

Appendices

Appendix E:

Monitoring Adherence to the NIH Policy on Inclusion of Women and Minorities as Subjects in Clinical Research

Comprehensive Report: Tracking of Human Subjects Research As Reported in Fiscal Year 2005 and Fiscal Year 2006

Following is an excerpt of the report—all of the report except for the appendices. The full report can be found at:

[http://orwh.od.nih.gov/inclusion/2007 Annual Comprehensive Report - Web Version Rev 8-22-07.pdf](http://orwh.od.nih.gov/inclusion/2007%20Annual%20Comprehensive%20Report%20-%20Web%20Version%20Rev%208-22-07.pdf)

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Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research

The establishment and implementation of policies for the inclusion of women and minorities in clinical research funded by the National Institutes of Health (NIH) has its origins in the women's health movement. Following the issuance of the report of the Public Health Service Task Force on Women's Health in 1985, the NIH established a policy in 1986 for the inclusion of women in clinical research. This policy, which **urged** the inclusion of women, was first published in the NIH Guide to Grants and Contracts in 1987. Later that year, minority and other scientists at the NIH recognized the need to address the inclusion of minority populations. Therefore, in a later 1987 version of the NIH guide, a policy **encouraging** the inclusion of minorities in clinical studies was first published.

In order to ensure that the policies for inclusion were firmly implemented by NIH, the Congress made what had previously been policy into Public Law, through a section in the NIH Revitalization Act of 1993 (PL 103-43)¹, entitled *Women and Minorities as Subjects in Clinical Research*. In 1994, the NIH revised its inclusion policy to meet this mandate that women and minorities must be included in all of its clinical research studies. The Revitalization Act essentially reinforced the existing NIH policies, but with four major differences:

- that NIH ensure that women and minorities and their subpopulations be included in all clinical research;

- that women and minorities and their subpopulations be included in Phase III clinical trials in numbers adequate to allow for valid analyses of differences in intervention effect;
- that cost is not allowed as an acceptable reason for excluding these groups; and,
- that NIH initiate programs and support for outreach efforts to recruit and retain women and minorities and their subpopulations as participants in clinical studies

Revised inclusion guidelines developed in response to this law were published in the Federal Register² in March 1994, and they became effective in September 1994. The result was that NIH could not and would not fund any grant, cooperative agreement or contract or support any intramural project to be conducted or funded in Fiscal Year 1995 and thereafter which did not comply with this policy.

Strategies to ensure uniform implementation of the revised guidelines across the NIH were developed through the establishment and deliberations of an NIH Tracking and Inclusion Committee made up of representatives of the directors of each of the ICs. This trans-NIH committee, convened by the Office of Research on Women's Health (ORWH) and co-chaired with a senior IC official, meets on a regular basis, focusing on consistent and widespread adherence to the NIH guidelines by all the ICs. Working in collaboration with the Office of Extramural Research (OER), the Office of Intramural Research (OIR), and other components of the NIH, the ORWH coordinates the activity of developing and establishing data collection and reporting methodologies to ensure uniform standards and definitions in the reporting of data on women and minority participants in NIH-funded clinical research.

To ensure NIH-wide adherence to the revised inclusion guidelines, in 1994 NIH conducted extensive training on the revised inclusion guidelines. In June 1994, the ORWH convened a meeting of Institutional Review Board (IRB) chairs to discuss their role in implementing the revised policy. Training was especially important in light of 1990 GAO findings that an earlier policy was inconsistently applied and had not been well communicated or understood within the NIH or in the research community. A variety of outreach activities were initiated to explain the revised policy to the scientific research community and to clear up common misunderstandings about the new requirements.

Continuing Implementation and Monitoring Activities

Following a Congressional request for an assessment of NIH's progress in implementing the 1994 guidelines on including women in clinical research, the GAO issued another report in May, 2000, entitled Women's Health - NIH Has Increased Its Efforts to Include Women in Research.³ It concluded that in the past decade, NIH has made significant progress in implementing a strengthened policy on including women in clinical research.

The GAO report also included two specific recommendations to the Director of NIH to ensure the following:

- that the requirement be implemented that Phase III clinical trials be designed and carried out to allow for the valid analysis of differences between women and men and communicate this requirement to applicants as well as requiring peer review groups to determine whether each proposed Phase III clinical trial is required to have such a study design, and that summary statements document the decision of the initial reviewers; and
- that the NIH staff who transmit data to the inclusion tracking data system receive ongoing training on the requirements and purpose of the system.

Immediately following the release of this report, an *NIH Subcommittee Reviewing Inclusion Issues* was formed, consisting of representatives from several ICs, ORWH, OER, and OIR, to reexamine NIH's system for tracking data on the inclusion of women and minorities in clinical research, recommend any necessary changes to improve its accuracy and performance, and reiterate the NIH policy. Several actions resulted to clarify the requirement for NIH-defined Phase III clinical trials to include women and minority groups, if scientifically appropriate, and for analysis of sex/gender and/or racial/ethnic differences to be planned and conducted by investigators engaged in NIH-funded research. Significant actions in 2001 included:

- **Updating the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research** and posting it on the ORWH home page <http://orwh.od.nih.gov/inclusion.html> and NIH web page, Inclusion of Women and Minorities Policy Implementation at: http://grants.nih.gov/grants/funding/women_min/women_min.htm.
- **Developing a new term and condition of award** statement for awards made after October 1, 2000 that have NIH-defined Phase III clinical trials.
- **Incorporating language in the NIH solicitations for grant applications and contract proposals to clarify the submission requirement for NIH-defined Phase III clinical trials**, a description of plans for sex/gender and/or race/ethnicity analysis including subgroups, if applicable, and reporting accrual annually and results of analyses, as appropriate.
- **Guidelines and instructions for reviewers and Scientific Review Administrators (SRAs) were developed** to emphasize and clarify the need to review research proposals that are classified as NIH-defined Phase III clinical trials for both inclusion requirements and issues related to analyses by sex/gender and/or race/ethnicity. Instructions were developed for the proper documentation to include in summary statements to address adherence to these policies.

Training to ensure compliance with this policy was provided to NIH program and review officials, grants and contracts management staff, and current and prospective research investigators. Several initiatives were implemented for review, grants management and program staff since 2000, including specific topics addressing revisions to the NIH Inclusion policy, a grants policy update and Scientific Review Administrator (SRA) orientation on specific issues related to review meetings and proceedings.

The PHS 398 Grant Application was significantly revised to provide additional instructions about the Women and Minorities Inclusion Policy and the revised form became mandatory as of May 10, 2005. These PHS 398 instructions about the Women and Minorities Inclusion Policy have also been included in the new federal application form SF-424 (R&R) for NIH grants using the federal Grants.gov system (see <http://era.nih.gov/ElectronicReceipt/>). The application instructions included two significant changes in definitions. First, the NIH required use of a revised definition of clinical research that was reported in the 1997 Report of the NIH Director's Panel on Clinical research and adopted by NIH. Secondly, the Office of Management and Budget (OMB) Directive 15, "Race and Ethnic Standards for Federal Statistics and Administrative Reporting", revised the definitions for the racial and ethnic categories to be used when reporting population data (see: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html>). In addition, NIH policy reemphasized that that NIH-defined Phase III clinical trials must be designed and conducted in a manner to allow for a valid analysis of whether the variables being studied affect women or members of minority groups differently than other subjects.

Many of the training sessions are available electronically for all NIH staff, and the Office of Extramural Research (OER) has made available existing training materials on the Population tracking system website on the NIH Intranet. A training subcommittee of the full NIH Tracking and Inclusion committee has been established to develop new training documents and methods of training for NIH staff and the extramural research community. Further information regarding training initiatives since the 2000 GAO report is discussed in the background section of the Appendices (See Appendix A)

Communication and Outreach Efforts to the Scientific Community

NIH staff provides outreach to the scientific community to help increase understanding of the revised inclusion policy and OMB requirements. These training and outreach efforts are designed to improve understanding of the sex/gender and minority inclusion policy and assist investigators and NIH staff to appropriately address these issues throughout the research grant and contract process. Investigators are instructed to address women and minority inclusion issues in the development of their applications and proposals for clinical research.

Reference documents such as the Outreach Notebook for the NIH Guidelines on Inclusion of Women and Minorities as Subjects in Clinical

Research (<http://orwh.od.nih.gov/inclusion/outreach.pdf>) and the Frequently Asked Questions (FAQs) for the Inclusion , Recruitment and Retention of Women and Minority Subjects in Clinical Research (<http://orwh.od.nih.gov/inclusion/outreachFAQ.pdf>) have been published and distributed for investigators and NIH staff. These publications discuss the elements of recruitment and retention, the NIH inclusion policy, 1997 OMB requirements for reporting race and ethnicity data, as well as information for application submission, peer review, and funding. Both are posted on the ORWH website <http://orwh.od.nih.gov> as well as on the NIH website for the inclusion of women and minorities policy implementation at: http://grants1.nih.gov/grants/funding/women_min/women_min.htm. The revised Outreach Notebook and FAQs continue to be available to the research community to further explore the inclusion policy and its intent. Additionally, a slide show available electronically and in hard copy, "Sex/Gender and Minority Inclusion in NIH Clinical Research: What Investigators Need to Know!" was developed for NIH staff to assist them in working with the extramural community.

Monitoring Compliance: Extramural and Intramural Population Data Analysis

When assessing inclusion data, enrollment figures should not be directly compared to the national census figures. The goal of the NIH policy is not to satisfy any quotas for proportional representation, but rather to conduct biomedical and behavioral research in such a manner that the scientific knowledge acquired will be generalizable to the entire population of the United States. The numbers of women or minority subgroups included in a particular study depends upon the scientific question addressed in the study and the prevalence among women and minority subpopulations of the disease, disorder, or condition under investigation.

