Director of NCCAM.

February 1999 – The Secretary of Health and Human Services signs the organizational change memorandum creating NCCAM and making it the 25th independent component of the NIH. The NCCAM Director is vested with broad decision-making authority, especially concerning financial and administrative management and fiscal and review responsibility for grants and contracts.

May 1999 – NCCAM independently awards its first research project grant.

The NCCAM Trans-Agency CAM Coordinating Committee (TCAMCC) is established by the NCCAM Director to foster the Center's collaboration across the DHHS and other Federal agencies. This committee supersedes a trans-agency committee established by the NIH Director in 1997.

June 1999 – A Special Emphasis Panel is chartered to enable NCCAM to conduct peer review of mission-specific CAM applications.

August 1999 – The National Advisory Council on Complementary and Alternative Medicine (NACCAM) is chartered.

October 1999 – Stephen E. Straus, M.D., is appointed the first Director of NCCAM.

NCCAM and the NIH Office of Dietary Supplements establish the first Dietary Supplements Research Centers with an emphasis on botanicals.

September 2000 – NCCAM's first strategic plan is published.

February 2001 – NCCAM and the National Library of Medicine launch *CAM on PubMed*, a comprehensive Internet source of research-based information on CAM.

April 2001 – The Division of Intramural Research is established.

April 2002 – Results of NCCAM's first clinical trial, of St. John's wort for major depression, are released.

June 2002 – NCCAM's first intramural study, of electroacupuncture to treat chemotherapy-induced nausea, is launched.

July 2002 – NCCAM initiates a new lecture series at NIH, "Distinguished Lectures in the Science of Complementary and Alternative Medicine."

October 2003 – NCCAM awards the first grants for three new types of research centers, to expand the scope and impact of its portfolio: [Centers of Excellence for Research on CAM](#), Developmental Centers for Research on CAM, and Planning Grants for International Centers for Research on CAM.

January 2004 – NCCAM celebrates its fifth anniversary during the year 2004. A strategic planning initiative is launched for the Center's second five years (2005-2009), inviting input from the public, researchers, health care professionals, and others with an interest in research on CAM.

May 2004 – NCCAM and the National Center for Health Statistics (NCHS) of the Centers for Disease Control and Prevention (CDC) announce the release of the largest, most comprehensive, and most reliable survey findings to date on Americans' use of CAM. The survey, developed by

NCCAM and NCHS, was included as part of CDC's annual National Health Interview Survey.

January 2005 — NCCAM publishes its second strategic plan, *Expanding Horizons of Health Care: Strategic Plan 2005-2009*, following a year-long process of input from the public, staff, and groups of outside experts.

NCCAM Legislative Chronology

October 1991 – Public Law 102-170 provided \$2 million to the National Institutes of Health (NIH) to establish an office and advisory panel to recommend a research program that would investigate promising unconventional medical practices.

June 1993 – Public Law 103-43, the NIH Revitalization Act of 1993, established the OAM within the Office of the Director of NIH. The purpose of the Office was to facilitate the evaluation of alternative medical treatment modalities and to disseminate information to the public via an information clearinghouse.

October 1998 – Public Law 105-277, the Omnibus Consolidated and Emergency Supplemental Appropriations Act, elevated the status and expanded the mandate of the OAM by authorizing the establishment of the NCCAM. This act amended Title IV of the Public Health Service Act.

Biographical Sketch of NCCAM Director Stephen E. Straus, M.D.

Dr. Stephen E. Straus was appointed the first director of the National Center for Complementary and Alternative Medicine (NCCAM) on October 6, 1999. Dr. Straus received his B.S. in life sciences from the Massachusetts Institute of Technology in 1968 and his M.D. from the Columbia University College of Physicians and Surgeons in 1972. His postgraduate training included an internship and residency in medicine at Barnes Hospital, St. Louis, Missouri, and a fellowship in infectious disease at Washington University, St. Louis, Missouri. Dr. Straus is board certified in internal medicine and infectious diseases.

Dr. Straus began his NIH career in 1973 as a research associate in the National Institute on Allergy and Infectious Diseases (NIAID), and he returned to NIAID in 1979 upon completion of his training in St. Louis. In pursuit of his research interests in molecular biology, pathophysiology, and treatment and prevention of human viral and immunological diseases, Dr. Straus has conducted both basic and clinical research. Dr. Straus has published close to 400 research articles and edited several books. While at NIAID, he assumed progressively higher levels of leadership, serving first as senior investigator and subsequently as Head of the Medical Virology Section in the Institute's Laboratory of Clinical Investigation and then as Chief of the Laboratory. He holds the position of senior investigator at NIAID concurrently with the Directorship of NCCAM.

Among Dr. Straus's accomplishments is his demonstration that acyclovir suppresses recurrent genital and oral herpes and the characterization of a previously unrecognized genetically determined disease, the autoimmune lymphoproliferative syndrome. The recipient in 1999 of the Dutch National ME Fund Award (the leading national prize from the Netherlands for research in myalgic encephalomyelitis/chronic fatigue syndrome), Dr. Straus has been recognized by election to the Infectious Diseases Society of America, the Association of American Physicians, and the American Society for Clinical Investigation. He is a recipient of five medals and other commendations from the U.S. Public Health Service, including the Distinguished Service Medal for innovative clinical research and the DHHS Secretary's Distinguished Service Award for drafting the blueprint to reinvigorate clinical research at the NIH. He serves on the editorial boards of several scientific journals, including the *Journal of Virology* and *Virology*.

Major Offices and Divisions

The **Office of the Director** plans, directs, coordinates, and evaluates the development of programs

and activities of the Center. This office also coordinates the activities of congressionally mandated committees and advisory councils. Within the Office of the Director:

- The *Office of Science Policy and Operations* provides planning for and evaluation of the Center's scientific initiatives and operating programs. In addition, the Office oversees NCCAM's chartered committees, congressional testimony, and implementation of the Freedom of Information Act.
- The *Office of Communications and Public Liaison* handles activities pertaining to the dissemination of information about NCCAM and CAM. Its work includes operating the Information Clearinghouse, serving as liaison with the media, and implementing education and outreach initiatives.
- The *Office of Administrative Operations* is responsible for financial management, administrative operations, and grants management, including the design and implementation of innovative business and management systems.

The **Division of Extramural Research and Training** is primarily responsible for scientific management of NCCAM's portfolio of Federally supported research grants and fellowships. In addition, the Division:

- Provides guidance in developing research, research training, and career development programs;
- Designs and develops specific CAM research projects, announced through such mechanisms as Requests for Applications (RFAs); and
- Coordinates with other components of NIH in research endeavors.

Within the Division, three offices have a specialized focus:

- The *Office of Special Populations* oversees NCCAM's activities pertaining to the Department of Health and Human Services' Initiative to Eliminate Racial and Ethnic Disparities in Health.
- The *Office of International Health Research* oversees NCCAM's global scientific research activities.
- The *Office of Clinical and Regulatory Affairs* helps plan, coordinate, and monitor NCCAM's clinical trials; serves as a resource for investigators; and oversees staff and grantee compliance with all Federal guidelines pertaining to research using human subjects.

The Division of Intramural Research conducts clinical, translational, and basic research on the efficacy, safety, and mechanisms of action of diverse CAM modalities; facilitates integration of effective CAM and conventional practices into the interdisciplinary health care system at the NIH Clinical Center; and fosters development of research and training curricula that include information about safe and effective CAM and conventional practices.

The Office of Scientific Review is responsible for the peer review of solicited investigator-initiated, fellowship, career-development, training, program, and center grants and contracts.

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National Center on Minority Health and Health Disparities

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Mission

The National Center on Minority Health and Health Disparities (NCMHD) promotes minority health and leads, coordinates, supports, and assesses the NIH effort to reduce and ultimately eliminate health disparities. The NCMHD works independently and in partnership with the NIH Institutes and Centers and with other Federal agencies and grassroots organizations in minority and in other medically underserved communities to:

- Conduct and support basic, clinical, social sciences and behavioral health disparities research and research training.
- Strengthen the infrastructure of qualified research institutions that conduct health disparities research and training.
- Increase the participation of minorities and other medically underserved populations in clinical research.
- Promote outreach and the dissemination of health information to medically underserved populations.
- Develop a culturally sensitive cadre of researchers and clinicians dedicated to eradicating health disparities.

Important Events in NCMHD History

1990 – The Office of Research on Minority Health (ORMH) was established, with the encouragement of Congress, by the Director, National Institutes of Health (NIH).

1991 – The ORMH convened an advisory Fact-Finding Team (FFT) to conduct three regional conferences with grassroots constituencies. The FFT issued a report with 13 recommendations from the community that guided the initial efforts of the ORMH.

1992 – The *Minority Health Initiative* (MHI), the centerpiece of the ORMH agenda, was launched and initially funded at \$45 million. This multi-year biomedical and behavioral research and research training program co-funds through its partnerships 1) interventions to improve prenatal health and reduce infant mortality; 2) studies of childhood and adolescent lead poisoning; HIV infection and AIDS; and alcohol and drug use; 3) research in adult populations focused on cancer, diabetes, obesity, hypertension, cardiovascular diseases, mental disorders, asthma, visual impairments, and alcohol abuse; and 4) training for faculty and for students at all stages of the educational pipeline B from precollege and undergraduate through graduate and postdoctoral levels.

The ORMH initiated a study designed to present an overview of NIH extramural research training programs for minority students and to assess the feasibility of conducting a trans-NIH assessment of these programs.

1993 – Public Law 103-43, the Health Revitalization Act of 1993, established the Office of Research on Minority Health in the Office of the Director, NIH.

1994 – The National Conference on Minority Health Research and Research Training was held in Chicago.

1996 – Conferences were held in Honolulu, Hawaii; Miami, Florida; and Puerto Rico to inform ORMH constituencies of the progress made, to solicit feedback on those achievements, and to obtain information on the needs of minority populations.

1997 – The Advisory Committee on Research on Minority Health was established to provide advice to the Director, ORMH, and to the Director, NIH, regarding research and research training with respect to minority health issues.

1998 – The first meeting of the Advisory Committee on Minority Health was held.

2000 – The ORMH celebrated its 10th anniversary.

The National Center on Minority Health and Health Disparities was established by the passage of the Minority Health and Health Disparities Research and Education Act of 2000, Public Law 106-525, which was signed by the President of the United States on November 22, 2000.

2001 – Dr. John Ruffin was sworn in as the first director of the National Center on Minority Health and Health Disparities.

Programs mandated by Congress were implemented to expand the infrastructure of Institutions committed to health disparities research and to encourage the recruitment and retention of highly qualified minority and other scientists in the fields of biomedical, clinical, behavioral, and health services research: (1) *the Endowment Program*, (2) *the Loan Repayment Program for Health Disparities Research*, and (3) *the Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds*.

2002 – The Congressionally mandated program, *Project EXPORT – Centers of Excellence*, was launched.

The first National Advisory Council of the NCMHD was convened.

The NCMHD assumed responsibility for the Research Infrastructure in Minority Institutions Program (RIMI).

2003 – The first *NIH Strategic Research Plan and Budget to Reduce and Ultimately Eliminate Health Disparities* was issued.

2005 – The NCMHD assumed responsibility for the Minority International Research Training Program (MIRT) and renamed it the Minority Health and Health Disparities International Research Training Program (MHIRT).

NCMHD Legislative History

1993 – P.L. 103-43, the Health Revitalization Act of 1993, established the Office of Research on Minority Health in the Office of the Director of the National Institutes of Health.

2000 – P.L. 106-525, Minority Health and Health Disparities Research and Education Act of 2000, established the National Center on Minority Health and Health Disparities.

Biographical Sketch of NCMHD Director John Ruffin, Ph.D.

Dr. Ruffin was appointed the first director of the National Center on Minority Health and Health Disparities at the National Institutes of Health (NIH) on January 9, 2001. In this role he leads the NIH effort to address health disparities in racial and ethnic populations and in other medically underserved populations, including the urban and rural poor. The former director of the NIH Office of Research on Minority Health, NIH, Dr. Ruffin developed the largest program in the country promoting biomedical research and research training. Dr. Ruffin received his Baccalaureate degree from Dillard University and a Master's degree from Atlanta University. He earned a Ph.D. at Kansas State University in systematic and developmental biology and then pursued postdoctoral studies at Harvard University.

Dr. Ruffin's professional life has been devoted to improving the health status of minority populations in the United States and to developing and supporting education programs for minority researchers and health care practitioners. Prior to joining the NIH, he was Dean of the College of Arts and Science at North Carolina Central University.

Dr. Ruffin's life-long commitment to academic excellence and promotion of numerous partnerships with government, private industry, and academic institutions to support minority health research and research training have earned him much recognition. He has received Samuel L. Kountz Award for his significant contribution to the cause of increasing access and participation in organ and tissue transplantation in minorities, the NIH Director's Award, the National Hispanic Leadership Award, the Beta Beta Beta Biological Honor Society Award, the National Medical Association Award of Appreciation, a Special Recognition Award by the Secretary of Health and Human Services, and most recently the Presidential Merit Award.

NCHMD Directors

Name	In Office From	To
John Ruffin	January 2001	Present

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National Center for Research Resources

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Mission

The National Center for Research Resources (NCRR) provides laboratory scientists and clinical researchers with environments and tools that they can use to prevent, detect, and treat a wide range of diseases. This support enables discoveries that begin at the molecular and cellular level, move to animal-based studies, and then are translated to patient-oriented clinical research, resulting in cures and treatments for both common and rare diseases. NCRR connects researchers with each other, as well as with patients and communities across the nation, to bring the power of shared resources and research to improve human health. NCRR's extramural grant support is concentrated in four programmatic Divisions: Division for Biomedical Technology Research and Research Resources, Division for Clinical Research Resources, Division of Comparative Medicine, and Division of Research Infrastructure.