Scientific Review Groups are instructed to focus on scientific considerations when assessing the planned enrollment for a particular study. The Scientific Review Group (SRG) determines if the implementation plan for an application is unacceptable if it: 1) fails to provide sufficient information about target enrollment; 2) does not adequately justify limited or lack of inclusion of women or minorities; or 3) does not realistically address recruitment and retention. For NIH-defined Phase III clinical trials, the Scientific Review Group (SRG) also evaluates the description of plans to conduct analyses, as appropriate, to address differences in the intervention effect by sex/gender and/or racial/ethnic groups. Applications with unacceptable inclusion plans cannot be funded until NIH staff is assured that revised inclusion plans from the investigators meet the inclusion policy requirements. Research awards covered by this policy require the grantee to report annually on enrollment of women and men, and on the race and ethnicity of research participants so that accrual can be monitored.

NIH has monitored aggregate demographic data for study populations through the evolving NIH computerized tracking system since fiscal year 1994, and tracking the inclusion of women and minorities in clinical studies is well established in all ICs. Members of the NIH Tracking and Inclusion Committee continuously work on ways to refine and improve data collection methods and the quality of the data entered by each IC

into this system. In May 2002, the NIH successfully deployed a new population tracking system for monitoring the inclusion of women and minorities in clinical research. This system provides easier data entry and project monitoring of investigator data reporting for NIH staff. An eRA Population Tracking User Group consisting of representatives from several ICs provides continuous feedback related to system use.

The aggregate data enable the NIH to measure inclusion in order to formulate more specific questions about gaps in enrollment and to design studies to respond to those questions. Data compiled in future years allows for longitudinal examination of trends and continued monitoring of compliance, although this will be more difficult for minority trends because of a change in how these data are collected (see next section).

A review of intramural inclusion data indicates that the intramural research program continues to be compliant with the reporting requirements adhered to by the extramural community and outlined in the NIH Implementation Guidelines on the Inclusion of Women and Minority Subjects in Research Studies. The Clinical Center Medical Executive Committee (MEC) has taken a leading role in assuring that investigators conducting clinical research protocols in the Clinical Center are trained and competent in the conduct of clinical research. The MEC designed and endorsed the Standards for Clinical Research within the NIH Intramural Research Program which set forth guidelines for the infrastructure, training, education, and monitoring required for safe and effective conduct of clinical research.

Format Changes for Reporting Race and Ethnicity Data

Beginning in FY2002, NIH changed how data are reported based on the 1997 Office of Management and Budget (OMB) Directive 15 minimum standards for maintaining, collecting and reporting data on race and ethnicity. Implementation of the 1997 OMB standards involved a number of changes including collecting and reporting information on race and ethnicity separately, whereas the 1977 OMB standards used a combined race and ethnicity format. NIH aggregate population data tables describe data using both the 1997 and 1977 OMB standards for reporting data on race and ethnicity. Since 2002, the number of studies reporting data using the 1997 format (NEW FORM) has steadily increased, while the number of studies using the 1977 format (OLD FORM) has steadily decreased as the studies funded prior to FY2002 are completed.

The 1997 OMB reporting format (NEW FORM) and standards does not allow direct comparison of ethnic and racial data with similar data collected under the 1977 OMB reporting format (OLD FORM) and standards because the categories and methods for collecting the data are fundamentally different. Changes in the standardization of definitions and business rules across the NIH for improving the data entered in the population tracking system are reflected in data reported beginning in FY2002. While implementation of these changes will improve the consistency and comparability for future reporting, comparisons with prior FY 2002 data are difficult.

As demonstrated below, the primary differences are: (1) the Hispanic population is considered an ethnic category and reported separately from racial data; (2) there is a separate racial category for Asian population data and Hawaiian and Pacific Islander population data; and 3) respondents are given the option of selecting more than one race. (See Appendix H)

Race and ethnicity data from the OLD and NEW Forms are combined differently as described below for purposes of reporting on the minority population enrolled in NIH clinical research:

- the OLD FORM uses the 1977 OMB combined Race and Ethnicity Format, which has mutually exclusive categories, and allows Hispanics to be reported as either "Hispanic, Not White" or "White".
- the NEW FORM uses the 1997 OMB Race and Ethnicity Categories, with separate reporting for Ethnicity (Hispanic or Latino; Not Hispanic or Latino) and Race (Part A); in this format, an individual is classified both by Ethnic Category and by Race Category. Part B of the NEW FORM therefore provides a distribution of only "Hispanics or Latinos" by the five main Race categories. Since minority categories are defined to include both "Hispanic or Latino ethnicity" and non-white racial categories when providing summary totals of minorities, it is necessary to add "White Hispanics" and "Unknown/Other Hispanics" based on their ethnicity to the non-white racial categories.
- Hispanics are defined by country of origin, and may be identified as belonging to any one, or more than one, race category.

OLD FORM (1977) versus NEW FORM (1997)							
Race/Ethnicity Category	Minority Total		Minority Total				
	Old Form		New Form				
OLD FORM: Combined 1977 OMB Race/Ethnicity Categories							
American Indian/Alaska Native	X						

Asian/Pacific Islander	X				
Black or African American	X				
Hispanic, Not White	X				
White					
Unknown/Other					

NEW FORM: Separate 1997 OMB Race/Ethnicity Categories					
Part A: Total Enrollment Report					
Ethnic Category					
Hispanic or Latino**					
Not Hispanic or Latino					
Unknown (ethnicity not reported)					
Ethnic Category Total of All Subjects*					
Racial Categories					
American Indian/Alaska Native				X	

Asian		X			
Black or African American		X			
Hawaiian/Pacific Islander		X			
White					
More Than One Race		X			
Unknown/Other					
Racial Categories: Total of all Subjects*					
Part B: Hispanic Enrollment by RACE					
American Indian/Alaska Native					
Asian					
Black or African American					
Hawaiian/Pacific Islander					
White (Hispanic)		X			
More Than One Race					

Unknown/Other (Hispanic)		X	
Racial Categories: Total of Hispanics or Latinos**			

* The "Ethnic Category Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects"

** The "Hispanic or Latino"(Part A) must be equal to "Racial Categories: Total of Hispanics or Latinos"(Part B).

DEFINITIONS:

Clinical Research as defined by the 1997 Report of the NIH Director's Panel on Clinical Research,

<http://www.nih.gov/news/crp/97report/execsum.htm>

1. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies;
2. Epidemiologic and behavioral studies; and
3. Outcomes research and health services research

NIH-Defined Phase III Clinical Study

For the purpose of these guidelines, an NIH-defined "clinical trial" is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or control intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

Valid Analysis

The term “valid analysis” means an unbiased assessment. Such an assessment will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need to have a high statistical power for detecting a stated effect. The principal requirements for ensuring a valid analysis of the question of interest are:

- allocation of study participants of both sexes/genders (males and females) and different racial/ethnic groups to the intervention and control groups by an unbiased process such as randomization,
- unbiased evaluation of the outcome(s) of study participants, and
- use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects among the sex/gender and racial/ethnic groups.

Significant Difference

For purposes of this policy, a “significant difference” is a difference that is of clinical or public health importance, based on substantial scientific data. This definition differs from the commonly used “statistically significant difference,” which refers to the event that, for a given set of data, the statistical test for a difference between the effects in two groups achieves statistical significance. Statistical significance depends upon the amount of information in the data set. With a very large amount of information, one could find a statistically significant, but clinically small difference that is of very little clinical importance. Conversely, with less information one could find a large difference of potential importance that is not statistically significant.

Domestic Organization

A public (including a State or other governmental agency) or private non-profit or for-profit organization that is located in the United States or its territories, is subject to U.S. laws, and assumes legal and financial accountability for awarded funds and for the performance of the grant-supported activities.

Foreign Institution

An organization located in a country other than the United States and its territories that is subject to the laws of that country, regardless of the citizenship of the proposed PI.

Conclusion and Current Status

NIH staff continues to monitor, document, and work with grantees and contractors to ensure compliance with the inclusion policy. Program Officials provide technical assistance to investigators as they develop their applications and proposals throughout the application process. Review Officials introduce and discuss with reviewers the Guidelines/Instructions for reviewing the Inclusion of Women and Minorities in Clinical Research as well as the instructions and requirements for designing Phase III Clinical Trials in order that valid analyses can be conducted for sex/gender and ethnic/racial differences. At the time of award and submission of progress reports, program officials monitor and verify that inclusion policy requirements are met. When new and competing continuation applications that are selected for payment are deficient in meeting policy requirements, grants management staff and program officials are required to withhold funding until the principal investigator has satisfactorily addressed the policy requirements.

References

1. Public Law 103-43. National Institutes of Health Revitalization Act of 1993. 42 USC 289 (a)(1).
2. NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, 59 Fed. Reg. 14508-14513 (1994).
3. Women's Health: NIH Has Increased Its Efforts to Include Women in Research (GAO/HEHS-00- 96, May, 2000).
4. NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, NIH Guide for Grants and Contracts, Amended 2001.

For Additional Information on the implementation of the inclusion policy, please visit:

NIH Office of Extramural Research Inclusion of Women and Minorities Policy Implementation Website:

http://grants.nih.gov/grants/funding/women_min/women_min.htm

Revitalization Act of 1993, 42 USC 289 (a)(1): <http://grants.nih.gov/grants/guide/notice-files/not94-100.html>

NIH Policy on Reporting Racial and Ethnicity Data: Subjects in Clinical Research, NIH Guide for Grants and Contracts Web page:
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html>

Office of Research on Women's Health Website: <http://orwh.od.nih.gov/inclusion.html>

Aggregate Enrollment Data Tables For Extramural and Intramural Research Protocols

Fiscal Year 2006 Summary Reports

Twelve-year Trend Summary Reports

Summary Report of NIH Inclusion Data

NIH AGGREGATE POPULATION DATA REPORTED IN FY2005 AND FY2006

The following section is provided in order to guide consideration of the data especially in trend of human subjects participation in NIH-funded extramural and intramural clinical research. Because new studies are added each year and other studies are ending, it is not appropriate to compare data over time or to compare data with census population data. Looking at the trend data represents the best interpretation of the aggregate data. Data on inclusion is tabulated from human subject populations in NIH-defined Phase III clinical trials and other human subject research studies. NIH clinical research studies are determined in accordance with the NIH definition of clinical research to include, for example, non-intervention clinical research, clinical trials, epidemiologic studies, behavioral studies, and database studies.

Analysis of aggregate NIH data on inclusion for FY2005 and FY2006 document that substantial numbers of women and men, especially non-minority men, and minorities have been included as research subjects in NIH-defined Phase III clinical trials and other human subject research studies during these fiscal years. Because the data included in the tables are aggregate data from across NIH, it does provide documentation of the tracking and inclusion across the NIH, and some degree of analysis of the data. But caution should be utilized in not over-interpreting the

figures that are provided. The NIH Tracking and Inclusion committee has provided for the reader's interest, conclusions that can be reasonably drawn from the data.

Previous inclusion reports and aggregate enrollment figures for women, men and minority groups for FY1994 to the present can be found on the ORWH website at <http://orwh.od.nih.gov/inclusion.html>. For this report, the FY2005 and FY2006 data tables have been reformatted and some tables may vary slightly or differ from prior reported summary data in an effort to better clarify reporting.

NIH CLINICAL RESEARCH: Fiscal Years 2005 and 2006

In FY2005, there were 14,798 extramural and intramural clinical research protocols, including Phase III and other clinical studies, of which 10,233 protocols reported human subject participation. Of these, 96.4% were domestic protocols and 3.6% were foreign protocols. Approximately 15.7 million participants were enrolled in extramural and intramural research protocols of which 80.6% were domestic participants and 19.4% were foreign participants. Of the 15.7 million participants, 60.4% were women, 37.8% were men and 1.8% did not provide sex identification. Further, 39.7% of the total participants, and 27.4% of the Domestic-only participants, were reported as minorities following the OMB categories for race and ethnicity. (Table 6)

Correspondingly, in FY2006 there were 15,320 extramural and intramural clinical research protocols, including Phase III and other clinical studies, of which 10,758 protocols reported human subject participation as noted in this report's trend summary tables. Of these, 95.7% were domestic protocols and 4.3% were foreign protocols. Approximately 14.8 million participants were enrolled in extramural and intramural research protocols of which 77.0% were domestic participants and 23.0% were foreign participants. Of the 14.8 million participants, 63.9% were women, 34.9% were men and 1.3% did not provide sex identification. Further, 43.1% of the total participants, and 28.9% of the Domestic-only participants, were reported as minorities following the OMB categories for race and ethnicity. (Table 1)

While the number of participants in all extramural and intramural clinical research decreased (15.7M in FY2005 and 14.8M in FY2006), there was no significant change in the ratio of women and men (60.4%F and 37.8%M in FY2005; and 63.9%F and 34.9%M in FY2006). One large study involving approximately 1.6M participants that ended in FY2005 and therefore was not included in the FY2005 figures, accounted for the net decreased number of participants reported.

NIH Defined Phase III Clinical Research: FY2005 and FY2006

In FY2005, there were 665 extramural and intramural Phase III clinical research protocols, of which 547 protocols reported human subject participation. Of these, 94.5% were domestic protocols and 5.5% were foreign protocols. Approximately 493,000 participants were enrolled in extramural and intramural Phase III research protocols of which 88.8% were domestic participants and 11.2% were foreign participants. Of the 493,000 participants, 59% were women, 40% were men and 1% did not provide sex identification. Further, 31.3% of the total participants, and 25.1% of the Domestic-only participants, in Phase III clinical research were reported as minorities following the 1997 OMB categories for race and ethnicity. (Table 7)

According to the trend summaries in this report, of the 210 extramural and intramural Phase III research protocols that report following the 1977 OMB standards, minority representation was highest for Blacks (not Hispanic) at 12.5 % and lowest for American Indian/Alaska Natives at 0.4%. Hispanics represented approximately 6.9%, Asian/Pacific Islanders were 5.6% and Whites (not Hispanic) 73.2% of the participants. The categories Hawaiian/Pacific Islander and More Than One Race were not designations with the 1977 OMB standards. (Table 7)

Furthermore, in FY2005, there were 337 extramural and intramural Phase III research protocols reporting data following the current 1997 OMB standards for reporting by both race and ethnicity. Accordingly, minority representation by race was highest for Blacks at 28.5% and lowest for Hawaiian/Pacific Islanders 0.3%. Asians represented 5.2%, American Indian/Alaska Natives 1.2% and Whites 57.3% of participants. Participants identifying as More Than One Race were 1.7% of the total number of participants. In addition, 5.8% did not identify a race category. Of the 337 extramural and intramural Phase III research protocols designating an ethnicity in FY2005, 88.6 % of total participants identified as "Not Hispanic", 5.9% of the total participants identified as "Hispanic or Latino" and 5.5% of the total participants did not identify an ethnicity category. The racial distribution of the "Hispanic or Latino" participants is also provided separately. (Table 7)

Correspondingly, in FY2006 there were 760 extramural and intramural Phase III clinical research protocols, of which 624 protocols reported human subject participation as noted in this report's trend summary tables. Of these, 90.4% were domestic protocols and 9.6% were foreign protocols. Approximately 499,430 participants were enrolled in extramural and intramural Phase III research protocols of which 80.2% were domestic participants and 19.8% were foreign participants. Of the 499,430 participants, 62.9% were women, 36.0% were men and 1.1% did not provide sex identification. Further, 33.5% of the total participants, and 20.7% of Domestic-only participants, in Phase III clinical research were reported as minorities following the OMB categories for race and ethnicity. (Table 3)

According to the trend summaries in this report, of the 215 extramural and intramural Phase III research protocols that report following the 1977 OMB standards in FY2006, minority representation was highest for Blacks (not Hispanic) at 8.9% and lowest for American Indian/Alaska Natives at 0.4%. Hispanics represented approximately 4.1%, Asian/Pacific Islanders were 7.3% and Whites (not Hispanic) 76.5% of the

participants. The categories Hawaiian/Pacific Islander and More Than One Race were not designations with the 1977 OMB standards. (Table 7)

Moreover, in FY 2006, there were 409 extramural and intramural Phase III research protocols reporting data following the current 1997 OMB standards for reporting by both race and ethnicity. Accordingly, minority representation by race was highest for Blacks at 18.8% and lowest for Hawaiian/Pacific Islanders 0.2%. Asians represented 12.0%, American Indian/Alaska Natives 1.7% and Whites 47.0% of participants. Participants identifying as More Than One Race were 1.6% of the total number of participants. In addition, 18.7% did not identify a race category. Of the 409 extramural and intramural Phase III research protocols designating an ethnicity in FY2006, 75.0 % of total participants identified as "Not Hispanic", 11.5 % of the total participants identified as "Hispanic or Latino", and 13.5% of the total participants did not identify an ethnicity category. The racial distribution of the "Hispanic or Latino" participants is also provided separately. (Table 7)

While the number of participants in Phase III extramural and intramural clinical research slightly increased (493,000 in FY2005 and 499,430 in FY2006), there was no significant change in the ratio of women and men (59.0% F and 40.0%M in FY2005; and 62.9%F and 36.0%M in FY2006).

The following sections provide data on extramural research and intramural research separately.

EXTRAMURAL CLINICAL RESEARCH: Fiscal Years 2005 and 2006

In FY2005, there were 13,003 extramural clinical research protocols, including Phase III and other clinical studies, of which 8,763 protocols reported human subject participation as noted in this report's trend summary tables. Approximately 13.8 million participants were enrolled in extramural research protocols of which 62.1% were women, 36.1% were men and 1.9% did not provide sex identification. (See 2006 Report, Table 2 and Appendix table 3A)

Correspondingly, in FY2006, there were 13,522 extramural clinical research protocols, including Phase III and other clinical studies, of which 9,235 protocols reported human subject participation. Of these, 95.7% were domestic protocols and 4.3% were foreign protocols. Approximately 13.02 million participants were enrolled in extramural research protocols of which 76.6% of the total enrollment is domestic participants and 23.4% of the total enrollment is foreign participants. Of the 13.02 million participants, 65% were women, 33.8% were men and 1.2% did not provide sex identification. Further, 45.9% of the total participants were reported as minorities following the OMB categories for race and ethnicity. (Table 2 and Appendix Table 3A)

While the number of participants in all extramural clinical research decreased (13.8 million in FY2005 and 13.02 million in FY2006), there was no significant change in the ratio of women and men (62%F and 36%M in FY2005 and 65%F and 34%M). However, when sex-specific studies were excluded, the proportions of women and men in all extramural clinical research were proportional to the percentages of the general population. (52.4%F and 45.8 % M)

NIH Defined Phase III Extramural Clinical Research: FY2005 and FY2006

In FY2005 of the 273 extramural Phase III research protocols that report following the 1977 OMB standards, minority representation was highest for Blacks (not Hispanic) at 12.9% and lowest for American Indian/Alaska Natives at 0.4%. Hispanics represented approximately 7%, Asian/Pacific Islanders were 1.9% and Whites (not Hispanic) 76% of the participants. The categories Hawaiian/Pacific Islander and More Than One Race were not designations with the 1977 OMB standards. (See 2006 Report)

In FY2006 there were 707 extramural Phase III clinical research protocols, of which 580 protocols reported human subject participation as noted in this report's trend summary tables. Approximately 467,954 participants were enrolled in extramural Phase III research protocols of which 63.5% were women, 35.4% were men and 1% did not provide sex identification. (Table 4 and Appendix Table 5A)

According to trend summaries in the 2006 report, in FY2005, there were 621 extramural Phase III clinical research protocols, of which 511 protocols reported human subject participation. Of these, 88.5% were domestic protocols and 4.9% were foreign protocols. Approximately 465,956 participants were enrolled in extramural Phase III research protocols of which 86% of total enrollment is domestic participants and 8.6% of total enrollment is foreign participants. Of the 465,956 participants, 59.5% were women, 39.5% were men and 1% did not provide sex identification. Further, 29.9% of the total participants in Phase III clinical research were reported as minorities following the OMB categories for race and ethnicity. (See 2006 Report, Table 4 and Appendix Table 5A)