Many NCRR-supported research resources – often one-of-a-kind or in short supply – are expensive to create, develop, and maintain. NCRR-funded, shared resources include networks of General Clinical Research Centers, Clinical Research Centers at Research Centers in Minority Institutions, Islet Cell Resource Centers, Biomedical Technology Research Centers, National Primate Research Centers, and resources for mutant mice and rats, as well as special animal colonies and repositories; biological models and materials; and biomedical instrumentation. Shared resources, an NCRR hallmark, also allow scientists to react rapidly and effectively to emerging health problems and unexpected research opportunities.

A number of NCRR grant programs help build and strengthen the biomedical research infrastructure of the United States, including physical facilities and human resources. For example, NCRR provides support to develop basic and clinical biomedical research capabilities through the Institutional Development Award (IDeA) Program. NCRR funding also enables institutions to construct, renovate, and improve biomedical research facilities; provides teachers and students with hands-on science education experiences; and assists researchers in developing education models that will ultimately increase student and public understanding of biomedical science. Other NCRR support provides postgraduate and postdoctoral special-emphasis training and career-development opportunities.

Important Events in the Division of Research Resources* (DRR) History (*Predecessor to NCRR)

1962 – On April 13 Dr. Luther L. Terry, PHS Surgeon General, announced the creation of the Division of Research Facilities and Resources (DRFR) – officially established on June 15.

In June, the Regional Primate Research Centers transferred from the National Heart Institute to DRFR.

1967 – The Biotechnology Resources Program (BRP) was established with the transfer of centers for biomedical computing and bioengineering to DRFR from another NIH component. BRP funded the first centers in mass spectrometry and nuclear magnetic resonance.

1969 – DRFR, in the PHS Bureau of Health Professions Education and Manpower Training, was renamed the Division of Research Resources (DRR).

1970 – DRR was removed from the Bureau of Health Professions Education and Manpower Training and became an independent NIH division.

1972 – The Minority Biomedical Research Support Program was formed.

1975 – The NIH director approved a broadened mission for the division and an internal reorganization.

1979 – The BRP funded the first synchrotron facility for use in X-ray crystallography by NIH investigators.

1980 – The Minority High School Student Research Apprentice Program was begun.

1985 – The Research Centers in Minority Institutions Program was established.

The biological models and materials research section was created in the Animal Resources Program.

1986 – The only national laboratory dedicated to biomedical applications of fluorescence was funded at the University of Illinois.

1987 – The Pittsburgh Supercomputer Center was funded.

1988 – The Research Facilities Improvement Program was begun.

1989 – The biological models and materials resources section of the Animal Resources Program became the Biological Models and Materials Research Program.

The Minority Biomedical Research Support Program was transferred from DRR to NIGMS.

Important Events in NCRR History

1990 – On February 15, Dr. Louis W. Sullivan, Secretary of the Department of Health and Human Services, approved the merger of the Division of Research Resources and the Division of Research Services to form the National Center for Research Resources.

NCRR's extramural programs included: Biological Models and Materials Research, Biomedical Research Support, Biomedical Research Technology, Animal Resources, General Clinical Research Centers, Research Centers in Minority Institutions, and Research Facilities Improvement. NCRR intramural resources included: the Biomedical Engineering and Instrumentation Program, the Library Branch, the Medical Arts and Photography Branch, and the Veterinary Resources Program.

The center received appropriated funding for the Research Centers in Minority Institutions (RCMI) program, which had been previously administered by DRR but funded by the Office of the Director, NIH, since the program's inception in 1985.

NCRR supported the First Annual Research Centers in Minority Institutions' International AIDS Symposium focused on AIDS in minority populations in the United States, Africa, and Latin America.

1991 – The Science Education Partnership Award (SEPA) program was established.

The center sponsored a workshop of multidisciplinary experts in structural biology research which generated recommendations for future directions in the report, *Technologies for the Future: Opportunities and Needs in Structural Biology and Molecular Medicine*.

1993 – NCRR began the Science Teaching Enhancement Award Program (STEAP), a 2-year pilot program to create a corps of master teachers to form institutional partnerships that would improve biology education at the precollege level.

The Institutional Development Award (IDeA) program and the Research Facilities Improvement program were established, as mandated by the NIH 1993 Revitalization Act.

NCRR discontinued the Biomedical Research Support Grant program.

1994 – The Minority K-12 Teachers and High School Students Program was initiated to replace the Minority High School Student Research Apprentice Program (MHSSRAP).

NCRR convened expert biomedical investigators, academic administrators, and staff to develop NCRR's first comprehensive strategic plan, *NCRR: A Catalyst for Discovery, A Plan for the National Center for Research Resources*.

The center released *Technologies for the Future – Biomedical Computing: A Critical Tool for Research*, describing opportunities in key biomedical computing areas such as neural systems and biomolecular simulations.

1995 – NCRR's 5th anniversary was marked with a "Partnership for Discovery Symposium" to highlight biomedical advances accomplished with NCRR support.

The center collaborated with the NIH Office of Research on Minority Health to establish the Research Infrastructure in Minority Institutions (RIMI) initiative, a demonstration project to assist nondoctoral degree minority institutions to develop their research infrastructure, primarily through collaborations with research-intensive universities.

The *Report of the Panel to Formulate Recommendations for the GCRC Program* was released.

NCRR reorganized the original seven extramural programs into: Biomedical Technology, Clinical Research, Comparative Medicine, and Research Infrastructure.

The center established the RCMI Clinical Research Infrastructure Initiative (RCRII) to enable RCMI-eligible institutions with affiliated medical schools to develop their clinical research infrastructure.

Three National Gene Vector Laboratories were established with joint funding by NCRR, NCI, NHLBI, NIDDK, and the Office of AIDS Research.

The NCRR home page was created on the World Wide Web to enhance researchers' access to information on research resources and scientific opportunities.

1996 – An agreement was formalized between the NIH/NCRR Shared Instrumentation Grant program and the National Science Foundation's Multi-user Equipment program to jointly review and fund single scientific instruments costing more than \$500,000.

The *Evaluation of the NIH Shared Instrumentation Grant (SIG) Program: Reports from Users* was issued.

1997 – NCRR published the *National Survey of Laboratory Animal Use, Facilities, and Resources*.

NCCR's intramural programs transferred to the NIH Division of Intramural Research Services within the Office of Research Services.

The "Neuroscience Technology Development Workshop" participants recommended new scientific opportunities NCCR should pursue in order to develop research resources to enhance neuroscience research activities.

The *NCCR Reporter*, a quarterly magazine formerly published by DRR as the *Reporter*, celebrated its first 20 years of publication.

1998 – A comprehensive 5-year strategic plan, *NCCR – A Catalyst for Discovery – A Plan for the National Center for Research Resources: 1998-2003*, was published.

The minority clinical associate physician and clinical research scholar career development elements of the GCRC program were merged into the clinical associate physician career program.

NCCR established the NIH Chimpanzee Management Program (ChiMP).

1999 – NCCR established the Nation's eighth Regional Primate Research Center (RPRC) at the Southwest Foundation for Biomedical Research – the first center to be added to the RPRC network since the 1960s.

NCCR established the Mutant Mouse Regional Resource Centers Program.

NCCR established a career-enhancing award in Mouse Pathobiology Research for veterinarians engaged in pathobiology. The award protects time devoted to pathobiology research studies in genetically altered mice and enhances mentoring activities to increase the pool of future mouse pathobiologists.

The first annual scientific meeting of NCCR-supported comparative medicine resource directors was hosted by the Miami National Resource for Aplysia, University of Miami.

Eight "collaboratory" projects were initiated within the NCCR-supported biomedical technology resource centers to demonstrate and evaluate the efficiency and effectiveness of conducting multi-investigator research utilizing the Internet.

Through a collaboration with the Cystic Fibrosis (CF) Foundation, several NCCR-supported General Clinical Research Centers became part of a CF treatment and diagnostic center network, enhanced by an NCCR-funded GCRC Data Management Unit to collate and analyze the CF clinical trial results.

A full-scale biosafety level-4 (BL4) laboratory partially funded by NCCR was dedicated at the Southwest Foundation for Biomedical Research in Texas. It is one of four Federally supported BL4 labs nationwide, but the only such facility dedicated to basic molecular studies and investigation of long-term pathogenesis of deadly microbes.

2000 – NCCR published the *Cost Analysis and Rate Setting Manual* (last revised in 1979) to reflect a cost-allocation change in DHHS policy for research-related direct and indirect costs incurred by institutional animal research facilities.

NCCR and several other NIH components cofunded a number of new initiatives to enhance research priority areas such as bioengineering (including nanotechnologies) and biocomputing (including informatics), and new animal models.

NCRR published the results of an evaluation of the Research Centers in Minority Institutions Program and a mid-course assessment of the Research Infrastructure in Minority Institutions program.

NCRR published the *Full-Scale Evaluation of the Regional Primate Research Centers (RPRC) Program*.

NCRR established a number of new faculty mentoring and student training grant opportunities, utilizing existing NIH funding mechanisms, to encourage medical students to pursue clinical research careers and research veterinarians to become independent researchers.

As part of the IDeA program, NCRR established Centers of Biomedical Research Excellence (COBRE) at independent institutions located in states with historically low aggregate success rates for obtaining NIH grants. The COBRE Program funds independent research centers focused on specific scientific themes to increase research capacity.

NINDS, ORMH, and NCRR established the Specialized Neuroscience Research Program at Minority Institutions to strengthen faculty and student neuroscience research capabilities.

NCRR continued activities to transition from the National Chimpanzee Biomedical Research Program to the NIH Chimpanzee Management Program, established in 1998. NCRR funded an expanded database of pertinent information on NIH-owned chimpanzees and assumed the ownership of approximately 300 chimpanzees previously used for Federally supported biomedical research from a private entity.

2001– NCRR launched the Biomedical Informatics Research Network (BIRN), a shared network of neuroimaging databases that serves as a test bed for development of hardware, software, and protocols for mining data in a site-independent manner for both basic and clinical research.

The first NIH-wide High-End Instrumentation is established to enable institutions to purchase instruments that cost more than \$1 million.

A Research Subject Advocate (RSA) Program, established at the GCRCs, informs patients and volunteers about the research studies in which they participate and facilitates the timely reporting of serious adverse events to appropriate oversight boards and agencies.

Islet Cell Resource Centers are established to isolate, characterize, and distribute human pancreatic islets for transplantation into patients with type I diabetes.

A network of National Gene Vector Laboratories (NGVL) is established to produce clinical-grade vectors for human gene transfer protocols and to perform related toxicology studies for Phase I and Phase II human clinical gene transfer protocols.

The Mutant Mouse Regional Resource Centers network began accepting transgenic animals from researchers to add to its collection for broad dissemination to the biomedical research community.

A National Stem Cell Resource established at the American Type Culture Collection in Manassas, Virginia acquires and distributes cells, reagents, and information about nonhuman embryonic and postnatally derived stem cells from a variety of species.

The Centers of Veterinary Research Excellence (COVRE) Program is established to address the shortage of research veterinarians by providing support for faculty, infrastructure, and recruitment of promising young investigators.

As part of the Institutional Development Awards (IDeA) Program, NCRR established Biomedical

Research Infrastructure Network (BRIN) grants to help IDeA institutions attract established investigators, develop the research skills of resident investigators, alter and renovate laboratories, and purchase modern equipment.

The NCRR began providing Science Education Partnership Awards to science centers and museums nationwide to enhance the reach of unique health-related education programs.

2002 – NCRR, along with five other NIH components, issued infrastructure enhancement awards to increase the capacity for basic research using human embryonic stem (ES) cells for preclinical investigations. The awards, which support entities listed on the NIH Human Embryonic Stem Cell Registry, are designed to increase the supplies and access to cells that are self-renewing and well characterized for quality controls.

A private, nonprofit organization received a contract to establish and operate a sanctuary for chimpanzees no longer needed for biomedical research. The Chimpanzee Health Improvement, Maintenance, and Protection (CHIMP) Act of December 2000 mandated such a sanctuary.

NCRR expanded breeding of Specific-Pathogen-Free (SPF) Rhesus Macaques in response to a national shortage and demand for these models. To explore alternatives to the use of rhesus macaques in biomedical research, experts met at the National Academy of Sciences in Washington, D.C. to develop recommendations intended to alleviate scientific demands for rhesus macaques.

The eight Regional Primate Research Centers were renamed as the National Primate Research Centers to reflect their enhanced emphasis on providing nonhuman primates and related resources to biomedical scientists nationwide.

The Argonne National Laboratory's Advanced Photon Source (APS) and the NCRR-supported Northeastern Collaborative Access Team, or NE-CAT agreed to build three experimental stations, known as beamlines, at the APS for synchrotron radiation research to study protein complexes and other biomolecular structures.

The Rat Resource and Research Center (RRRC), established at the University of Missouri (Columbia), serves as a resource for the study of rat models for biomedical research worldwide. The RRRC imports, cryopreserves, produces, and distributes high-quality laboratory rats.

2003 – To address the challenges inherent in diagnosing and treating rare diseases, NCRR and other components of NIH established the Rare Disease Clinical Research Network, which consists of seven Rare Diseases Clinical Research Centers and a Data and Technology Coordinating Center. Each research center consists of a consortium of clinical investigators partnering with patient support groups and institutions within and outside of the United States that have agreed to work together studying a group of rare diseases. The data-coordinating center works with the sites to integrate various kinds of data including genetic, microarray, clinical, laboratory, and imaging.

A biomedical computing science and technology program, established by NCRR and 16 other NIH components, supports fundamental research as well as the development and application of new biocomputing tools or technologies. The program promotes research and development in computational science and technology that supports rapid progress in areas of scientific opportunity in biomedical research.

The Stroke Prevention/Intervention Research Program (SPIRP) was established to identify racial and geographical disparities related to stroke and cerebrovascular disease and to establish programs aimed at reducing or eliminating these disparities. The SPIRP is funded by the National Institute of Neurological Disorders and Stroke (NINDS); the National Center for Research Resources (NCRR), and the National Heart, Lung, and Blood Institute (NHLBI).

NCRR and the National Center on Minority Health and Health Disparities awarded a grant to

Tuskegee University to complete its National Center for Bioethics in Research and Health Care. The grant allows the university to provide research and teaching facilities for faculty, researchers and visiting scholars for studies in bioethics, public health, and integrated bioscience programs. The center is the Nation's first bioethics institute dedicated to addressing issues that involve African Americans and other vulnerable or disadvantaged populations.

IDeANET began with the funding of a test-bed consortium of six IDeA states (called the Lariat Project) to provide increased connectivity for high-bandwidth science applications and facilitate collaborations among these and other institutions. IDeANET will eventually provide support for a national IDeA network — beginning with Lariat — to include all participants in the IDeA Program, as well as participants in the Research Centers in Minority Institutions (RCMI) Program, connecting with other Networks supported by NCCR. IDeANET enhances IT infrastructure by providing support for staff in bioinformatics and data management cores, computer hardware and software, and Internet2 broad-bandwidth access for biomedical applications. It is intended to relieve strategic bottlenecks in connectivity entering states and improve Internet performance at many sites throughout the IDeA states.

A Viper Resource Center was established at Texas A&M University in Kingsville, Texas to provide a resource of more than 400 venomous snakes. The snake venoms — a rich, stable source of biomedically important proteins such as disintegrins, metalloproteases, and fibrinolytic enzymes — are of particular interest because they can alter the shape, orientation, and movement of cells, and may play a role in the treatment of cancer, heart attacks, and strokes.

A National Swine Research and Resource Center was established at the University of Missouri-Columbia to serve as a national repository and distribution center for genetically modified swine. The center houses 150-250 pathogen-free swine and cryopreserves genetic material and reproductive cells so that important swine models can be rederived as needed. Because the anatomy and physiology of pigs are remarkably similar to humans, the animals are ideal models for studying diabetes, cardiovascular disease, and obesity. The swine resource also conducts research aimed at improving cryopreservation, eliminating pathogens, and producing transgenic and knockout swine.

The *Drosophila* Genomics Resource Center (DGRC), housed at the Center for Genomics and Bioinformatics at Indiana University in Bloomington, was created to assist researchers in applying genomics in the model organism *Drosophila*, by assuring economical access to quality-controlled genomics materials. The DGRC produces and distributes DNA microarray slides for gene expression analyses; tests new and alternative genomics technologies; facilitates the collection and analysis of array expression data; and collects and distributes other reagents and materials essential for *Drosophila* genomics research, including large clone sets, common transformation vectors, and cell lines.

Three new resources were developed to integrate technologies that enhance the study of proteomics and glycomics, two emerging fields that seek to identify and uncover the structures, functions, and interactions of the thousands of proteins (proteomics) or carbohydrates (glycomics) found in cells. The new resources are the Proteomics Research Resource for Integrative Biology at Pacific Northwest National Laboratory, Integrated Technology Resource for Biomedical Glycomics at the University of Georgia, and the Integrated Proteome Technologies for Pathway Mapping resource at the University of Michigan, which houses a high-throughput robotic analysis system.

Tulane University, in New Orleans, Louisiana, established a center for the preparation, quality testing, and distribution of adult stem cells. The center prepares and distributes a continuous supply of marrow stromal cells (MSCs) derived from adult human and rat bone marrow, using standardized protocols.

2004 — A comprehensive 5-year strategic plan, *2004-2008 Strategic Plan: Challenges and Critical Choices*, was published, based on the input of biomedical investigators, high-level administrators in research organizations, scholarly organizations, and NIH senior program staff. The Strategic Plan

will guide NCRR's priorities for investments, including local and national networks, research resources, technology development, instrumentation, biological models, and biomedical informatics tools to facilitate research intended to prevent, alleviate, or treat human disease.

NCRR funds the first national center for high-throughput genotyping dedicated solely to large-scale SNP (single nucleotide polymorphism) analysis. This high-capacity resource will allow U.S. researchers to quickly and cost-effectively carry out large-scale studies of genetic variation in humans and animals to advance disease gene identification. Research on genetic variation is aimed at improving the diagnosis and treatment of numerous diseases of humans that may have significant genetic components – such as type I diabetes, schizophrenia, and some types of cancer – by identifying specific genetic markers, or genotypes, that are associated with particular diseases or responses to drug therapies.

Using existing resources and centers, NCRR serves as a significant partner in many NIH Roadmap initiatives, including those under the theme of Re-engineering the Clinical Research Enterprise. Additionally, NCRR is the lead Center partnering with other NIH components to support Exploratory Centers for Interdisciplinary Research, which seeks to lower the artificial barriers that divide researchers and impede scientific progress. NCRR is also the lead NIH component supporting National Technology Centers for Networks and Pathways to develop new technologies to study the dynamics of molecular interactions within cells. NCRR also supports the National Centers for Biomedical Computing initiative, which will build the computational infrastructure for biomedical computing, ranging from basic research in computational science to providing the tools and resources needed by biomedical and behavioral researchers.

The Resources for X-Ray Tomography of Whole Cells was established by NCRR and the U.S. Department of Energy at the Lawrence Berkeley National Laboratory in Berkeley, California. Employing the new field of cryo X-ray tomography, in which samples are rapidly frozen and viewed using a transmission X-ray microscope, researchers will be able to create and examine high-resolution, three-dimensional images of the inside of cells.

The Stanford Synchrotron Radiation Laboratory (SSRL) at Stanford University in California received a \$58 million upgrade with support from NCRR, NIGMS, and the U.S. Department of Energy. The upgrade project essentially rebuilt the existing storage ring – the machine in which electrons circulate at nearly the speed of light, producing visible and invisible forms of light called synchrotron radiation. This venture, which increased the brightness of the synchrotron radiation by one or two orders of magnitude, was begun in 1999 and completed in mid-December 2003.

The University of North Carolina, Chapel Hill received support to further develop and make more widely available a Genome Fingerprint Scanning (GFS) program. The tool allows researchers to match mass spectrometry data directly to raw, unannotated genetic sequences to identify proteins and locate novel genes. Proteomics, the study of how proteins interact and respond to changing conditions in complex systems, is increasingly being used to help decipher diseases such as cancer, diabetes, and Alzheimer's.

Comprehensive Centers on Health Disparities (CCHD) were established to systematically address one or more of the health disparities that negatively impact racial and ethnic minority populations served by the grantee institutions. The new centers are: Meharry Medical College in Nashville, Tennessee; Charles R. Drew University of Medicine and Science in Los Angeles, California; and the Puerto Rico consortium, which consists of the three accredited medical schools in Puerto Rico (the University of Puerto Rico School of Medicine, the Universidad Central del Caribe School of Medicine, and the Ponce School of Medicine.) The health disparities to be studied include a variety of cancers (breast, prostate, and colorectal); diabetes mellitus; renal disease; infant mortality; AIDS; and cerebrovascular and cardiovascular diseases.

2005 — In October 2005, NCRR (on behalf of NIH) launched a new NIH Roadmap for Medical Research initiative — the Clinical and Translational Science Awards (CTSAs) — designed to speed the process by which biomedical discoveries are translated into effective medical care for patients.

Developed with extensive input from the scientific community, the awards will help institutions nationwide create an academic home for clinical and translational science. CTSA's will provide an opportunity for institutions to develop critical resources and integrate clinical and translational science across multiple disciplines and academic departments, schools, clinical and research institutes, and hospitals. By lowering barriers among disciplines and encouraging creative, innovative approaches to solve complex medical problems, the new CTSA's are expected to fundamentally transform the conduct of clinical and translational science in the United States and usher in a new approach for preemptive medical care.

The Science Education Partnership Awards (SEPA) program awarded approximately \$22 million to fund 21 SEPA projects. SEPA programs serve K-12 students and teachers, as well as science centers and museums across the country. Many of the programs target underserved and/or minority populations that are less likely to pursue science careers. In addition, SEPA partnerships develop projects that educate the general public about health and disease, with the aim of helping people make better lifestyle choices as new medical advances emerge.

NCCR expanded its Islet Cell Resource (ICR) Program to provide cells for basic research studies. Previously, human islet cells had only been provided for clinical transplantation. The cells will be made available to researchers for basic science studies at no cost, if their proposals are approved by the ICR's Administrative and Bioinformatics Coordinating Center. With support from NCCR, NIDDK, and the Juvenile Diabetes Research Foundation, 10 Islet Cell Resource (ICR) Centers isolate, purify, and characterize human pancreatic islets for use in scientific research and for subsequent transplantation into patients with type I diabetes.

The NCCR Research Centers in Minority Institutions (RCMI) Program celebrates its 20th anniversary. Launched in 1985 with Congressional support, the RCMI Program fosters environments that are conducive to excellence in basic, clinical, and behavioral research. Through training and career development opportunities, the RCMI program also establishes a critical mass of scientists that more closely reflect the growing ethnic and cultural diversity of the U.S. population. The program commemorated its 20th anniversary with events such as a national symposium at Texas Southern University in Houston, an awards program and lecture at Howard University in Washington, D.C., and a Symposium on Addiction, Neurosciences, and HIV/AIDS at the Universidad Central del Caribe in Bayamon, Puerto Rico.

The Biomedical Technology Resource Centers Program awarded \$18.2 million to create two new centers to develop new image guided therapies and to further biochemistry studies of diseases such as alcoholism and cancer. Brigham and Women's Hospital of Boston will receive \$15 million over five years in a cooperative agreement to establish a national Image Guided Therapy (IGT) Center. The new resource will provide a unique, "one-stop-shopping" research, training, and service center that will develop and make available to scientists and clinicians image processing and display tools; dynamic and adaptive Magnetic Resonance Imaging methods; novel therapy techniques; and image-guided robotics. Through the second award, NCCR will provide Indiana University in Bloomington with \$3.2 million over three years to launch the National Center for Glycomics and Glycoproteomics to advance the study of carbohydrate molecules. A relatively new field that uses sophisticated tools and methods, glycomics is the study of complex sugar molecules that are attached to many proteins and lipids found in the blood, on the surfaces of cells, and in other places in the human body.

The High-End Instrumentation (HEI) program awarded 11 grants totaling \$18 million to fund the purchase of new state-of-the-art equipment required to advance biomedical research. Awarded to research institutions around the country, the one-time grants support the acquisition of instruments that cost more than \$750,000, with a maximum of \$2 million each. Since its inception in 2002, the HEI Program has provided 62 awards and 2 supplements to biomedical research institutions in 23 states, totaling \$95,652,561.

The WiCell Research Institute in Wisconsin was awarded \$16.1 million over four years to fund a National Stem Cell Bank. The National Stem Cell Bank, awarded to the WiCell Research Institute in Wisconsin, will consolidate many of the Federally funded eligible human embryonic stem (ES) cell

lines in one location, reduce the costs that researchers have to pay for the cells, and maintain quality control over the cells. The Stem Cell Bank will provide scientists affordable and timely access to Federally approved human embryonic stem cells and other technical support that will make it easier for scientists to obtain the cell lines currently listed on the NIH Human Embryonic Stem Cell Registry

Through its Research Facilities Improvement Program (RFIP), NCRP awarded nearly \$30 million for 10 construction projects across the country. The grants will allow institutions to construct new laboratory space, improve research imaging capabilities, renovate existing infrastructure systems, and create facilities for research animals. The FY 2005 RFIP awards will fund the design, construction, and fixed equipment costs for new research facilities such as The Northern Plains Center for Behavioral Research at the University of North Dakota; the Center for Human Genetics and Complex Traits at the University of Pennsylvania; and the Breast and Women's Cancer Laboratory at the University of California, Irvine. The program will support new resources for research animals at the Tulane University Health Sciences Center and the University of Alaska, Fairbanks. Grants will allow the Massachusetts General Hospital and Vanderbilt University to increase their research imaging capabilities. Finally, funding will enable major renovations to research laboratories at Meharry Medical College, Montana State University, and the University of Washington.

The University of North Carolina, Chapel Hill — funded by a five-year NCRP grant totaling \$2.46 million — launched the National Gnotobiotic Rodent Research Center, significantly expanding the existing Mutant Mouse Regional Resource Center at the university. The center will provide scientists across the Nation with access to gnotobiotic mice and rats, which will allow more precise explorations of how genes interact with the environment. Gnotobiotic organisms either are germ-free or have some contaminants that are known to the experimenter. Gnotobiotic techniques serve to produce germ-free and disease-free laboratories.

Chimp Haven, the first Federally funded chimpanzee sanctuary, opened on October 28, 2005. The sanctuary, funded by an NCRP contract, provides lifetime care for Federally owned or supported chimpanzees that are no longer needed for biomedical research. NCRP also awarded construction grants so that Chimp Haven could develop and build a state-of-the-art facility that closely resembles the chimpanzees' natural habitat. At capacity, Chimp Haven will be able to accommodate about 175 chimpanzees. The sanctuary was established in response to the Chimpanzee Health Improvement, Maintenance, and Protection (CHIMP) Act of December 2000, which authorized \$30 million in Federal dollars for the sanctuary.

NCRP Legislative Chronology

July 30, 1956 – The Health Research Facilities Act of 1956 (Title VII of the PHS act) authorized a PHS program of Federal matching grants to public and nonprofit institutions for health research facilities construction. Congress extended title VII through 1971. No grants were made under this authority after 1969.

August 19, 1959 – Congress appropriated \$2 million to establish two primate research centers.

September 15, 1960 – Public Law 86-798 amended the PHS act to authorize grants-in-aid to universities, hospitals, laboratories, and other public and nonprofit institutions to strengthen their programs of research and research training in sciences related to health. The act also authorized the use of funds appropriated for research or research training to be set aside by the Surgeon General in a special account for general research support grants. Passage of this law resulted in the Biomedical Research Support Program.