Correspondingly, in FY2006, there were 382 extramural Phase III research protocols reporting data following the current 1997 OMB standards for reporting race and ethnicity. Accordingly, minority representation by race was highest for Blacks at 19.7% and lowest for Hawaiian/Pacific Islanders 0.2%. Asians represented 12.67%, American Indian/Alaska Natives 1.8% and Whites 46.32% of participants. Participants identifying as More Than One Race were 15% of the total number of participants. In addition, 17.8 % did not identify a race category. Of the 382 extramural Phase III research protocols designating an ethnicity in FY 2006, 75.8 % of total participants identified as "Not Hispanic", 11.14 % of the total participants identified as "Hispanic or Latino", and 13.1 % of the total participants did not identify an ethnicity category. The racial distribution of the "Hispanic or Latino" participants is also provided separately. (Appendix Table 5A)

In FY 2005, there were 319 extramural Phase III research protocols reporting data following the current 1997 OMB standards for reporting race and ethnicity. Accordingly, minority representation by race was highest for Blacks at 30.00 % and lowest for Hawaiian/Pacific Islanders 0.28%. Asians represented 5.44%, American Indian/Alaska Natives 1.30% and Whites 55.75% of participants. Participants identifying as More Than One Race were 1.56% of the total number of participants. In addition, 5.66 % did not identify a race category. Of the 319 extramural Phase III research protocols designating an ethnicity in FY2005, 88.7 % of total participants identified as "Not Hispanic", 5.98 % of the total participants identified as "Hispanic or Latino", and 5.32 % of the total participants did not identify an ethnicity category. The racial distribution of the "Hispanic or Latino" participants is also provided separately. (See 2006 Report, Appendix Table5A)

Of the 192 extramural Phase III research protocols that report following the 1977 OMB standards, minority representation was highest for Blacks (not Hispanic) at 13.03 and lowest for American Indian/Alaska Natives at 0.4%. Hispanics represented approximately 7.23%, Asian/Pacific Islanders were 1.81% and Whites (not Hispanic) 76.1% of the participants. The categories Hawaiian/Pacific Islander and More Than One Race were not designations with the 1977 OMB standards. (See 2006 Report, Appendix Table 5A)

While the number of participants in Phase III extramural clinical research protocols slightly increased, there was also some change in the ratio of women and men (59.5%F and 39.5%M in FY2005 and 63.5 %F and 35.4% M in FY2006).

INTRAMURAL CLINICAL RESEARCH: Fiscal Years 2005 and 2006

Substantial numbers of women and minorities were included in NIH intramural studies in FY 2005 and FY2006.

In FY2005, there were 1,795 intramural clinical research protocols, including Phase III and other clinical studies, of which 1,470 protocols reported human subject participation. Of these, 13.7% of the total protocols were domestic protocols and 0.7% of the total protocols were foreign protocols. Approximately 1.94 million participants were enrolled in intramural research protocols of which 10.4% of the total enrollment is domestic participation and 1.9% of the total enrollment is foreign participation. Of the 1.94 million participants, 48.7% were women, 50.5% were men and 0.79% did not provide sex identification. (See 2006 Report, Table 2 and Appendix Table 7A)

In FY2005, approximately 1.94 million participants were reported in all intramural research including Phase III clinical trials, and other clinical studies. Of the 733 intramural research protocols that report data following the 1977 OMB standards, minority representation was highest for Asian/Pacific Islanders at 17.8% and lowest for American Indian/Alaska Natives at 1.8%. Blacks (not-Hispanic) represented 7.5%, Hispanics 4.7%;

and Whites (not Hispanic) 60.9% of the intramural research study population. The categories Hawaiian/Pacific Islander and More Than One Race were not designations with the 1977 OMB standards. (See 2006 Report, Appendix Table 7A)

For the 737 intramural clinical research studies that reported data following the current 1997 OMB standards in FY 2005 the largest racial minority group was Blacks at 4.74% and the smallest racial minority group was Hawaiian/Pacific Islanders at 0.19%. Asians represented 3.1%, American Indian/Alaska Natives 0.42% and Whites 86.2% of participants in all intramural clinical research. Approximately 1% of participants reported More Than One Race as their racial category. In addition, 4.42 % did not identify a race category. Of the 737 intramural research protocols following the current 1997 OMB standards designating an ethnicity in FY 2005, 95.58 % of total participants identified as "Not Hispanic", 2.10 % of the total participants identified as "Hispanic or Latino", and 2.32 % of the total participants did not identify an ethnicity category. The racial distribution of the "Hispanic or Latino" participants is also provided separately. (See 2006 Report, Appendix 7A)

Correspondingly, in FY2006 there were 1,798 intramural clinical research protocols, including Phase III and other clinical studies, of which 1,523 protocols reported human subject participation. Approximately 1.8 million participants were enrolled in intramural research protocols of which 55.4% were women, 43.0% were men and 1.6% did not provide sex identification. (See Table 2 and Appendix Table 7A)

In FY 2006, approximately 1.8 million participants were reported in all intramural research including Phase III clinical trials, and other clinical studies. Of the 590 intramural research protocols that report data following the 1977 OMB standards, minority representation was highest for Asian/Pacific Islanders at 19.9% and lowest for American Indian/Alaska Natives at 3.3%. Blacks (not-Hispanic) represented 7.2%, Hispanics 3.5%; and Whites (not Hispanic) 62.0% of the intramural research study population. The categories Hawaiian/Pacific Islander and More Than One Race were not designations with the 1977 OMB standards. (See Appendix Table 7A)

For 933 intramural clinical research studies that reported data following the current 1997 OMB standards in FY 2006, the largest racial minority group was Asian at 8.6 % and the smallest racial minority group was Hawaiian/Pacific Islanders at 0.07%. Blacks represented 5.0%, American Indian/Alaska Natives 0.4% and Whites 79.1% of participants in all intramural clinical research. Approximately 0.8% of participants reported More Than One Race as their racial category. In addition, 6.0 % did not identify a race category. Of the 933 intramural research protocols following the current 1997 OMB standards designating an ethnicity in FY2006, 91.3 % of total participants identified as "Not Hispanic", 4.1 % of the total participants identified as "Hispanic or Latino", and 4.6 % of the total participants did not identify an ethnicity category. The racial distribution of the "Hispanic or Latino" participants is also provided separately. (See Appendix Table 7A)

There was an increase in female participants from 48.7% to 55.4% and a corresponding decrease in male participants from 50.5% to 43.0%. The number of participants in all intramural clinical research decreased slightly from 1.9M to 1.8M from FY2005 to FY2006.

NIH Defined Phase III Intramural Clinical Research: FY2005 and FY2006

In FY2005, there were 44 intramural Phase III clinical research protocols, of which 36 protocols reported human subject participation. Of these, 6% of the total protocols is domestic protocols and 0.5% of the total protocols is foreign protocols. Approximately 27,044 participants were enrolled in intramural Phase III research protocols of which 2.86% of total enrollment is domestic participation and 2.6% of total enrollment is foreign participation. Of the 27,044 participants, 50.5% were women, 49.5% were men and 0% did not provide sex identification. Further, 54.5% of the total participants in Phase III clinical research were reported as minorities following the OMB categories for race and ethnicity. (See 2006 Report, Table 4 and Appendix Table 9A)

Correspondingly, in FY2006 there were 53 intramural Phase III clinical research protocols, of which 44 protocols reported human subject participation. Of these, 6.3% of the total number of protocols is domestic and 0.7% of the total number of protocols is foreign. Approximately 31,476 participants were enrolled in intramural Phase III research protocols of which 2.34% of the total enrollment is domestic participants and 3.5% are foreign participants. Of the 31,476 participants, 54% were women, 46% were men and 0% did not provide sex identification. Further, 54% of total participants in Phase III clinical research protocols were reported as minorities following the OMB categories for race and ethnicity. (Table 4 and Appendix Table 9A)

There was a small increase in women (50.5% to 54.0%) and corresponding decrease in men (49.5% to 46.0%). The number of participants in Phase III intramural clinical research increased from 27,044 to 31,476.

TREND REPORT ON NIH AGGREGATE POPULATION DATA: FY 1995 – FY 2006

The following section is a new addition to the Annual Comprehensive report. Tables 5-11 provide trend data on the collection and reporting of human subject participation in NIH funded clinical research, which includes Phase III clinical studies; trend data are also provided in terms of foreign and domestic participation. Trend data vary over time because the data for each year represent the net total of data resulting from: (1) studies continuing from the prior year; (2) the addition of new studies reported; and (3) the subtraction of studies that are no longer reported.

Table 5 is a twelve year summary report showing a steady increase in the number of protocols and enrollment. The number of protocols with

enrollment increased from 3,188 in FY1995 to 10,758 in FY2006 – a 3.4 fold increase. Reported enrollment increased from approximately 1.0 million (FY1995) to 14.8 million (FY2006) – a 14.5 fold increase; minority enrollment increased from approximately 0.4 million (FY2002) to 6.4 million (FY2006) – a 17.1 increase in minority representation in NIH clinical research. Over the last five years, the total number of protocols reported with enrollment data has leveled off at about 10,000 protocols per year.

With the deployment of a new population tracking system in 2002 and the requirement to report data using a new format, NIH was able to report domestic and foreign data in a better way. Thus, trend data are now available for domestic and foreign protocols and participation beginning in FY2002. Domestic enrollment increased from 10.2 million (FY2002) to 11.4 million (FY2006) – a 1.1 fold increase. Foreign enrollment increased from 0.9 million (FY2002) to 3.4 million (FY2006) – a 3.6 fold increase. Overall, the total enrollment has increased with domestic participation averaging between 75.9-91.5% and foreign participation averaging between 8.5-24.1%. In FY2006, domestic and foreign enrollment was 77.0% and 23.0% respectively.