July 29, 1971 – The Minority Biomedical Research Support Program was created with \$2 million from the Senate Appropriations Committee under authority of sec. 301(c) of the amended PHS act.

October 3, 1984 – The Research Centers in Minority Institutions Program was created with a \$5 million congressional appropriation to the NIH Office of the Director. DRR was given administrative authority for the program.

December 22, 1987 – Public Law 100-202 provided \$23,935,000 for the "repair, renovation, modernization, and expansion of existing research facilities, and for the purchase of associated equipment." The accompanying report, H.R. 100-498, directed that the money be spent on improving AIDS research facilities. The Research Facility Improvement Program was created in DRR in response to this legislation.

November 6, 1990 – Public Law 101-613, NIH Revitalization Act of 1990, mandated new programs, specified program funding levels, and reauthorized existing activities.

June 10, 1993 – Public Law 103-43, NIH Revitalization Act of 1993, provided the statutory authority to redesignate DRR as NCRR; and authority to fund construction of biomedical and behavioral research facilities, with a special provision for centers of excellence and regional centers for research utilizing nonhuman primates. It also authorized the Institutional Development Award Program, which supports programs in states that historically have been unsuccessful in competing for NIH grants.

November 13, 2000 – The Clinical Research Enhancement Act of 2000, which is Title II of the Public Health Improvement Act [Minibus] (P.L. 106-505), provides the NCRR Director with statutory authority to award grants for the establishment of general clinical research centers. The bill also requires the NIH Director to establish a loan repayment program to encourage recruitment of new clinical investigators and to award grants that will enhance clinical research career development.

November 13, 2000 – The Twenty-First Century Research Laboratories Act, which is Title III of the Public Health Improvement Act [Minibus] (P.L. 106-505), authorizes \$250 million for FY 2001 to the NCRR Director to make grants or contracts to public and nonprofit private entities to expand, remodel, renovate, or alter existing research facilities or to construct new research facilities, including centers of excellence. It also authorizes such sums as necessary for FY 2002 and FY 2003. In addition, the Act creates, in statute, a specific authorization for NCRR's Shared Instrumentation Grant Program, authorizing \$100 million for FY 2000 and such sums as necessary for subsequent fiscal years.

December 20, 2000 – The Chimpanzee Health Improvement, Maintenance, and Protection Act (P.L. 106-551) requires NIH to enter into a contract with a nonprofit private entity for the purpose of operating a sanctuary system for the long-term care of chimpanzees that are no longer needed in research conducted or supported by the Federal Government. The law provides for standards for permanent retirement of chimpanzees into the system, including prohibiting using sanctuary chimpanzees for research except in specified circumstances.

Biographical Sketch of NCRR Acting Director Barbara M. Alving, M.D.

Dr. Barbara M. Alving is the Acting Director of the National Center for Research Resources (NCRR) at the National Institutes of Health. She earned her medical degree — cum laude — from Georgetown University School of Medicine, where she also completed an internship in internal medicine. She received her residency training in internal medicine at the Johns Hopkins University Hospital, followed by a fellowship in hematology.

Dr. Alving then became a research investigator in the Division of Blood and Blood Products at the Food and Drug Administration. In 1980, she joined the Department of Hematology at the Walter Reed Army Institute of Research and became Chief of the Department in 1992. She left the Army at the rank of Colonel in 1996 to become the Director of the Medical Oncology/Hematology section at Washington Hospital Center in Washington, D.C.

In 1999, she joined the National Heart, Lung, and Blood Institute (NHLBI), serving as the Director of the extramural Division of Blood Diseases and Resources until becoming the Deputy Director of the Institute in September 2001. In October 2002, she assumed directorship of the Women's Health Initiative. From September 2003 until February 1, 2005, she served as the Acting Director of NHLBI. In April 2005, she became the Acting Director of NCRR.

Dr. Alving is a Professor of Medicine at the Uniformed Services University of the Health Sciences in Bethesda, a Master in the American College of Physicians, a former member of the subcommittee on Hematology of the American Board of Internal Medicine, and a previous member of the FDA Blood Products Advisory Committee. She is a co-inventor on two patents, has edited three books, and has published more than 100 papers in the areas of thrombosis and hemostasis.

NCRR Directors

Name	In Office From	To
Barbara M. Alving (Acting)	April 2005	Present
Judith L. Vaitukaitis	September 1992	March 2005
Robert A. Whitney, Jr	November 1988	August 1992

DRR* Directors (*NCRR's predecessor organization)

Name	In Office From	To
Betty H. Pickett	October 1982	October 1988
James F. O'Donnell (Acting)	January 1981	September 1982
Thomas G. Bowery	November 1969	December 1981
Thomas J. Kennedy	July 1965	November 1969
Frederick L. Stone	July 1962	June 1965

Major Extramural Programs

Division for Biomedical Technology Research and Research Resources

Biomedical Technology (BT) Resource Centers

A network of more than 50 BT resource centers, located across the country primarily at major academic institutions, makes the newest and most advanced technologies and techniques accessible to the biomedical research community. These centers function as both technological and intellectual resources, with an infrastructure that permits staff scientists to react rapidly and effectively to emerging biomedical research needs. Principal investigators at these centers lead scientific teams to discover, create, develop, and disseminate technological innovations that have broad applications to studies of biology, medicine, behavior, and health. The multidisciplinary environment of each center stimulates innovation and collaborations among physical scientists, engineers, and biomedical scientists.

Biomedical Informatics Research Network (BIRN)

BIRN is an NCRR-supported initiative that will test a new method of doing large-scale medical science. The goal of the BIRN is to establish a readily available infrastructure to support collaborative research among biomedical and clinical investigators, including the wide sharing of software tools, distributed computation, and data. The BIRN program is a cooperative effort between information and computer scientists, as well as biomedical and clinical scientists. The

program consists of components focused on multi-site structural MRI; multi-site functional MRI; multi-site integrated imaging of the mouse from whole animal to the sub-cellular level; and a technology development core. The purpose of the components is to drive development of an open robust infrastructure, demonstrate that the infrastructure does indeed enhance research (including clinical research), and ensure that the infrastructure is transportable to other areas of science.

Shared Instrumentation Grant (SIG)

The SIG Program provides funding – using the S10 funding mechanism – to institutions to purchase commercially available, expensive, technologically sophisticated equipment for use by groups of NIH-supported researchers. Shared use of these high-sensitivity and high-resolution instruments, essential to understanding fundamental biological processes, optimizes this Federal investment. The SIG mechanism provides between \$100,000 and \$500,000 for the purchase of such instruments. To obtain instruments that cost more than \$500,000, applicant institutions may be eligible for joint funding arranged by agreement between NIH and the National Science Foundation.

High-End Instrumentation (HEI)

Rapid technological development has led to the production of a new generation of advanced instruments. As the capabilities of these high-sensitivity, high-resolution instruments increases, so does their cost. To meet the investigators needs for this advanced technology, in FY 2002, NCRR began the High-End Instrumentation (HEI) Program, which allows institutions to acquire equipment that costs more than \$750,000. The maximum award is \$2.0 million. The HEI grant program complements the Shared Instrumentation Grant Program and also uses the S10 funding mechanism.

Division for Clinical Research Resources

Clinical and Translational Science Awards

Drawing from experience of the NIH Roadmap and extensive community input, the National Institutes of Health is launching a new program designed to transform clinical and translational research, so that new treatments can be developed more efficiently and delivered more quickly to patients. The Clinical and Translational Science Awards (CTSAs) program, which NCRR is leading on behalf of the NIH Roadmap, will create a definable academic home for the discipline of clinical and translational science. Specifically, this program will encourage the development of novel methods and approaches to clinical and translational research, enhance informatics and technology resources, and improve training and mentoring to ensure that new investigators can navigate the increasingly complex research system. To create this "home," the program allows for local flexibility so that each institution can determine whether to establish a center, department, or institute in clinical and translational science.

General Clinical Research Centers (GCRCs)

Currently, a network of 78 GCRCs, located primarily at U.S. academic medical centers across the country, offers NIH-supported investigators and other researchers specialized environments to safely and effectively conduct controlled inpatient and outpatient studies. Each GCRC offers a range of resources. A center is typically a discrete unit located within a medical center hospital. GCRC staff includes research nurses, dietitians, biostatisticians, technicians, and administrative personnel who are highly trained to provide a supportive environment for patients and to help investigators by facilitating the day-to-day research process. In most instances, a GCRC will have a core laboratory, metabolic and dietary resources, and a computerized database management and analysis system. The GCRC network will gradually be transformed under the new CTSA program, described above.

National Gene Vector Laboratories (NGVLs)

NIH established the NGVLs in 1995 to produce certain vectors needed by researchers to

systematically advance the use of human genes from the realm of basic research into clinical studies of research patients. The NGVL network is currently composed of four facilities. In 2000, vector production was consolidated into processes overseen by the NGVL Steering Committee and implemented by the NGVL Coordinating Center at Indiana University. Currently, the NGVLs provide lentiviral and retroviral vectors, adenoviral vectors, and nonviral vectors. In addition, toxicology studies for selected types of vectors are now supported through the NGVL program and a database of toxicology study results is available to appropriate investigators through a generally accessible master file. Investigators submit requests for vectors to Indiana University, which coordinates the application review through the NGVL Steering Committee. Committee members often make suggestions to applicants to help improve the proposals.

Rare Diseases Clinical Research Network

The Rare Diseases Clinical Research Network (RDCRN), an initiative of the Office of Rare Diseases and NCRR — in collaboration with many NIH Institutes, facilitates clinical research of rare diseases through support for 1) collaborative clinical research in rare diseases; 2) training of clinical investigators in rare diseases research; 3) distributed clinical data management that incorporates novel approaches and technologies for data management, data mining, and data sharing across rare diseases, data types, and platforms; and 4) access to information related to rare diseases for basic and clinical researchers, academic and practicing physicians, patients, and the lay public. Each of the ten Rare Diseases Clinical Research Consortia addresses a subset of rare diseases and works closely with relevant patient support organizations, while the Data and Technology Coordinating Center provides innovative approaches to incorporate standards and technologies for data exchange among sites, partners, and resources.

Islet Cell Resource (ICR) Centers

In 2001, NCRR established a network of ten ICR centers to isolate, purify, and characterize human pancreatic islets for subsequent transplantation into patients with type I diabetes. The ICR centers will procure whole pancreata and acquire relevant data about the donors; improve islet isolation and purification techniques; distribute islets for use in approved clinical protocols; and perfect the methods of storage and shipping. In this way, the centers will optimize the viability, function, and availability of islets and help clinical researchers to capitalize on the recently reported successes in islet transplantation. These activities will expand the ability of clinical researchers to bring this experimental therapy into practice.

Human Tissues and Organs Resource

The Human Tissues and Organs Resource (HTOR) Cooperative Agreement supports a procurement network developed by the National Disease Research Interchange (NDRI) – a not-for-profit organization. By collaborating with various medical centers, hospitals, pathology services, eye banks, tissue banks, and organ procurement organizations, HTOR provides a wide variety of human tissues and organs – both diseased and normal – to researchers for laboratory studies. Such samples include tissues from the central nervous system and brain; cardiovascular system; endocrine system; eyes, bone, and cartilage.

Science Education Partnership Award (SEPA)

The SEPA Program encourages scientists to work with educators and other organizations to improve students' (K-12) and the public's understanding of the health sciences. The award supports development of a variety of model programs in biomedical and behavioral science education that make it feasible for scientists, educators, media, and community leaders to partner in order to promote science by increasing science literacy. Past models have included a national video education program, a traveling and fixed museum exhibit about AIDS and other health issues, biotechnology research experiences for students and teachers, and health promoting outreach programs for inner-city and rural communities.

Division of Comparative Medicine

National Primate Research Centers (NPRCs)

Eight NCRR-supported NPRCs are strategically located across the country to provide highly specialized facilities and convenient access to biomedical investigators using nonhuman primates as animal models of human diseases. Together, the NPRCs have more than 26,000 animals — mostly macaques — representing more than 20 species of nonhuman primates. Each NPRC is staffed by a core of scientific experts in nonhuman primate research and by technical-support professionals. The multidisciplinary nature of each NPRC stimulates innovative collaborations on studies of major human diseases. Each year approximately 1,400 investigators, supported by their individual grant funding, collaborate with NPRC core scientists and use NPRC resources. The NPRCs also sponsor a Visiting Scientist Program. NPRC areas of research emphasis include reproductive biology, infectious diseases, neurosciences, biobehavioral research, metabolic, nutritional and cardiovascular diseases, and environmental health and toxicology. Based on the availability of facilities and other resources, the centers maintain extensive collaborative programs for scientists from many institutions.

Laboratory Animal Sciences (LAS)

LAS Program activities support research animal resources and scientific training in the field of comparative medicine. Of particular interest is development of new and improved animal models of human disease. LAS-supported resources include mutant mice, other transgenics, and rat models. To assist institutions in their efforts to meet animal care guidelines established by the Public Health Service and the requirements of the Animal Welfare Act, LAS supports projects to enhance the environmental conditions of laboratory animals and improve their health. One LAS goal is to support training that will motivate graduate veterinarians with research skills to develop careers in biomedical and health research.

Animal Models

The Specific-Pathogen-Free (SPF) Rhesus Monkey Breeding and Research Program, established in 1988, eventually phased out and then reestablished in 2002, creates self-sustaining rhesus breeding colonies free from contamination with certain simian retroviruses and herpes B virus. These animals are made available to PHS-supported research projects.

Biological Models and Materials Research (BMMR)

BMMR Program focuses on extramural research activities that explore and develop nonmammalian models, vertebrate and invertebrate, for biomedical investigations. Support for this research develops and broadens the utility of a variety of models, including cell systems, nonmammalian organisms, and nonbiological systems such as mathematical and computer systems. NCRR also supports resources that supply critical biological materials such as cultures or genetic stocks, and nonbiological materials such as on-line information on model organisms to the biomedical research community. Through these resources, investigators have access to stocks of widely used organisms ranging from yeast, mutant flies, and worms to fish and cephalopods.

NIH Chimpanzee Management Program

The NIH Chimpanzee Management Program (ChiMP) supports long-term, cost-effective housing and maintenance at three NIH-supported facilities for chimpanzees, funded by NCRR through cooperative agreements. In addition, a reserve colony of chimpanzees previously used in virological research is supported by a contract. Furthermore, cooperative agreements and grants also support a database and applied research that optimize the use of chimpanzees in research.

Division of Research Infrastructure

Research Centers in Minority Institutions (RCMI)

Begun in 1985, the RCMI Program is a congressionally mandated initiative. Through grant support, NCCR assists predominately minority academic institutions that award doctoral degrees in the health or health-related sciences to conduct biomedical and behavioral research in order to become more competitive in obtaining NIH research funding. NCCR support helps institutions attract additional research faculty in health-science disciplines, provides necessary training in specialized analytical methods, upgrades facilities, purchases advanced scientific equipment, and, through its faculty, addresses research questions that are relevant to the health needs of all Americans, especially ethnic and racial minorities.

Institutional Development Award (IDeA)

The IDeA Program was initiated by Congress to broaden the geographical distribution of NIH grant funding for biomedical and behavioral research. The Program makes merit-based, peer-reviewed awards to support various research activities that stimulate sustainable improvement in the biomedical research capacities of research institutions located in states with historically low success rates for obtaining NIH funding. Overall, IDeA funding enhances an institution's competitiveness and increases the probability of long-term growth of its investigators. The IDeA Program is carried out through two approaches: Centers of Biomedical Research Excellence (COBRE) and IDeA Networks of Biomedical Research Excellence (INBRE). A grant for a COBRE enables a doctoral degree-granting institution to build a thematically-focused, multidisciplinary research center led by an established investigator, which provides research support and mentoring for three to five junior investigators as part of a long-term plan for developing and sustaining the Center, research program, investigators, collaborations, and physical infrastructure. INBRE is the second generation of the Biomedical Research Infrastructure Networks (BRIN) Program, which began in 2001 by providing grants for planning and implementing state-wide networks. The INBRE grants, first awarded in 2004, develop the BRINs into statewide multi-disciplinary research networks of doctoral degree-granting and undergraduate institutions to help build a competitive research base within an IDeA-eligible state by bringing together research institutions within a state; funding institutional renovations and the purchase of modern laboratory equipment; and recruiting new research faculty.

Research and Animal Facilities Improvements (RFI and AFI)

RFI grants fund construction that expands, remodels, renovates, or alters existing extramural facilities that are used for biomedical and behavioral research and research training. Through the AFI Program, NCCR provides institutional funding to improve animal research facilities, including facility upgrades and the development of programs and policies related to laboratory animal care and use.

NCCR Information Dissemination

NCCR produces three online directories that list NCCR-supported biomedical technology, clinical research, and comparative medicine resource centers that can be accessed by biomedical investigators who have their project funding from other sources. Each directory listing provides a point of contact at the center, the center's research emphasis, and the center's resource capabilities available to outside investigators. Biomedical investigators interested in learning more about NCCR-supported resource centers may access these directories from the NCCR Web site: www.ncrr.nih.gov.

The *NCCR Reporter* is a quarterly publication of the National Center for Research Resources. Its purpose is to foster communication, collaboration, and resource sharing in areas of current interest to scientists and others in the biomedical field. Subscriptions to the *NCCR Reporter* are available free of charge by contacting the NCCR Information Officer at info@ncrr.nih.gov.

This page was last reviewed on January 30, 2006 .

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National Institutes of Health (NIH)
9000 Rockville Pike
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NIH Clinical Center

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Mission

The NIH Clinical Center (CC) is the clinical research hospital for the National Institutes of Health. Through clinical research, physician-investigators translate laboratory discoveries into better treatments, therapies and interventions to improve the nation's health.

Clinical and laboratory research is conducted shoulder-to-shoulder at the CC and this tandem approach drives all aspects of its operations. The first patients were admitted in 1953. More than one-quarter million patients from across the nation have participated in clinical research studies here. In 2005 their care accounted for about 7,000 inpatient admissions and more than 100,000 outpatient visits.

Late in 1997, Vice President Al Gore and Senator Mark O. Hatfield broke ground for the new Mark O. Hatfield Clinical Research Center. The center, completed in 2004, houses 240 inpatient beds, 90 day-hospital stations and research labs. Together, the Magnuson and Hatfield centers provide the environment today's researchers need to spark new medical discovery.

Important Events in CC History

November 1948 – Construction of the Clinical Center was started.

June 22, 1951 – The cornerstone ceremony was officiated by Oscar R. Ewing, Federal security administrator. President Harry S. Truman was the honored guest.

July 2, 1953 – The CC was dedicated by DHEW Secretary Oveta Culp Hobby.

July 6, 1953 – The first patient was admitted to the Clinical Center.

1954 – The Clinical Center's diagnostic x-ray department acquires the only Schonander angiocardiographic unit in the U.S. It takes films in two planes at the rate of six films per second, permitting a graphic demonstration of contrast substances as they pass through the heart, making diagnosis faster and more accurate.

1957 – The Clinical Pathology Department starts an approved residency training program, admitting its first two residents. Develops the first automated machine for counting red and white blood cells (until then counted manually), from which later comes the Coulter counter.

1957 – The Blood Bank publishes its first research paper, delineating the post-transfusion hepatitis problem, firing the first salvo in a long but largely successful campaign.

1959 – A new, circular surgical wing (10A) begins construction, adding 45,000 square feet.

September 5, 1963 – A new surgical wing for cardiac and neurosurgery was dedicated by Dr. Luther L. Terry, Surgeon General. The two cardiac operating rooms are unique in being dedicated to cardiac surgery, with special systems for monitoring, lighting, communications, and storage and retrieval of large amounts of research data. Open-heart surgery can be viewed through an observation room directly above, on the third floor. Disposable surgical gloves are also introduced.

1963 – The Blood Bank moves to a new circular building (the "fish bowl"); blood collections begin on the NIH campus.

1964 – Harvey Alter (Clinical Center) and Baruch Blumberg (NIDDK) codiscover the Australian antigen, which Blumberg later shows to be the surface coating of the hepatitis B virus, leading to the isolation of this medically important virus. Blumberg later wins Nobel Prize. Alter does pioneering work in the causes and prevention of blood-transmitted infections, which helps lead to the discovery of the virus that causes hepatitis C and the development of screening methods that will reduce the risk of transfusion-transmitted hepatitis.

1964 – John L. Doppman and associates in diagnostic radiology report the first successful imaging of the arteries that supply the spinal cord. The technique of spinal angiography makes surgical intervention possible where spinal arterial malformations, lesions, or tumors cause paralysis.

1965 – Clinical Pathology (CPD) acquires a Control Data 3200 computer, which fills a room the size of a small living room. Some instruments are placed online; other data are entered on key-punched cards. CPD begins using computers to manipulate lab data and report test results.

1966 – A Department of Nuclear Medicine is established in the Clinical Center, headed by Jack Davidson, to centralize imaging facilities for patients in any institute. Radiation Safety, Diagnostics, and the Whole Body Counter Division become part of Nuclear Medicine and the old Radiation Safety Division is abolished. President Lyndon B. Johnson visits the new department.

1966 – Wanda S. Chappell, chief nurse in the Blood Bank, comes up with a simple but ingenious method for separating blood platelets (the smallest blood cells) from blood plasma, so that the platelets can be used for transfusion to leukemia patients and the rest of the blood can be used by others, including patients undergoing open heart surgery.

1966 – Additions to the Clinical Center (a library, cafeteria) are begun.

1968 – Diagnostic radiologist John L. Doppman develops a method for locating the parathyroid, a group of glands (each about the size of a BB pellet) that regulates calcium metabolism.

1968 – The first cancer patient enters the laminar flow room on 13 East

July 2, 1969 – A dedication ceremony was held to name the Clinical Center's Jack Masur Auditorium.

1970 – The Blood Bank switches to an all-volunteer donor system, adding a test for hepatitis B surface antigen. Those two measures alone reduce the hepatitis rate from 30 percent before 1970 to about 11 percent after. Later, when it adds more sensitive tests for hepatitis B, hepatitis B virtually disappears as a problem in the Blood Bank.

1972 – Clinical Pathology's Richard B. Friedman develops a computer program to teach students to diagnose illnesses by having the computer report symptoms, inform on test availability and cost, test results, and reactions to treatment.

1972 – Blood Bank scientists develop a test for AU antigen-agent associated with hepatitis. The test

will be used nationally.

1974 – The Clinical Center Blood Bank develops a nationally recognized program in automated blood collection (apheresis), tissue typing (HLA), and an international reputation for research studies of red cell serology and hepatitis.

1976 – The new medical information system (MIS) goes live, one nursing unit at a time.

April 1977 – Construction of the ambulatory care research facility was started.

September 1977 – *Medicine for the Layman*, a series of health seminars for the public, is launched

November 1977 – The Critical Care Medicine Department was established.

1977 – The Blood Bank establishes therapeutic apheresis/exchange programs that for decades will improve the lifespan and welfare of patients with such illnesses as sickle cell disease, hyperlipidemia, and autoimmune disorders. It also establishes the first automated platelet-pheresis center, collecting platelets for transfusion from volunteer donors using automated instrumentation.

October 22, 1981 – The outpatient clinic facility was dedicated. The research hospital was renamed the Warren Grant Magnuson Clinical Center, in honor of the former chairman of the Senate Committee on Appropriations, who has actively supported biomedical research at NIH since 1937. (P.L. 96-518.)

1981 – As part of the design for the new ACRF, Clinical Pathology services (previously scattered) are brought under one roof—working together in one vast open room, except for specialized functions sequestered for safety purposes (such as the containment of radionuclides).

1982 – A new surgical facility opens on the second floor of the ACRF, with more space for equipment, larger operating suites, two viewing galleries, and better delivery systems.. Surgical Services performs more than 2,000 cancer, eye, and general surgical procedures a year. A surgical intensive care unit (2J) opens in conjunction with new surgical suites. Nurses in the new nursing unit face new challenges in caring for patients in septic shock and providing such therapies as continuous veno-venous hemofiltration (CVVH), hemodynamic monitoring, and ventilator support.

September 20, 1982 – The NIA Laboratory of Neurosciences was dedicated.

1983 – Clinical Pathology creates an immunology service, reflecting growing demand for sophisticated antibody and cellular-level diagnostic services.

March 22, 1984 – The first magnetic resonance imaging unit became operational for patient imaging.

October 1984 – NCI's Radiation Oncology Building was dedicated.

1984 – Clinical Center Blood Bank is renamed the Department of Transfusion Medicine (DTM) because its activities extend well beyond traditional blood banking. DTM achieves the first transmission of HIV (HTLV III) to a primate through transfusion and describes the HIV seronegative window.

April 13, 1985 – Two cyclotrons were delivered to the underground facility operated by the Nuclear Medicine Department.

1986 – As a charter member of the National Marrow Donor Program (NMDP), on December 2 the Clinical Center signs an agreement to become one of the first donor centers participating in the

NMDP

November 20, 1987 – The Lipsett Amphitheater in the clinic was dedicated.

September 14, 1990 – A 4-year-old patient with adenosine deaminase deficiency was the first to receive gene therapy treatment.

April 8, 1991 – The Department of Transfusion Medicine opened its state of the art facility.

1991 – A thrombosis unit is established in Clinical Pathology's hematology service to help manage patients with coagulopathies. A virology section is redeveloped within Clinical Pathology's microbiology service. The original viral diagnostic unit had long since lapsed, for lack of clinical utility, but with the development of new diagnostic methodologies and new therapies, the need for such a service has become increasingly apparent.

June 1992 – The A-wing addition was completed, adding NCI and NIAID labs focusing on AIDS research.

July 1993 – The hematology/bone marrow unit opened to improve transplant procedures and develop gene therapy techniques.

May 1994 – First multi-institute unit designed and staffed for children opened.

1995 – Diagnostic Radiology installs a 20,000-pound magnetic resonance scanner in the courtyard outside Transfusion Medicine.

February 1996 – Details on clinical research studies conducted at the Clinical Center are made available on the World Wide Web (<http://clinicalstudies.info.nih.gov/>), increasing opportunities for physicians to participate in NIH clinical investigations.

November 1996 – A Board of Governors was appointed by the Secretary of HHS, marking a new governing system for the Clinical Center.

July 1997 – Transfusion Medicine Department launches a 3,000-square foot model core [cGMP] cell processing facility, created to meet increasing investigative needs for cell products used in research into new cellular therapies such as immunotherapy, gene therapy, stem cell transplantation, and pancreatic islet cell transplantation.

July 1997 – To meet increasing investigative needs for cell products used in immunotherapy, gene therapy, and stem cell transplantation, a cell processing facility was created.

November 4, 1997 – Vice President Al Gore and Senator Mark O. Hatfield attended groundbreaking ceremonies for the Mark O. Hatfield Clinical Research Center. The new center, which will include a modern research facility with a 250-bed hospital, outpatient care capability and research laboratories, is scheduled to be completed in 2004.

1999 – Clinical Pathology Department is renamed Department of Laboratory Medicine. A new laboratory information system is put in place for Laboratory Medicine, Transfusion Medicine, and the Pathology Lab.

2000 – The NIDDK and the Clinical Center (in collaboration with Walter Reed Army Medical Center, the Naval Medical Research Center, and the Diabetes Research Institute of the University of Miami) launch a new kidney, pancreas, and islet transplant program. The idea is to test novel therapies that may eliminate the need for the immunosuppressive drugs patients take to keep their bodies from rejecting new transplanted organs. Soon after the program starts, Allan Kirk performs the NIH's first

successful kidney transplant procedure and David Harlan performs one of the first successful islet allotransplants in the United States.