Table 6 is a summary report of all extramural and intramural clinical research by sex/gender and minority representation following the old and new data formats for domestic and foreign studies. The report demonstrates that female participation in all extramural and intramural research generally averaged between 51.7% and 63.9%, male participation in all extramural and intramural research averaged between 34.9% and 45.0%. Overall minority participation in all extramural and intramural clinical research averaged between 31% and 43%. Table 6E provides a comparison of domestic and foreign participation between FY2002 and FY2006. The vast majority of protocols are domestic (~94%-96%) of the total clinical research protocols. While the number of foreign protocols has increased, they incorporate only about 4%-6% of the total clinical research protocols with enrollment. Table 6F shows domestic and foreign enrollment for the five-year period. Domestic minority enrollment varied between 24.1% and 28.9% of total domestic participation, while foreign minority enrollment varied between 82.2% and 90.9% of total foreign participation.

Table 7 is a summary report of NIH-funded Phase III extramural and intramural clinical research by sex/gender and minority representation following the old and new data reporting formats for domestic and foreign studies. The report demonstrates that female participation in NIH funded Phase III extramural and intramural clinical research generally averaged between 54.1% and 74.8% and male participation in NIH-funded Phase III extramural and intramural clinical research averaged between 24.3% and 44.6%. Overall minority participation in NIH-funded Phase III extramural and intramural clinical research increased from 26.9% to 33.5%. Table 7E provides a comparison of domestic and foreign participation between FY2002 and FY2006. The vast majority of protocols are domestic (75.5% and 95.8%) of the total clinical research protocols. While the number of foreign protocols has decreased, they incorporate only about 4.2%-9.6% of the total clinical research protocols with enrollment in the last three years. Table 7F shows domestic and foreign enrollment for the five-year period. Domestic minority enrollment

varied between 20.7% and 25.4% of total domestic participation, while foreign minority enrollment in NIH-funded Phase III clinical research varied between 48.4% and 85.2% of total foreign participation. Comparing both domestic and foreign Phase III enrollment over the five year period shows that the small percentage of foreign protocols(9.6%) in FY2006 account for a significant proportion (19.8%) of the total enrollment.

Tables 8-11 provide summary reports of domestic and foreign participation for NIH funded clinical research and NIH-funded Phase III clinical research. For extramural and intramural clinical research, domestic participants enrolled in domestic protocols, female participation averaged between 61.8 and 67.3% while male participation averaged between 31.2 and 36.9%. (Table 8) For NIH-funded Phase III extramural and intramural clinical research, domestic participants enrolled in domestic protocols, female participation averaged between 54.8 and 64.6% while male participation averaged between 34.4 and 44.8%. (Table 9) For all extramural and intramural clinical research, foreign participants enrolled in foreign protocols, female participation varied from 39.2% to 58.5% while male participation varied from 40.1% to 60.4%. (Table 10) For NIH-funded Phase III extramural and intramural clinical research, foreign participants enrolled in foreign protocols, female participation varied from 47.4% to 56.7% while male participation varied from 42.0% to 52.5%. (Table 11)

Table 1. Summary of NIH Clinical Research Reported In FY2006: Total Number of Protocols and Enrollment By Sex and Domestic versus Foreign Protocols

1A. Protocols Reported	Total All Clinical Studies*	Domestic	%	Foreign	%
Protocols with Enrollment	10,758	10,294	95.7%	464	4.3%
%	70.2%	70.3%		69.3%	
Protocols with zero enrollment. Enrollment data has not yet been submitted	4,562	4,356	95.5%	206	4.5%
	29.8%	29.7%		30.7%	

Total Number of Protocols	15,320	14,650	95.6%	670	4.4%
%	100.0%	100.0%		100.0%	

1B. Enrollment Reported	Total All Clinical Studies*	Domestic	%	Foreign	%
Females Enrolled	9,473,273	7,684,453	81.1%	1,788,820	18.9%
%	63.9%	67.3%		52.5%	
Males Enrolled	5,172,205	3,566,577	69.0%	1,605,628	31.0%
%	34.9%	31.2%		47.2%	
Sex of Subjects is Unknown	185,452	174,671	94.2%	10,781	5.8%
%	1.3%	1.5%		0.3%	
Total Subjects Enrolled	14,830,930	11,425,701	77.0%	3,405,229	23.0%
%	100.0%	100.0%		100.0%	

1C. Minority Enrollment Reported	Total All Clinical Studies*	Domestic	%	Foreign	%
Minority Total**	6,388,316	3,301,135	51.7%	3,087,181	48.3%
% Minority Enrollment	43.1%	28.9%		90.7%	

* Clinical research studies include non-intervention clinical research, clinical trials, epidemiologic studies, behavioral studies, database studies, etc., based on the NIH definition of clinical research. "Total All Clinical Studies" includes NIH Defined Phase III Clinical Trials.

** See Appendix H for the Race and Ethnicity categories included in Minority Enrollment Data from the 1977 and 1997 U.S. OMB race/ethnicity categories. Foreign enrollment was reported using the U.S. race and ethnicity categories.

NOTE: Percentages are reported with one decimal point; due to rounding, adding percentages may not equal 100%.

Comments

Table 1. Summary of NIH Clinical Research Reported In FY2006: Total Number of Protocols and Enrollment By Sex and Domestic versus Foreign Protocols

Table 1A: Total Number of Protocols

1. The total number of protocols reported in the NIH database in FY2006 was 15,320; of these, 10,758 (70.2%) reported subject enrollment.
2. Subsequent Tables reporting "Enrollment Reported" are based on the 10,758 protocols reporting subject enrollment, or a defined subset.
3. Protocols with zero enrollment (data not yet submitted) are not included in subsequent tables reporting "Enrollment reported."

Total Domestic Protocols

- Domestic protocols made up the vast majority of protocols (14,650; 95.6%); of these, 10,294 (70.3%) reported domestic subject enrollment.
- Clinical Research involving both domestic and foreign sites are reported as separate domestic and foreign protocols in subsequent tables.

Table 1B: Total Enrollment Reported

- The total “Enrollment Reported” in the NIH database in FY2006 was 14,830,930 subjects in 10,758 protocols with enrollment.
- Females made up 63.9% (9.5M) of the total subjects enrolled, while Males made up 31.2%(5.2M), with 1.3% unknown.

Total Domestic Enrollment Reported

- The total Domestic Enrollment reported was 11,425,701 (77%).
- Females made up 67.3%(7.7M) of the domestic subjects enrolled, while Males made up 31.2%(3.56M), with1.5%(.17M) unknown.

Table 1C Comments: Minority Enrollment Reported

- Minorities made up 43.1% (6.4M) of the total subjects enrolled.
- Minorities made up 28.9%(3.3M) of the Domestic Enrollment.
- The Total Minority Enrollment was made up of 51.7% Domestic and 48.3% Foreign enrollment The small percentage of foreign protocols (4.0%) account for a significant proportion (48.3%) of the total minority enrollment.

Table 2: Overview of NIH Extramural and Intramural Clinical Research Reported in FY2006: Number of Sex-Specific Protocols, and Domestic versus Foreign Protocols

		Domestic				Foreign			
2A. Protocols Reported	Total All Clinical Studies	Extramural	%	Intramural	%	Extramural	%	Intramural	%
Number of Protocols reporting females only	1,338	1,162	86.8%	124	9.3%	46	3.4%	6	0.4%

%	8.7%	9.0%		7.3%		8.1%		6.1%	
Number of Protocols reporting males only	581	468	80.6%	93	16.0%	17	2.9%	3	0.5%
%	3.8%	3.6%		5.5%		3.0%		3.0%	
Number of Protocols with Both Female and Male Enrollment (excluding sexspecific protocols)	8,839	7,221	81.7%	1,226	13.9%	321	3.6%	71	0.8%
%	57.7%	55.8%		72.2%		56.2%		71.7%	
Total Number of Protocols with Enrollment	10,758	8,851	82.3%	1,443	13.4%	384	3.6%	80	0.7%
%	70.2%	68%		84.9%		67.3%		80.8%	
Number of Protocols with zero enrollment. Enrollment data has not yet been submitted.	4,562	4,100	89.9%	256	5.6%	187	4.1%	19	0.4%
%	29.8%	31.7%		15.1%		32.7%		19.2%	
Total Number of Protocols	15,320	12,951	84.5%	1,699	11.1%	571	3.7%	99	0.6%
%	100.0%	100.0%		100.0%		100.0%		100.0%	

		Domestic				Foreign			
2B. Enrollment Reported	Total All Clinical Studies*	Extramural	%	Intramural	%	Extramural	%	Intramural	%
In Protocols reporting females only	4,120,055	3,678,382	89.3%	202,024	4.9%	115,369	2.8%	124,280	3.0%
%	27.8%	36.9%		13.9%		3.8%		35.0%	
In Protocols reporting males only	336,717	274,774	81.6%	3,294	1.0%	32,552	9.7%	26,097	7.8%
%	2.3%	2.8%		0.2%		1.1%		7.3%	
In Protocols excluding female-only and male-only enrollment protocols	10,374,158	6,018,281	58.0%	1,248,946	12.0%	2,902,088	28.0%	204,843	2.0%
%	69.9%	60.4%		85.9%		95.2%		57.7%	
Enrollment Totals for all studies	14,830,930	9,971,437	67.2%	1,454,264	9.8%	3,050,009	20.6%	355,220	2.4%
%	100.0%	100.0%		100.0%		100.0%		100.0%	

		Domestic				Foreign			
2C. Minority Enrollment Reported**	Total All Clinical Studies*	Extramural	%	Intramural	%	Extramural	%	Intramural	%
Minority Totals for all studies	6,388,316	3,102,731	48.6%	198,404	3.1%	2,878,826	45.1%	208,355	3.3%
% Minority enrollment	43.1%	31.1%		13.6%		94.4%		58.7%	

**See Appendix H for the Race and Ethnicity categories included in Minority Enrollment Data from the 1977 and 1997 U.S. OMB race/ethnicity categories. Foreign enrollment was reported using the U.S. race and ethnicity categories.