2000 – Clinical Center launches a new Pain and Palliative Care Consult Service.

2000 – Harvey Alter, Department of Transfusion Medicine, receives the Lasker Award “for pioneering work leading to the discovery of the virus that causes hepatitis C and the development of screening methods that reduced risk associated with transfusion-associated hepatitis in the United States from 30 percent in 1970 to virtually zero in 2000.” Alter, who is also elected to the National Academy of Sciences, shares the award with Chiron’s Michael Houghton.

2000 – The Imaging Sciences Program takes first steps toward filmless radiology, unveiling the pilot phase of its new Picture Archiving and Communication System (PACS) and Radiology Information System (RIS). RIS is a sophisticated patient tracking system, which will track patient arrival and departure times, the start and end of exams, and when reports are dictated, read, and signed. It is expected to reduce patient waiting times, improve image availability, and minimize loss and misidentification of images and reports. Images stored in PACS/RIS originate from procedures and exams conducted in the Diagnostic Radiology, Nuclear Medicine, and PET Departments. They include CT scans, MR scans, PET scans, nuclear medicine scans, ultrasound examinations, and digital radiography examinations.

2001 – A second bone marrow transplant unit opens to support NCI protocols.

2002 – DTM establishes a model program for collecting blood from subjects with hereditary *hemochromatosis*. This program supplies 10% of the hospital's red cell needs.

October 29, 2002 – Groundbreaking ceremony was held for the Edmond J. Safra Family Lodge at NIH. Located steps away from the Mark O. Hatfield Clinical Research Center, the lodge will provide a comfortable home away from home for the families and caretakers of Clinical Center patients.

2004 – As recommended by the NIH Director's Blue Ribbon Panel on the Future of Intramural Clinical Research, the former Clinical Center Board of Governors assumed a new and larger identity, becoming the NIH Advisory Board for Clinical Research. The Board will oversee all intramural clinical research, while continuing its oversight of Clinical Center resources, planning and operations.

August 21, 2004 – The new \$32-million Clinical Research Information System goes live.

September 22, 2004 – Dedication ceremony held for the Mark O. Hatfield Clinical Research Center. In attendance are former Sen. Mark O. Hatfield, DHHS Secretary Tommy G. Thompson, Sen. Paul Sarbanes, (D. MD) Sen. Paul Harkin, (D. Io) and Rep. C.W. Bill Young (R. Fla), Chairman of the House Appropriations Committee.

April 2, 2005 – Patients are moved into the Mark O. Hatfield Clinical Research Center and the building becomes fully operational.

May 26, 2005 – An opening ceremony is held for the Edmond J. Safra Family Lodge, offering a temporary residence for families and loved ones of adult patients receiving care at the NIH Clinical Center. The Lodge opens its doors to guests on June 1.

CC Legislative Chronology

July 1, 1944 – Public Law 78-410, the Public Health Service Act, authorized establishment of the Clinical Center.

July 8, 1947 – Under P.L. 80-165, research construction provisions of the Appropriations Act for FY

1948 provided funds "For the acquisition of a site, and the preparation of plans, specifications, and drawings, for additional research buildings and a 600-bed clinical research hospital and necessary accessory buildings related thereto to be used in general medical research...."

Biographical Sketch of CC Director John I. Gallin, M.D.

Dr. Gallin was appointed director of the NIH Clinical Center in 1994. During his tenure, a new research hospital for the Clinical Center, the Mark O. Hatfield Clinical Research Center, has been conceived, designed, constructed and made ready to occupy. The NIH Clinical Center serves the clinical research needs of 17 of NIH's institutes and centers and is the largest clinical research hospital in the world. While serving as Clinical Center director, Dr. Gallin has remained an active clinician and researcher. His primary research interest is rare hereditary immune disorders of the phagocytic cells, cells critical to inflammation. One of these disorders, chronic granulomatous disease (CGD), has been a focus of his attention and his laboratory has described the genetic basis for several forms of CGD and has done pioneering research that has reduced life-threatening bacterial and fungal infections in CGD patients. He has published more than 290 articles in scientific journals and has edited the leading textbooks on inflammation and clinical research.

Dr. Gallin graduated cum laude from Amherst College and earned his medical degree at Cornell University Medical College. After a medical internship and residency at New York University's Bellevue Hospital Medical Center, he received postdoctoral training in basic and clinical research in infectious diseases at the NIH from 1971-1974. He then served at Bellevue as senior chief medical resident for two years before returning to the NIH. In 1985, Dr. Gallin began a nine-year period as scientific director of intramural activities at the National Institute of Allergy and Infectious Diseases (NIAID); he also was chief of NIAID's Laboratory of Host Defenses from 1991 to 2003, and he continues as chief of the lab's clinical pathology section. Among Dr. Gallin's many awards and honors, the U.S. Public Health Service named him Physician Executive of the Year in 2001. In 2002, the Society for Leukocyte Biology gave him its Bonazinga Award for lifetime achievement in research. He holds memberships in the American Society for Clinical Investigation, the Association of American Physicians, and the Institute of Medicine of the National Academy of Sciences.

Clinical Center Directors

Name	In Office From	To
Jack Masur	1948 1951	1956 1969
John A. Trautman	1951	1954
Donald W. Patrick	1954	1956
Thomas C. Chalmers	1970	1973
Robert S. Gordon, Jr.	1974	1975
Mortimer B. Lipsett	1976	1982
John L. Decker	1983	1990
Saul Rosen (Acting)	1990	1994
John I. Gallin	May 1, 1994	present

Major Programs

Clinical Research. Clinical Center departments conducting and supporting clinical research are: Anesthesia and Surgical Services; Clinical Pathology; Critical Care; Hospital Epidemiology; Imaging Sciences (comprising Diagnostic Radiology, the Laboratory of Diagnostic Radiology Research, Nuclear Medicine, and Positron Emissions Tomography Departments); Nursing; Pharmacy; Rehabilitation Medicine; and Transfusion Medicine.

Patient Care and Support. Departments that provide direct care and support for patients include

Housekeeping and Fabric Care; Information Systems; Materials Management; Medical Record; Nutrition; Outpatient; Social Work; and Spiritual Ministry, along with the Patient Representative Program. The Clinical Center operates a guest house for families involved with clinical research here.

Office of the Director. Programs within this office support the management and operational needs of the CC, including administrative management and planning; patient recruitment and public liaison; communications; the children's school; clinical bioethics; hospital safety; facilities management; financial management; human resources; and technology transfer.

Education. The Clinical Center has assumed a broad role in helping prepare the next generation of clinical researchers and strengthen educational opportunities for today's physician-scientists. New programs include "Introduction to the Principles and Practice of Clinical Research"; postdoctoral training in clinical pharmacology; a clinical bioethics fellowship; training in biomedical imaging research; and a collaboration with the School of Medicine at Duke University that leads to graduate degree.

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Amounts in thousands of dollars

FY	GRS-NIH	NCI	NIMH	NHLBI	NIDCR	NIDDK	NIAID	NINDS	HRF	DBS	NICHD	NIGMS ¹³	RMP	NIA ¹⁹	NIEHS
1938	64	400													
1939	64	400													
1940	137	570													
1941	141	570													
1942	135	565													
1943	743	535													
1944	2,025	530													
1945	2,274	561													
1946	2,866	549													
1947	6,255	1,821													
1948	10,126	14,500	4,250												
1949	11,333	14,000	5,821	2,835	1,733										
1950	11,705	18,900	9,234	10,725	1,780										
1951	14,006	20,086	6,970	14,200	1,955										
1952	5,400	19,657	9,813	10,083	1,618	4,064	5,501	1,562							
1953	4,989	17,887	10,474	12,000	1,650	4,335	5,534	1,814							
1954	4,669	20,237	11,741	15,168	1,740	7,000	5,738	4,500							
1955	5,124	21,737	14,030	16,668	1,990	8,270	6,180	7,601							
1956	6,769	24,978	18,052	18,898	2,176	10,840	7,775	9,861							
1957	12,612	48,432	30,006	33,396	6,026	15,885	13,299	18,650							
1958	17,041	56,402	38,457	35,936	6,430	20,385	17,400	21,387							
1959	28,957	75,268	49,853	45,613	7,420	31,215	24,071	29,403							
1960	40,367	91,257	67,470	62,237	10,019	46,862	34,054	41,487							
1961	75,957	111,000	91,923	86,900	15,500	61,200	44,000	56,600							
1962	121,103	142,836	107,711	132,912	17,340	81,831	56,091	70,812	3,036						
1963	136,003	155,742	139,517	147,398	21,119	103,388	66,142	83,506	3,523						

1964	45,737	144,340	170,990	132,404	19,689	113,679	68,723	87,675	4,273	34,000 ¹	104,460				
1965	49,998	150,011	186,068 ²	124,824	20,083	113,051	69,847	87,821	4,423	42,696	113,718				
1966³	58,561	163,768	226,588	141,462 ²	23,677	123,203	77,987	101,153	5,256	55,024	127,188	2,553			
1967	67,623	175,656	(2)	164,770	28,308	135,687	90,670	116,296	40,419	7,784	64,922	145,113	29,256	24,298	
1968	76,640	183,356	(4)	167,954	30,307	143,954	94,422	128,633	38,369	7,699	68,621	160,284		17,289	
1969	82,920	185,150		166,928	29,984	143,888	96,841	128,935		8,030	73,127	163,514		17,820	
1970⁶	4,360	181,454		160,634	28,754	131,761	97,342	97,315	(7)	8,235	76,095	148,294		17,423	
1971⁶	(8)	233,160		194,925	35,440	137,986	102,368	103,502		9,277	94,760	160,194		20,151	
1972⁶		378,794 ⁹		232,627	43,388	153,337	109,117	116,732		9,280	116,427	173,474		26,436	
1973¹⁴		492,205		300,000	46,991	167,316	113,414	130,672		(10)	130,429	183,171		30,956	
1974¹⁶		527,486		289,550	43,959	153,561	111,089	121,358			125,455	168,329		28,397	
1975		691,666		324,630	50,033	173,514	119,452	142,498			142,435	187,400		35,171	
1976		761,727		370,013	51,291	179,516	126,852	144,446			136,404	187,312	19,288	36,660	
1976TQ		152,901		58,763	7,854	43,719	27,638	34,272			24,201	34,078	8,743	9,519	
1977		815,000		396,661	55,573	219,600	141,000	155,500			145,543	205,000	30,000	51,141	
1978		872,388		447,909	61,728	260,253	162,341	178,438			166,390	230,796	37,305	64,241	
1979		937,129		510,527	65,213	302,767	191,328	212,365			197,630	277,628	56,911	78,080	
1980²⁰		999,869		527,488	68,303	341,206	215,364	241,966			208,953	312,468	(5)	69,988	83,893
1981		989,355		549,693	71,114	368,191	232,077	252,533			220,628	333,764	75,608	93,491	
1982		986,617		559,637	71,983	368,188	232,895	265,901			226,309	339,862	81,903	106,270	
1983		987,642		624,259	79,292	413,492	279,129	297,064			254,324	369,813	93,996	164,867	
1984		1,081,581		704,939	8,8674	464,026	319,596	335,883			276,046	415,937	115,292	180,597	
1985		1,183,806		805,269	100,688	543,576	370,965	396,885			313,295	482,260	144,521	194,819	
1986		1,203,369		822,292	98,841	544,858	366,964	414,727			307,958	492,630	149,762	188,986	
1987		1,402,837		930,001	117,945	511,124	545,523	490,233			366,780	570,916	177,681	209,294	
1988		1,469,327		965,536	126,297	534,733	638,800	534,692			396,811	632,676	194,746	215,666	
1989		1,570,349		1,045,509	130,709	559,494	740,257	472,292			425,375	682,213	222,639	223,403	
1990		1,634,332		1,072,354	135,749	581,477	832,977	490,409			442,914	681,782	239,455	229,234	
1991		1,714,784		1,126,942	148,918	615,272	906,251	541,743			478,956	760,010	323,752	241,028	
1992²⁵		1,962,587	560,285	1,188,593	158,417	658,925	959,082	577,938			518,251	816,844	383,382	248,575	
1993		1,981,351	583,651 ²⁶	1,214,793	161,301	681,342	979,471	600,078			527,788	832,581	399,924	251,187	
1994		2,082,267	613,444	1,277,880	169,520	716,054	1,065,593	630,650			555,195	875,511	420,303	264,249	
1995		1,913,819	542,200	1,257,374	162,430	726,949	535,199	627,045			512,165	876,778	431,991	266,566	
1996		2,254,940	660,549	1,354,946	182,923	770,582	1,168,483	680,902			594,547	946,896	453,541	288,378	

1997	2,381,149	701,107	1,432,529	195,825	815,607	1,256,659	726,407	631,365	998,387	485,806	308,487
1998²⁸	2,547,314	750,241	1,531,061	209,415	900,860	1,351,655	780,713	674,766	1,065,947	519,279	330,108
1999	2,925,247	860,638	1,792,509	234,183	1,020,559	1,569,063	902,680	750,485	1,197,026	596,126	375,494
2000	3,314,554	973,146	2,029,424	268,811	1,168,476	1,778,038	1,029,376	858,291	1,354,420	686,479	442,449
2001³⁰	3,754,456	1,106,305	2,298,512	306,211	1,399,684	2,041,698	1,175,854	975,766	1,535,378	785,590	564,810
2002	4,188,233	1,246,640	2,572,667	342,664	1,562,144	2,342,313	1,326,666	1,111,674	1,724,799	892,267	645,422
2003	4,592,348	1,341,014	2,793,733	371,636	1,722,730	3,606,789	1,456,476	1,205,927	1,847,000	993,598	697,767
2004	4,739,255	1,381,774	2,878,691	383,282	1,821,803	4,155,447	1,501,207	1,242,361	1,904,838	1,024,754	710,701

¹ Derived by transfers from other NIH appropriations as authorized by Congress.

² Includes funds for construction of community mental health centers (1965 = \$35,000,000; 1966 = \$50,000,000).

³ Includes supplemental.

⁴ Transferred to HSMHA, July 1, 1967.

⁵ Transferred to HSMHA, July 1, 1968.

⁶ Includes supplemental.

⁷ Discontinued as an appropriation July 1, 1969.

⁸ GR & S discontinued. Research Resources appropriation established. DCTR portion transferred to Management. Renamed National Center for Research Resources in 1990.

⁹ Includes Cancer Conquest Program of \$100,000,000.

¹⁰ Transferred to FDA July 1, 1972.

¹¹ Formerly a part of the Neurology Institute.

¹² Formerly a part of the Management Fund.

¹³ Formerly a part of GR & S.

¹⁴ No appropriation bill signed in 1973. Figures are based on the continuing resolution.

¹⁵ Totals exclude special foreign currency program.

¹⁶ Reserve legislated by P.L. 93-192 not reflected.

¹⁷ Transferred to Health Resources Administration, July 1, 1973.

¹⁸ GRSG transferred from IRD's to RR.

¹⁹ Formerly a part of NICHD.

²⁰ No enacted appropriation authorized under continuing resolution.

²¹ Formerly a part of NIDDK.

²² Transferred from Health Resources and Services Administration.

²³ Formerly part of NINDS.

²⁴ Prior to establishment of NCHGR in FY 1990, funds for this effort were appropriated to NIGMS. The Office of Human Genome Research provided overall planning and coordination with other agencies.

²⁵ Comparable for ADAMHA (NIMH, NIDA, and NIAAA).

²⁶ Formerly part of ADAMHA (NIMH, NIDA, and NIAAA).

²⁷ Became an institute in 1996.

²⁸ Beginning in FY 1998, the appropriation includes funds appropriated to NIDDK for Type 1 diabetes research.

²⁹ Established as a separate appropriation in FY 2000.

³⁰ Beginning in FY 2001, VA/HUD began appropriating Superfund Research funds directly to NIEHS.

³¹ Established as a separate appropriation in FY 2001.

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Amounts in thousands of dollars

FY	NIAMS ²¹	NIDCD ²³	FIC	BHME	NLM	NEI ¹¹	OD ¹²	NCRR ⁸	NCCAM ²⁹	NINR ²²	NHGRI ^{24, 27}	CONST (B&F)	NIDA ²⁶	NIAAA ²⁶	NCMHD ³¹	NIBIB	Total ¹⁵
1938								64									464
1939								64									464
1940								137									707
1941								141									711
1942								135									700
1943								743									1,278
1944								2,205									2,555
1945								2,274									2,835
1946								2,866									3,415
1947								6,254									8,075
1948								10,126									24,626
1949								14,540									28,540
1950								12,075									43,480
1951								14,314									50,555
1952								15,757									47,115
1953								16,599									48,136
1954								4,675									59,058
1955								4,675									67,121
1956								5,929									80,457
1957								12,122									147,810
1958								14,026									171,966
1959								28,974									241,964
1960								45,994									331,910
1961								83,900									459,100
1962								127,637									629,459
1963								159,826									737,201
1964								163,869									730,379
1965								164,759									773,091
1966 ³								60,469									873,931
1967								68,534									1,014,254

- 2 Includes funds for construction of community mental health centers (1965 = \$35,000,000; 1966 = \$50,000,000).
- 3 Includes supplemental.
- 4 Transferred to HSMHA, July 1, 1967.
- 5 Transferred to HSMHA, July 1, 1968.
- 6 Includes supplemental.
- 7 Discontinued as an appropriation July 1, 1969.
- 8 GR & S discontinued. Research Resources appropriation established. DCTR portion transferred to Management. Renamed National Center for Research Resources in 1990.
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- 11 Formerly a part of the Neurology Institute.
- 12 Formerly a part of the Management Fund.
- 13 Formerly a part of GR & S.
- 14 No appropriation bill signed in 1973. Figures are based on the continuing resolution.
- 15 Totals exclude special foreign currency program.
- 16 Reserve legislated by P.L. 93-192 not reflected.
- 17 Transferred to Health Resources Administration, July 1, 1973.
- 18 GRSF transferred from IRD's to RR.
- 19 Formerly a part of NICHD.
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- 23 Formerly part of NINDS.
- 24 Prior to establishment of NCHGR in FY 1990, funds for this effort were appropriated to NIGMS. The Office of Human Genome Research provided overall planning and coordination with other agencies.
- 25 Comparable for ADAMHA (NIMH, NIDA, and NIAAA).
- 26 Formerly part of ADAMHA (NIMH, NIDA, and NIAAA).
- 27 Became an institute in 1996.
- 28 Beginning in FY 1998, the appropriation includes funds appropriated to NIDDK for Type 1 diabetes research.
- 29 Established as a separate appropriation in FY 2000.
- 30 Beginning in FY 2001, VA/HUD began appropriating Superfund Research funds directly to NIEHS.
- 31 Established as a separate appropriation in FY 2001.

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Employment

Year	Number of employees	Year	Number of employees	Year	Number of employees	Year	Number of employees
1930	140	1950	2,888	1970	13,243	1990	16,181
1931	150	1951	3,012	1971	14,002	1991	16,947
1932	165	1952	3,277	1972	13,789	1992	17,405
1933	139	1953	3,888	1973	12,931	1993	18,664
1934	160	1954	4,621	1974	13,318	1994	17,210
1935	159	1955	5,412	1975	13,897	1995	16,537
1936	183	1956	6,334	1976	14,495	1996	16,440
1937	695	1957	7,215	1977	14,658	1997	16,551
1938	912	1958	7,145	1978	14,610	1998	16,565
1939	1,048	1959	8,484	1979	14,439	1999	16,993
1940	1,137	1960	9,109	1980	14,634	2000	17,615
1941	1,367	1961	10,175	1981	14,984	2001	18,250
1942	1,456	1962	11,037	1982	14,869	2002	18,923
1943	1,352	1963	11,511	1983	15,449	2003	18,837
1944	1,144	1964	11,822	1984	15,212	2004	18,363
1945	1,090	1965	12,194	1985	14,799	2005	18,056
1946	1,436	1966	12,643	1986	14,479		
1947	1,505	1967	11,730	1987	15,243		
1948	2,245	1968	13,105	1988	15,486		
1949	2,937	1969	13,350	1989	15,206		

Source: Division of Personnel Management, NIH.

Full-Time Civil Service Employees by GS, ST, SES², and Wage Grade

Year	GS	ST	SES	Wage Grade
1948	1,397	---	---	---
1949	1,760	---	---	---

1950	1,603	1	---	7
1951	1,712	4	---	8
1952	1,848	7	---	9
1953	2,248	8	---	9
1954	2,735	13	---	9
1955	3,513	19	---	890
1956	4,164	30	---	995
1957	4,682	44	---	1,080
1958	4,989	45	---	1,147
1959	5,324	53	---	1,184
1960	5,570	58	---	1,445
1961	6,226	82	---	1,597
1962	6,976	90	---	1,736
1963	7,294	96	---	1,780
1964	7,690	92	---	1,764
1965 ³	7,979	95	---	1,777
1966 ⁴	8,037	92	---	1,828
1967	7,315	79	---	1,847
1968	8,365	81	---	1,864
1969 ⁴	8,081	80	---	1,781
1970	8,063	86	---	1,665
1971	8,474	90	---	1,935
1972 ⁴	8,376	89	---	1,487
1973	8,047	84	---	1,489
1974	8,257	72	---	1,598
1975	8,398	71	---	1,622
1976	8,490	77	---	1,650
1977	8,331	79	---	1,526
1978	8,552	80	---	1,510
1979	8,447	5	190	1,538
1980	8,492	5	183	1,614
1981	8,800	5	179	1,598
1982	8,614	4	170	1,544
1983	8,873	3	167	1,559
1984	8,815	3	169	1,442
1985	8,650	3	170	1,397
1986	8,734	2	171	1,329
1987	9,354	1	172	1,313
1988	9,654	2	175	1,234
1989	9,635	2	177	1,197
1990	10,295	6	189	1,240
1991	10,908	7	190	1,188
1992	11,193	10	195	1,114
1993	12,172	15	226	1,094
1994	11,538	15	219	986

1995	10,007	13	208	873
1996	10,282	13	190	839
1997	10,611	13	180	793
1998	10,839	11	170	767
1999	11,205	8	172	733
2000	11,562	8	150	685
2001	11,888	8	134	641
2002	12,961	8	116	608
2003	12,092	8	116	598
2004	11,633	7	86	467
2005	11,444	7	70	414

² As of Sept. 1.

³ As of Oct. 1.

⁴ Civil Service Reform Act of 1978.

Source: Division of Personnel Management, NIH.

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The NIH Almanac – Nobel Laureates

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Nobel Laureates

Read about the [NIH Scientists](#) who have won Nobel prizes.

Laureate	Field	Year	Supporting NIH Institute (s)
Dr. Richard Axel, U.S.A., and Dr. Linda B. Buck, U.S.A.	Physiology or Medicine	2004	NIDCD, NCI, NIAID, NIMH, NINDS, NIDDK
Irwin A. Rose, U.S.A., Avram Hershko, Israel (shared with Aaron Ciechanover, Israel)	Chemistry	2004	NIAMD, NCI, NIAAA, NIGMS, NIDDK
Dr. Roderick MacKinnon, U.S.A., and Dr. Peter Agre, U.S.A.	Chemistry	2003	NHLBI, NEI, NIAAA, NIGMS, NCRR, NINDS, NIDDK
Paul C. Lauterbur, U.S.A. (shared with P. Mansfield, U.K.)	Physiology or Medicine	2003	NCRR, NCI, NHLBI, NIGMS, NIMH
John B. Fenn, U.S.A. (shared with K. Tanaka, Japan and K. Wüthrich, Switzerland)	Chemistry	2002	NIGMS
H. Robert Horvitz, U.S.A. (shared with S. Brenner, U.S.A. and J.E. Sulston, U.K.)	Physiology or medicine	2002	NIGMS, NCI, NICHD
Leland H. Hartwell, U.S.A. (shared with P.M. Nurse and R.T. Hunt, U.K.)	Physiology or medicine	2001	NIGMS, NCI, NCRR
K. Barry Sharpless, U.S.A. (shared with W.S. Knowles, U.S.A. and R. Noyori, Japan)	Chemistry	2001	NIGMS, NHLBI
Paul Greengard, U.S.A. (shared with E. Kandel, U.S.A. and A. Carlsson, Sweden)	Physiology or medicine	2000	NIMH, NIA, NIDA, NINDS, NIAAA, NHLBI, NIAMS
Erik R. Kandel, U.S.A. (shared with P. Greengard, U.S.A. and A. Carlsson, Sweden)	"	2000	NIMH, NIGMS, NINDS, NCRR
James J. Heckman, U.S.A. (shared with D. McFadden, U.S.A.)	Economic sciences	2000	NICHD, NIMH
Daniel L. McFadden, U.S.A. (shared with J. Heckman, U.S.A.)	"	2000	NIA
Günter Blobel, U.S.A.	Physiology or medicine	1999	NIGMS, NCI
Robert Furchgott, U.S.A. (shared with L. Ignarro and F. Murad, U.S.A.)	Physiology or medicine	1998	NIGMS, NHLBI, NINDS
Louis Ignarro, U.S.A. (shared with F. Murad and R. Furchgott, U.S. A.)	"	1998	NHLBI, NIAMS, NICHD
Ferid Murad, U.S.A. (shared with L. Ignarro and R. Furchgott, U.S.A.)	"	1998	NIGMS, NHLBI, NIDDK

Paul D. Boyer, U.S.A. (shared with J. C. Skou,)	Chemistry	1997	NIGMS, NIDDK
Jens C. Skou, Denmark (shared with P.D. Boyer)	"	1997	NINDS
Stanley B. Prusiner, U.S.A. Physiology or medicine	Physiology or medicine	1997	NINDS, NIA, NCRR, NIGMS
Edward B. Lewis, U.S.A. (shared with C. Nusslein-Volhard, Germany, and E.F. Wieschaus, U.S.A.)	"	1995	NICHD, NIGMS
Eric F. Wieschaus, U.S.A. (shared with E.B. Lewis, U.S.A., and C. Nusslein-Volhard, Germany)	"	1995	NICHD
Alfred G. Gilman, U.S.A. (shared with M. Rodbell, U.S.A.)	"	1994	NIGMS, NINDS
Martin Rodbell, U.S.A. (shared with A.G. Gilman, U.S.A.)	"	1994	NIEHS, NIDDK
George A. Olah, U.S.A.	Chemistry	1994	NCI, NIGMS
Phillip A. Sharp, U.S.A. (shared with R. Roberts, U.K.)	Physiology or medicine	1993	NIGMS, NCI, NIAID, DRS, NCRR
Richard Roberts, U.K. (shared with P. A. Sharp, U.S.A.)	"	1993	NCRR,.nlm, NCHGR, NCI, NIGMS
Kary B. Mullis, U.S.A. (shared with M. Smith, Canada)	Chemistry	1993	NHBLI, NIAID, NIGMS
Michael Smith, Canada (shared with K.B. Mullis, U.S.A.)	"	1993	NIGMS
Edwin G. Krebs, U.S.A (shared with E.H. Fisher, U.S.A.)	Physiology or medicine	1992	NIDDK, NIGMS, NIAMS
Edmond H. Fisher, U.S.A. (shared with E.G. Krebs, U.S.A.)	"	1992	NIDDK, NIGMS, NIAMS
Gary Becker, U.S.A.	Economics	1992	NICHD
Elias J. Corey, U.S.A.	Chemistry	1990	NIGMS, NCRR, NCI, NHLBI, NIAID
E. Donnall Thomas, U.S.A. (shared with J.E. Murray, U.S.A.)	Physiology or medicine	1990	NCI, NIAID, NIDDK
Joseph E. Murray, U.S.A. (shared with E.D. Thomas, U.S.A.)	"	1990	NHLBI, NIAID
Sidney Altman, U.S.A. (shared with T. Cech, U.S.A.)	Chemistry	1989	NIGMS, NICHD
Thomas Cech, U.S.A. (shared with S. Altman, U.S.A.)	"	1989	NIGMS, NCI
J. Michael Bishop, U.S.A (shared with H.E. Varmus, U.S.A.)	Physiology or medicine	1989	NCI
Harold E. Varmus, U.S.A. (shared with J.M. Bishop, U.S.A.)	"	1989	NCI, NIAID
Susumu Tonegawa, Japan	"	1987	NIAID
Donald J. Cram, U.S.A. (shared with C.J. Pederson, U.S.A., and Jean-Marie Lehn, France)	Chemistry	1987	NIGMS
Stanley Cohen, U.S.A. (shared with R. Levi-Montalcini, U.S.A./Italy)	Physiology or medicine	1986	NICHD, NIGMS