Comments

Table 2: Overview of NIH Extramural and Intramural Clinical Research Reported in FY2006: Number of Sex- Specific Protocols, and Domestic versus Foreign Protocols

Table 2A Total Number of Protocols with Enrollment

1. Female Only Protocols: There were 1,338 protocols reporting females only, representing 12.4 %(1338/10,758) of protocols with enrollment.

90% were Extramural projects(1,162+46); 10% were NIH intramural projects(124+6).

96% were Domestic protocols(1162+124);4% were Foreign protocols(40+6).

2. Male Only Protocols: There were 581 protocols reporting males only, representing 5%(558/10,758) of protocols with enrollment.

83 % were Extramural projects(468+17); 17% were NIH intramural projects(93+3)

97% were Domestic protocols(468+93); 3 % were Foreign protocols(17+3).

3. Protocols Reporting Both Females and Males (excluding sex-specific protocols): There were 8,839 protocols reporting both female and male participants representing 82%(8,839/10,758) of the total number of protocols.

85% were Extramural projects(7,221+321); 15% were NIH intramural projects(1,226+71)

Table 2B Total Enrollment Reported

1. In Female Only Protocols: There were approximately 4.1 M females, representing 28% of total enrollment.

92.1% were in Extramural projects; 7.9% were in NIH intramural projects.

94.2% were in Domestic protocols; 5.8% were in Foreign protocols.

2. In Male Only Protocols: There were approximately 336,717 males, representing 2.3% of total enrollment.

91.3% were in Extramural projects; 18.8% were in NIH intramural projects.

82.6% were Domestic in protocols 17.4 % were Foreign protocols.

3. In Protocols Reporting Both Females and Males (excluding sex-specific studies): There were approximately 10,374,158 subjects, representing 70% of total enrollment.

86% were in Extramural projects;14% were in NIH intramural projects. 70% were in Domestic protocols; 30% were in Foreign protocols. 96% were Domestic protocols(7,221+1,226);4% were Foreign protocols(321+71).

Table 2C Minority Enrollment Reported

1. Total Minority Enrollment: 43.1% of Total Enrollment (14.8M).

Total Minority Enrollment, Domestic only: 28.9% (3,301,135/11,425,701)

Total Domestic Minority Enrollment: 51.7% (3,301,135/6,388,316)

Total Foreign Minority Enrollment: 48.3% (3,087,181/6,388,316)

Total Extramural projects Minority enrollment: 40.33% (5,981,557/14,830,930)

Total Intramural Projects Minority enrollment: 2.74% (406,759/14,830,930)

Table 3. Summary of NIH Phase III Clinical Research Reported In FY2006: Total Number of Protocols and Enrollment by Sex, and Domestic versus Foreign Protocols

3A. Protocols Reported	Total of Phase III Clinical Trials*	Domestic	%	Foreign	%
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Protocols with Enrollment	624	564	90.4%	60	9.6%
%	82.1%	82.0%		83.3%	
Protocols with zero enrollment. Enrollment data has not yet been submitted.	136	124	91.2%	12	8.8%
	17.9%	18.0%		16.7%	
Total Number of Protocols	760	688	90.5%	72	9.5%
%	100.0%	100.0%		100.0%	

3B. Enrollment Reported	Total of Phase III Clinical Trials*	Domestic	%	Foreign	%
Females Enrolled	314,066	258,467	82.3%	55,599	17.7%
%	62.9%	64.6%		56.1%	
Males Enrolled	179,975	137,621	76.5%	42,354	23.5%
%	36.0%	34.4%		42.7%	

Sex of Subjects is Unknown	5,389	4,209	78.1%	1,180	0.0%
%	1.1%	1.1%		1.2%	
Total Subjects Enrolled	499,430	400,297	80.2%	99,133	19.8%
%	100.0%	100.0%		100.0%	

3C. Minority Enrollment Reported **	Total of Phase III Clinical Trials*	Domestic	%	Foreign	%
Minority Total for all Phase III studies	167,446	83,034	49.6%	84,412	50.4%
	33.5%	20.7%		85.2%	

* An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care.

**See Appendix H for the Race and Ethnicity categories included in Minority Enrollment Data from the 1977 and 1997 U.S. OMB race/ethnicity categories. Foreign enrollment was reported using the U.S. race and ethnicity categories.

NOTE: Percentages are reported with one decimal point; due to rounding, adding percentages may not equal 100%.

Comments

Table 3. Summary of NIH Phase III Clinical Research Reported In FY2006: Total Number of Protocols and Enrollment by Sex, and Domestic versus Foreign Protocols.

Table 3A Total Number of Protocols

1. The total number of NIH defined Phase III Clinical protocols reported in the NIH database in FY2006 was 760; of these, 624(82.1%) reported subject enrollment.
2. Subsequent Tables reporting “Enrollment Reported” are based on the 624 protocols reporting subject enrollment, or a defined subset.
3. Protocols with zero enrollment (data not yet submitted) are not included in subsequent tables reporting “Enrollment reported.”

Total Domestic Protocols

4. Domestic protocols made up the vast majority of protocols (688; 90.5%); of these 564(82%) reported domestic subject enrollment.
5. Clinical Research involving both domestic and foreign sites are reported as separate domestic and foreign protocols in subsequent tables.

Table 3B: Total Enrollment Reported

1. The total “Enrollment Reported” in NIH Defined Phase III Protocols in the NIH database in FY2006 was 499,430 subjects in 624 protocols.
2. Females made up 62.9% (314,068) of the total subjects enrolled, while Males made up 36.0%(179,975), with 1.1%(5,389) unknown.
3. Minorities made up 33.5% (167,446) of the total subjects enrolled.

Total Domestic Enrollment Reported

4. The total Domestic Enrollment reported was 400,297(80.2%).
5. Females made up 64.6%(258,467) of the domestic subjects enrolled, while Males made up 34.4%(137,621), with 1.1%(4,209) unknown.

Table 3C Comments: Minority Enrollment Reported

1. Minorities made up 33.5% of total subjects enrolled.
2. Minorities made up 20.7%(83,034) of the Domestic Enrollment (400,297).
3. The Total Minority Enrollment was made up of 49.6% Domestic and 50.4% Foreign enrollment.

Table 4: Overview of NIH Phase III Extramural and Intramural Clinical Research Reported In FY2006: Number of Sex-Specific Protocols and Enrollment, and Domestic versus Foreign Protocols

		Domestic				Foreign			
4A. Protocols Reported	Total All Clinical Studies*	Extramural	%	Intramural	%	Extramural	%	Intramural	%
Number of Protocols reporting females only	118	101	85.6%	2	1.7%	14	11.9%	1	0.8%
%	15.5%	15.8%		4.2%		20.9%		20.0%	
Number of Protocols reporting males only	47	39	83.0%	4	8.5%	4	8.5%	0	0.0%
%	6.2%	6.1%		8.3%		6.0%		0.0%	
Protocols with Both Female and Male Enrollment (excluding sex-specific protocols)	459	384	83.7%	34	7.4%	38	8.3%	3	0.7%
%	60.4%	60.0%		70.8%		56.7%		60.0%	
Total Number of Protocols with Enrollment	624	524	84.0%	40	6.4%	56	9.0%	4	0.6%
%	82.1%	82%		83.3%		83.6%		80.0%	
Phase III Protocols with zero enrollment. Enrollment data has not yet been submitted.	136	116	85.3%	8	5.9%	11	8.1%	1	0.0%

%	17.9%	18.1%		16.7%		16.4%		20.0%	
Total Number of Phase III Protocols	760	640	84.2%	48	6.3%	67	8.8%	5	0.7%
%	100.0%	100.0%		100.0%		100.0%		100.0%	

			Domestic				Foreign			
4B. Enrollment Reported		Total of Phase III Clinical Trials*	Extramural	%	Intramural	%	Extramural	%	Intramural	%
Protocols reporting female only		167,624	148,185	88.4%	4	0.0%	17,195	10.3%	2240	1.3%
%		33.6%	38.4%		0.0%		21.0%		13.0%	
Protocols reporting male only		27,723	23,312	84.1%	177	0.6%	4,234	15.3%	0	0.0%
%		5.6%	6.0%		1.2%		5.2%		0.0%	

Protocols excluding female-only and men-only enrollment protocols		304,083	214,619	70.6%	14,000	4.6%	60,409	19.9%	15,055	5.0%	
%		60.9%	55.6%		98.7%		73.8%		87.0%		
Total Subjects Enrolled		499,430	386,116	77.3%	14,181	2.84%	81,838	16.39%	17,295	3.5%	
%		100.0%	100.0%		100.0%		100.0%		100.0%		

		Domestic				Foreign			
4C. Minority Enrollment Reported**	Total of Phase III Clinical Trials*	Extramural	%	Intramural	%	Extramural	%	Intramural	%
Minority Total for all Phase III studies	167,624	80,622	48.1%	2,412	1.4%	69,820	41.7%	14,592	8.7%

%	33.5%	20.9%	17.0%	85.3%	84.4%
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* An NIH-defined Phase III clinical trial is a broadly based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care.

**See Appendix H for the Race and Ethnicity categories included in Minority Enrollment Data from the 1977 and 1997 U.S. OMB race/ethnicity categories. Foreign enrollment was reported using the U.S. race and ethnicity categories.

Comments

Table 4. Overview of NIH Phase III Extramural and Intramural Clinical Research Reported In FY2006 : Number of Sex-Specific Protocols and Enrollment, and Domestic versus Foreign Protocols

Table 4A Total Number of Protocols with Enrollment

1. Female Only: There were 118 protocols reporting females only, representing 19 % (118/624) of protocols with enrollment, and 15.5% of the Total Number of Protocols.

97% were Extramural projects (115);3% were NIH intramural projects (3).

87% were Domestic protocols (103); 13% were Foreign protocols (15).

2. Male Only: There were 47 protocols reporting males only, representing 8% (47/624) of protocols with enrollment, and 6.2% o the Total Number of Protocols.

91% were Extramural projects (43); 9% were NIH intramural projects (4).

91% were Domestic protocols (43);9% were Foreign protocols (4).

3. Protocols Reporting Both Females and Males (excluding sex-specific protocols): There were 459 protocols reporting both males and females representing 60.4 % of the total number of protocols.

92.0% were Extramural projects (422); 8.0% were NIH intramural projects (37).

91% were Domestic protocols (418); 9.0% were Foreign protocols (41).

Table 4B Total Enrollment Reported

1. In Female Only Protocols: There were approximately 167,624 females, representing 33.6% of total enrollment.

98.7% (165,380) were in Extramural projects; 1.3% (2,244) were in NIH intramural projects.

88.4% (148,189) were in Domestic protocols; 11.67% (19,435) were in Foreign protocols.

2. In Male Only Protocols: There were approximately 27,723 males, representing 5.6% of total enrollment.

99.4% (27,546) were in Extramural projects; 0.6% (177) were in NIH intramural projects.

84.7% (23,489) were in Domestic protocols; 15.3% (4,234) were in Foreign protocols.

3. Protocols Reporting Both Females and Males (excluding sex-specific protocols): There were approximately 304,083 subjects, representing 60.9% of total enrollment.

90.45% (275,028) were in Extramural projects; 9.55% (29,055) were in NIH intramural projects.

75.2% (228,619) were in Domestic protocols; 24.8% (75,464) were in Foreign protocols.

Table 4C Minority Enrollment Reported

1. Total Minority Enrollment was 33.5% (167,446) of Total Enrollment (499,430).

Total Minority enrollment, Extramural protocols (150,442), was 30.12% of Total Enrollment (499,430) and 89.9% of Total Minority Enrollment (167,446).

Total Minority enrollment, Intramural Projects (17,004), was 3.4% of Total Enrollment (499,430) and 10.15% of Total Minority Enrollment (167,446).

2. Total Minority Enrollment, Domestic only (83,034), was 20.7% of total Domestic Enrollment (400,297) and 49.6% of Total Minority Enrollment (167,446).

3. Total Minority Enrollment, Foreign (84,412), was 85.15% of Total Foreign Enrollment (99,133) and 50.4% of Total Minority Enrollment (167,446).

5A. Twelve Year Increases in Protocols and Enrollment Data

FY Reported	1995		2006	Relative Increase,
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				2006 / 1995
Total Protocols with Enrollment	3,188		10,758	3.4
Total Enrollment	1,021,493		14,830,930	14.5
Total Minorities	374,433		6,388,316	17.1
% of Minority	36.7%		43.1%	1.2
FY Reported	2002		2006	Relative Increase 2006 / 2002
Total DOMESTIC Enrollment data	10,192,401		11,425,701	1.1
Total FOREIGN Enrollment	946,083		3,405,229	3.6

Table 5A Comments:

1. There was a 3.4 fold increase in protocols with enrollment reported from 1995 to 2006, from 3,188 protocols to 10,758 protocols.
2. There was a 14.5 fold increase in enrollment reported from 1995 to 2006, from approximately 1M to 15 M.
3. There was a 17.1 fold increase in minority enrollment from 1995 to 2006, from approximately 0.4 M to 6.4 M.
4. Domestic and Foreign data were reported for FY 2002-2006, and showed 1.1 fold increase in domestic enrollment (from 10.2M to 11.4M) and a 3.6 fold increase in foreign enrollment (from 0.95M to 3.4M).
5. See Table 6 for 12 year enrollment totals 1995-2006.

*NOTE: Trend data varies over time because the data for each year represent the net total of data resulting from (1) studies continuing from the prior year; (2) the addition of new studies reported and (3) the subtraction of studies that are no longer reported.

5B. Twelve Year Summary of Total Number of Protocols Reported: FY 1995-2006

FY Reported	FY Funded	Number of Protocols with Enrollment data (Old +New Forms):	Number of DOMESTIC Protocols with Enrollment data	Number of FOREIGN Protocols with Enrollment data	Percent Domestic Protocols	Protocol Form*
1995	1994	3,188				OLD
1996	1995	6,036				
1997	1996	5,692				
1998	1997	7,602				
1999	1998	8,285				
2000	1999	9,390				
2001	2000	10,212				OLD
2002	2001	8,945	8,463	482	94.6%	Old + New
2003	2002	10,216	9,578	638	93.8%	
2004	2003	10,125	9,760	365	96.4%	
2005	2004	10,233	9,862	371	96.4%	

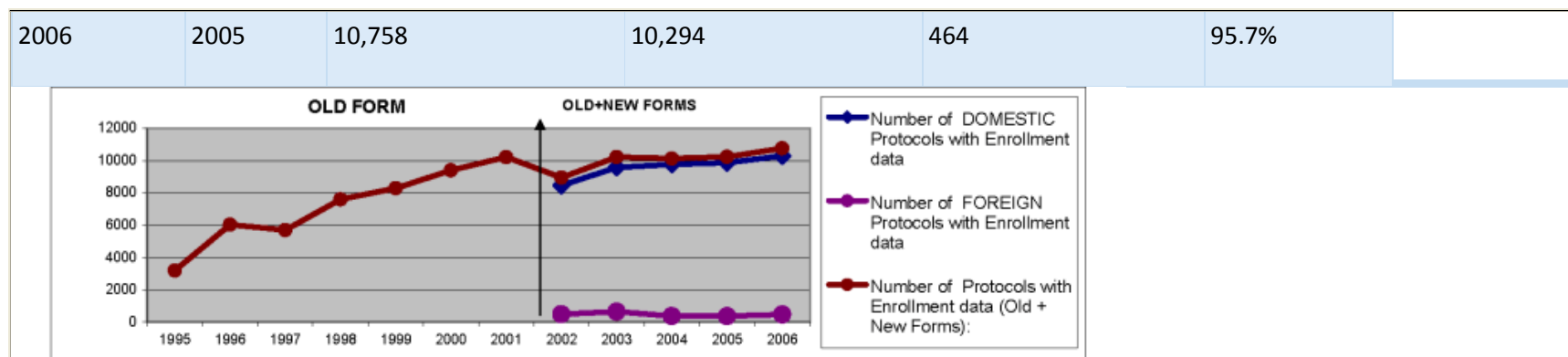


Table 5B Comments:

1. Table 5B and 5B Graph provide the number of OLD and NEW protocols year by year (1995-2006) and the distribution between domestic and foreign protocols for years 2002-2006.
2. The total number of protocols reported with enrollment have leveled off at about 15,000 over the last 4 years.
3. The vast majority of protocols were for domestic studies for 2002-2006, ranging from 93.8% to 96.4% of protocols.

* Data have been reported using a combined race/ethnicity format (OLD FORM) since 1995. New protocols began reporting separate race and ethnicity data in FY2002 (NEW FORM). During 2002-2006, data have been reported using both Old and New Forms.

*See Appendix H for the Race and Ethnicity categories included in Minority Enrollment Data from the 1977 and 1997 U.S. OMB race/ethnicity categories. Foreign enrollment was reported using the U.S. race and ethnicity categories.

5C. Comparison of Domestic and Foreign Enrollment Reported in FY 2002-2006						
FY Reported	FY Funded	Total Enrollment data (Old +NewForms):	Total DOMESTIC Enrollment data	PercentDOMESTIC Enrollment	Total FOREIGN Enrollment	Percent FOREIGNEnrollment
2002	2001	11,138,484	10,192,401	91.5%	946,083	8.5%

2003	2002	14,772,254	11,911,357	80.6%	2,860,897	19.4%
2004	2003	18,923,920	14,359,793	75.9%	4,564,127	24.1%
2005	2004	15,722,752	12,669,858	80.6%	3,052,894	19.4%
2006	2005	14,830,930	11,425,701	77.0%	3,405,229	23.0%

Percent Comparison of Domestic and Foreign Enrollment

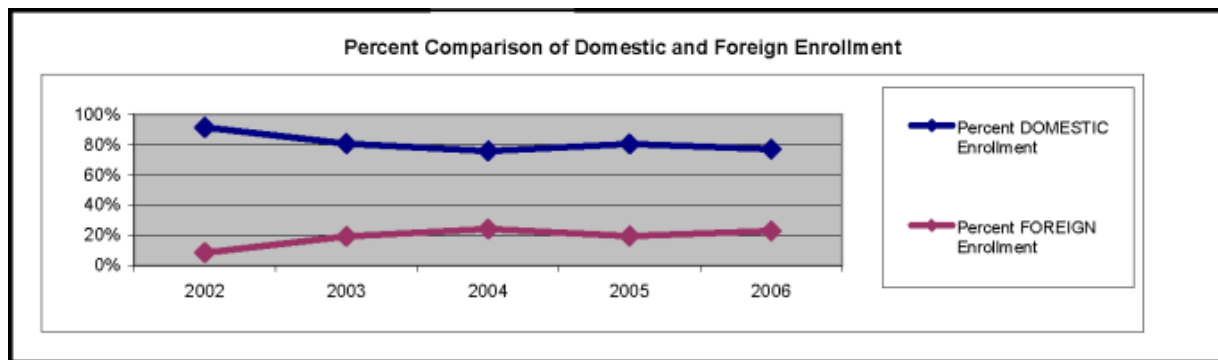


Table 5C Comments:

1. Overall total enrollment has increased, as well as total domestic and foreign enrollment during the last five years. The percentage of domestic enrollment has decreased to approximately 79% as the foreign enrollment has increased to approximately 21%.