Rita Levi-Montalcini, U.S.A./Italy (shared with S. Cohen, U.S.A.)	"	1986	NIMH, NINDS
Herbert A. Hauptman, U.S.A. (shared with J. Karle, U.S.A.)	Chemistry	1985	NIGMS, NIADDK, NHLBI, DRR
Michael S. Brown, U.S.A. (shared with J.L. Goldstein, U.S.A.)	Physiology or medicine	1985	NHLBI, NIGMS, DRR
Joseph L. Goldstein, U.S.A. (shared with M.S. Brown, U.S.A.)	"	1985	NHLBI, NIGMS, DRR
R. Bruce Merrifield, U.S.A.	Chemistry	1984	NIDDK
Henry Taube, U.S.A.	"	1983	NIGMS
Sune Bergstrom, Sweden (shared with J. R. Vane, U.K. and B. Samuelsson, Sweden)	Physiology or medicine	1982	NHLBI, NLM, NICHD
John R. Vane, U.K. (shared with S. Bergstrom and B. Samuelsson, Sweden)	"	1982	DRG, NIGMS, NIMH
Aaron Klug, U.K. Chemistry 1982 NIAID			
Roald Hoffmann, U.S.A. (shared with K. Fukui, Japan)	"	1981	NIGMS
David H. Hubel, U.S.A. (shared with T. N. Wiesel, U.S.A./Sweden, and R. W. Sperry, U.S.A.)	Physiology or medicine	1981	NEI, NIGMS, NINDS, DRR
Torsten N. Wiesel, U.S.A./Sweden (shared with D. H. Hubel and R. W. Sperry, U.S.A.)	"	1981	NEI, DRR, NINDS
Paul Berg, U.S.A. (shared with W. Gilbert, U.S.A., and F. Sanger, U.K.)	Chemistry	1980	NIGMS, NCI
Walter Gilbert, U.S.A. (shared with P. Berg, U.S.A., and F. Sanger, U.K.)	"	1980	NIGMS, NIDDK
Baruj Benacerraf, U.S.A. (shared with G. D. Snell, U.S.A., and J. Dausset, France)	Physiology or medicine	1980	NIAID, NCI
George D. Snell, U.S.A. (shared with B. Benacerraf, U.S.A., and J. Dausset, France)	"	1980	NIAID, NCI
Jean Dausset, France (shared with B. Benacerraf and G. D. Snell, U.S.A.)	"	1980	NIAID, NCI
Herbert C. Brown, U.S.A. (shared with G. Wittig, W. Germany)	Chemistry	1979	NIGMS
Hamilton O. Smith, U.S.A. (shared with D. Nathans, U.S.A., and W. Arber, Switzerland)	Physiology or medicine	1978	NIGMS, NIAID
Daniel Nathans, U.S.A. (shared with H. O. Smith, U.S.A., and W. Arber, Switzerland)	"	1978	NIGMS, NCI
Roger C. L. Guillemin, U.S.A. (shared with A. V. Schally and R. S. Yalow, U.S.A.)	"	1977	NIDDK, NICHD, DRR
Andrew V. Schally, U.S.A. (shared with R. C. L. Guillemin and R. S. Yalow, U.S.A.)	"	1977	NIDDK, NICHD, NIGMS

D. Carleton Gajdusek , U.S.A. (shared with B. S. Blumberg, U.S.A.)	"	1976	NINDS
Baruch S. Blumberg , U.S.A. (shared with D. C. Gajdusek, U.S.A.)	"	1976	NHLBI, NCI
William N. Lipscomb , U.S.A	Chemistry	1976	NIGMS, DRG
David Baltimore , U.S.A. (shared with R. Dulbecco and H. M. Temin, U.S.A.)	Physiology or medicine	1975	NIAID, NCI
Renato Dulbecco , U.S.A. (shared with D. Baltimore and H. M. Temin, U.S.A.)	"	1975	NIAID, NCI
Howard M. Temin , U.S.A. (shared with D. Baltimore and R. Dulbecco, U.S.A.)	"	1975	NCI
Albert Claude , Belgium (shared with C. de Duve, Belgium, and G. E. Palade, U.S.A.)	"	1974	NCI
George E. Palade , U.S.A. (shared with C. de Duve and A. Claude, Belgium)	"	1974	NHLBI, NIGMS
Christian de Duve , Belgium (shared with A. Claude, Belgium, and G. E. Palade, U.S.A.)	"	1974	NICHD, NIGMS, NHLBI, NIA
Gerald M. Edelman , U.S.A. (shared with R. R. Porter, U.K.)	"	1972	NIDDK, NIAID, NICHD
Rodney R. Porter , U.K. (shared with G. M. Edelman, U.S.A.) " 1972 NIAID	"	1972	NIAID
Christian B. Anfinsen , U.S.A. (shared with S. Moore and W. H. Stein, U.S.A.)	Chemistry	1972	NHLBI, NIDDK
Stanford Moore , U.S.A. (shared with C. B. Anfinsen and W. H. Stein, U.S.A.)	"	1972	NIGMS, NINDS
William H. Stein , U.S.A. (shared with C. B. Anfinsen and S. Moore, U.S.A.)	"	1972	NIGMS
Earl W. Sutherland, Jr. , U.S.A	Physiology or medicine	1971	NIGMS, NHLBI, NIDDK
Julius Axelrod , U.S.A. (shared with B. Katz, U.K., and U. von Euler, Sweden)	"	1970	NHLBI, NIMH
Ulf von Euler , Sweden (shared with J. Axelrod, U.S.A., and B. Katz, U.K.)	"	1970	NINDS
Luis Leloir , Argentina	Chemistry	1970	NIGMS, NIAID
Max Delbruck , U.S.A. (shared with A. D. Hershey and S. Luria, U.S.A.)	Physiology or medicine	1969	NIGMS
Alfred D. Hershey , U.S.A. (shared with M. Delbruck and S. Luria, U.S.A.)	"	1969	NIGMS, NCI, NICHD
Salvador Luria , U.S.A. (shared with M. Delbruck and A. D. Hershey, U.S.A.)	"	1969	NIAID, NIGMS, NCI
Robert W. Holley , U.S.A. (shared with H. G. Khorana and M. W. Nirenberg, U.S.A.)	"	1968	NIGMS, NCI

H. Gobind Khorana, U.S.A. (shared with R. W. Holley and M. W. Nirenberg, U.S.A.)	"	1968	NIGMS, NCI, NIAID
Marshall W. Nirenberg, U.S.A. (shared with R. W. Holley and H. G. Khorana, U.S.A.)	"	1968	NHLBI
Lars Onsager, U.S.A.	Chemistry	1968	NIGMS
Haldan K. Hartline, U.S.A. (shared with G. Wald, U.S.A., and R. Granit, Sweden)	Physiology or medicine	1967	NINDS, NEI
George Wald, U.S.A. (shared with H. K. Hartline, U.S.A., and R. Granit, Sweden)	"	1967	NINDS, NEI
Charles B. Huggins, U.S.A. (shared with P. Rous, U.S.A.)	Physiology or medicine	1966	NCI, NIDDK, NIGMS
Jacques L. Monod, France (shared with F. Jacob and A. Lwoff, France)	"	1965	NIAID
Robert B. Woodward, U.S.A.	Chemistry	1965	NIGMS, NHLBI, DRG, NIDDK
Konrad Bloch, U.S.A. (shared with F. Lynen, Germany)	Physiology or medicine	1964	NIGMS, NHLBI, DRG
James D. Watson, U.S.A. (shared with F. H. C. Crick and M. H. F. Wilkins, U.K.)	"	1962	NIGMS, NIDDK, NCI, DRR, NIAID
John C. Kendrew, U.K. (shared with M. F. Perutz, U.K.)	Chemistry	1962	NIDDK
Melvin Calvin, U.S.A.	"	1961	DRG, NCI
Peter B. Medawar, U.K. (shared with F. M. Burnet, Australia)	Physiology or medicine	1960	NIAID
Arthur Kornberg, U.S.A. (shared with S. Ochoa, U.S.A.)	"	1959	NIGMS, NIAID, NCI, NIDDK, NIA
Severo Ochoa, U.S.A. (shared with A. Kornberg, U.S.A.)	"	1959	NIDDK, NIGMS, NCI, DRG
George W. Beadle, U.S.A. (shared with J. Lederberg and E. L. Tatum, U.S.A.)	"	1958	NIGMS, NHLBI
Joshua Lederberg, U.S.A. (shared with G. W. Beadle and E. L. Tatum, U.S.A.)	"	1958	NIGMS, NIAID, NINDS, NICHD, DRR, NCI
Edward L. Tatum, U.S.A. (shared with G. W. Beadle and J. Lederberg, U.S.A.)	"	1958	NIGMS, NCI
Dickinson W. Richards, Jr., U.S.A. (shared with A. Cournand, U.S.A., and W. Forssmann, Germany)	"	1956	NIDDK, NCI, NHLBI, NIGMS
Vincent du Vigneaud, U.S.A.	Chemistry	1955	NHLBI, NCI, NIGMS, DRG
Thomas H. Weller, U.S.A. (shared with J. F. Enders and F. C. Robbins, U.S.A.)	Physiology or medicine	1954	NIAID, NIGMS
Linus C. Pauling, U.S.A.	Chemistry	1954	NIGMS, NHLBI, DRG, NIAID, NCI

Fritz A. Lipmann, U.S.A. (shared with H. A. Krebs, U.K.)	Physiology or medicine	1953	NIGMS, NCI
Philip S. Hench, U.S.A. (shared with E. C. Kendall, U.S.A., and T. Reichstein, Switzerland)	"	1950	NIGMS
E. O. Lawrence, U.S.A.	Physics	1939	NCI

NIH Scientists

1968 - Dr. Marshall W. Nirenberg, National Heart, Lung, and Blood Institute, shared the Nobel Prize in Physiology or Medicine for discovering the key to deciphering the genetic code. Dr. Nirenberg and two other researchers, working independently, with whom he shared the prize, made major advances in understanding the chemical mechanisms by which genetic language or information is translated into various proteins that determine the nature and characteristics of all living things. Dr. Nirenberg was the first NIH Nobelist and also the first Federal employee to receive a Nobel Prize.

1970 - Dr. Julius Axelrod, National Institute of Mental Health, shared the Nobel Prize in Physiology or Medicine with two scientists from England and Sweden for independent research into the chemistry of nerve transmission. The three were cited for their "discoveries concerning the humoral transmitters in the nerve terminals and the mechanisms for their storage, release and inactivation." Specifically, Dr. Axelrod found an enzyme that terminates the action of the nerve transmitter, noradrenaline. He also demonstrated that some antidepressant drugs act by preventing the reuptake of noradrenaline and thus prolong its action in the brain.

1972 - Dr. Christian B. Anfinsen (formerly with the National Institute of Arthritis, Metabolism, and Digestive Diseases) won the Nobel Prize in Chemistry for his work "on ribonuclease, especially concerning the connection between the amino acid sequence and the biologically active conformation." Dr. Anfinsen provided the first clue to the structure of ribonuclease by demonstrating that it is comprised of a single polypeptide chain. He and his colleagues at Rockefeller University (with whom he shared the prize) demonstrated that the information required to fold the polypeptide chain of ribonuclease into the specific three-dimensional form of the active enzyme resides in the sequence of amino acids. Therefore, it became clear that this protein could be synthesized in the laboratory by joining the proper amino acids in the correct order and then allowing the chain of amino acids to fold spontaneously. This led to the first synthesis of an enzyme from chemicals in the laboratory. Such studies are basic to an understanding of normal life processes as well as of inherited metabolic diseases.

1976 - Dr. D. Carleton Gajdusek, National Institute of Neurological Disorders and Stroke, shared the Nobel Prize in Physiology or Medicine with Dr. Baruch S. Blumberg, of the Institute for Cancer Research in Philadelphia. They won the award for their discoveries concerning new mechanisms for the origin and dissemination of infectious diseases. Dr. Blumberg was at NIH (with the National Institute of Arthritis and Metabolic Diseases) in the 1960s, and did part of his prizewinning research at NIH.

1994 - Dr. Martin Rodbell, National Institute of Environmental Health Sciences, shared the Nobel Prize in Physiology or Medicine with Dr. G. Alfred Gilman of the University of Texas Southwestern Medical Center in Dallas, Texas. Dr. Rodbell discovered in 1970 that signal transmission requires a cellular molecule called GTP. In 1977 Dr. Gillman identified the proteins to which GTP binds and named them "G proteins." They are a family of proteins bound to the cell surface membranes that serve as intermediaries between incoming signals and cellular proteins that respond to these signals. Dr. Rodbell conducted this research while an intramural scientist with the National Institute of Arthritis and Metabolic Diseases (now NIDDK).

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