PROTOCOLS (Old + New Forms)								
FY Reported	FY Funded	Form	Females	Males	Unknown	Total All Subjects (Old + New Forms)	Subtotal: All Subjects Enrolled by US Minority Categories	Number of Protocols with Enrollment data (Old + New Forms):
1995	1994	Old	528,421	459,921	33,151	1,021,493	374,433	3,188
	%		51.7%	45.0%	3.2%	100.0%	36.7%	
1996	1995	Old	4,130,385	2,583,865	91,054	6,805,304	2,125,958	6,036
	%		60.7%	38.0%	1.3%	100.0%	31.2%	
1997	1996	Old	3,320,610	1,930,783	65,540	5,316,933	1,709,223	5,692
	%		62.5%	36.3%	1.2%	100.0%	32.2%	
1998	1997	Old	4,246,130	2,716,880	115,566	7,078,576	2,923,662	7,602
	%		60.0%	38.4%	1.6%	100.0%	41.3%	
1999	1998	Old	5,102,306	2,712,068	169,863	7,984,237	3,108,228	8,285
	%		63.9%	34.0%	2.1%	100.0%	38.9%	
2000	1999	Old	5,585,042	3,919,065	64,990	9,569,097	3,406,297	9,390

	%		58.4%	41.0%	0.7%	100.0%	35.6%	
2001	2000	Old	6,808,822	4,740,887	44,547	11,594,256	3,619,119	10,212
2002	2001	Old + New	58.7%	40.9%	0.4%	100.0%	31.1%	8,945
	%		7,155,549	3,904,560	78,375	11,138,484	3,666,880	
2003	2002	Old + New	64.2%	35.1%	0.7%	100%	32.9%	
			8,514,481	6,121,496	136,277	14,772,254	5,387,692	10,216
2004	2003	Old + New	57.6%	41.4%	0.9%	100.0%	36.5%	10,125
	%		10,889,097	7,741,892	292,931	18,923,920	7,611,611	
2005	2004	Old + New	57.5%	40.9%	1.5%	100.0%	40.2%	
			9,503,922	5,941,907	276,923	15,722,752	6,245,436	10,233
2006	2005	Old + New	60.4%	37.8%	1.8%	100.0%	39.7%	10,758
	%		9,473,273	5,172,205	185,452	14,830,930	6,388,316	
			63.9%	34.9%	1.25%	100.0%	43.1%	
Total Minority Enrollment by Year Reported					Sex/Gender Enrollment by Year Reported			

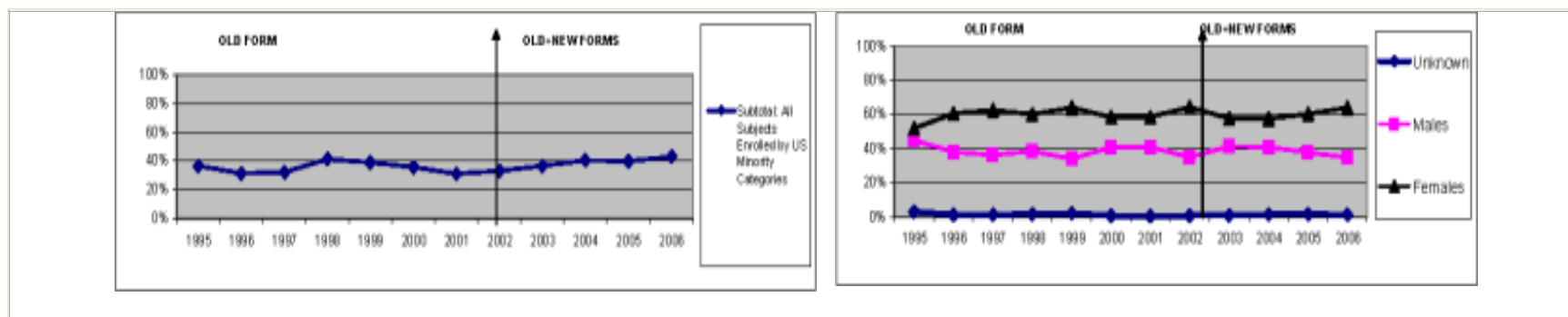


Table 6A Comments:

1. Table 6A summarizes enrollment by sex/gender and minority race/ethnicity categories for the twelve year reporting period (1995-2006). The data are compiled from Tables 6B, 6C and 6D below, which provide the detailed distributions by sex/gender and race/ethnicity using the OLD Enrollment Form (Table 6B) and the NEW Enrollment Form (Tables 6C and 6D).

2. The Race and Ethnicity data in the OLD FORM and the NEW FORM cannot be combined by individual race and ethnicity categories because the categories reflect the different OMB Formats used based on the 1977 OMB standards (OLD FORM) and the 1997 OMB Standards (NEW FORM).

NOTE: Trend data varies over time because the data for each year represent the net total of data resulting from:(1) studies continuing from the prior year; (2) the addition of new studies reported; (3) and the subtraction of studies that are no longer reported.

Notes Tables B-D

NOTE 1: The shaded portions of the Tables B, C and D below show the race/ethnicity categories that are identified as minority categories. The Data Reported in FY 2002 and later are from the new Population Tracking System that was deployed with data reported in FY 2002 and later, and allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

NOTE 2: Data from Tables 6B, 6C and 6D are combined to provide the summary data in Table 6A.

6B. OLD FORM: Total of All Subjects Reported Using the 1977 OMB Standards in a Combined Race/Ethnicity Format

FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown/Other	Total	Subtotal Using US Minority Categories shaded): OLD FORM	Number Protocols with Enrollment data (Old Form):
1995	1994	11,221	38,952	234,976	89,284	540,313	106,747	1,021,493	374,433	3,188
	%	1.1%	3.8%	23.0%	8.7%	52.9%	10.5%	100.0%	36.7%	
1996	1995	146,319	617,211	823,102	539,326	4,114,249	565,097	6,805,304	2,125,958	6,036
	%	2.2%	9.1%	12.1%	7.9%	60.5%	8.3%	100.0%	31.2%	
1997	1996	36,638	321,479	864,102	487,004	3,199,778	407,932	5,316,933	1,709,223	5,692
	%	0.7%	6.0%	16.3%	9.2%	60.2%	7.7%	100.0%	32.1%	
1998	1997	71,436	1,429,022	1,081,210	526,560	4,470,966	405,043	7,984,237	3,108,228	8,285
	%	1.2%	17.5%	15.5%	7.1%	52.5%	6.2%	100.0%	41.3%	
1999	1998	71,436	1,429,022	1,081,210	526,560	4,470,966	405,043	7,984,237	3,108,228	8,285

	%	0.9%	17.9%	13.5%	6.6%	56.0%	5.1%	100.0%	38.9%	
2000	1999	82,728	1,525,392	1,209,769	588,408	5,588,942	573,858	9,569,097	3,406,297	9,390
	%	0.9%	15.9%	12.6%	6.1%	58.4%	6.0%	100.0%	35.6%	
2001	2000	105,067	1,495,279	1,199,625	819,148	7,314,449	660,688	11,594,256	3,619,119	10,212
	%	0.9%	12.9%	10.3%	7.1%	63.1%	5.7%	100.0%	31.2%	
2002	2001	45,843	1,222,296	702,234	398,657	4,044,052	321,349	6,734,431	2,369,030	6,187
	%	0.7%	18.1%	10.4%	5.9%	60.1%	4.8%	100.0%	35.2%	
2003	2002	36,579	730,542	472,426	288,523	3,238,284	278,901	5,045,255	1,528,070	4,903
	%	0.7%	14.5%	9.4%	5.7%	64.2%	5.5%	100.0%	30.3%	
2004	2003	29,387	307,052	342,188	214,322	2,348,529	172,130	3,413,608	892,949	2,782
	%	0.9%	9.0%	10.0%	6.3%	68.8%	5.0%	100.0%	26.2%	
2005	2004	22,375	254,598	229,615	134,972	1,267,089	102,405	2,011,054	641,560	1,786
	%	1.1%	12.7%	11.4%	6.7%	63.0%	5.1%	100.0%	31.9%	

2006	2005	19,648	131,786	148,948	78,596	883,041	63,231	1,325,250	378,978	1,391
	%	1.5%	9.9%	11.2%	5.9%	66.6%	4.8%	100.0%	28.6%	

ORIENTATION TO TABLES 6C and 6D.

1. The New Form consists of Parts A and B (Tables 6C and 6D) for reporting years 2002-2006. This Form is provided as part of the annual progress report.
2. Table 6C displays the New Form Part A for reporting separate race and ethnicity data.
3. Table 6D displays the New Form Part B, which is the Distribution of Hispanics reported by race, using the totals from the “Hispanic or Latino” column in Part A.

6C. New Form Part A: Total of All Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity Formats													
Total of All Subjects by Race										Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian/Alaska Native	Asian	Black or African American	Hawaiian/Pacific Islander	White	More Than One Race	Unknown/Other	Total*	Not Hispanic	Hispanic or Latino**	Unknown/Not Reported	Total*
2002	2001	77,734	354,049	547,776	21,636	2,651,541	30,955	720,362	4,404,053	3,071,952	292,429	1,039,672	4,404,053
	%	1.8%	8.0%	12.4%	0.5%	60.2%	0.7%	16.4%	100.0%	69.8%	6.6%	23.6%	100.0%
2003	2002	63,544	2,138,002	960,090	37,569	5,415,711	99,462	1,012,621	9,726,999	8,162,259	611,641	953,099	9,726,999

			2			0		2					
	%	0.7%	22.0%	9.9%	0.4%	55.7%	1.0%	10.4%	100.0%	83.9%	6.3%	9.8%	100.0%
2004	2003	98,047	4,345,396	1,379,857	54,452	8,065,069	186,241	1,381,250	15,510,312	13,168,842	756,339	1,585,131	15,510,312
	%	0.6%	28.0%	8.9%	0.4%	52.0%	1.2%	8.9%	100.0%	84.9%	4.9%	10.2%	100.0%
2005	2004	292,215	3,046,370	1,358,262	53,286	7,672,890	182,953	1,105,722	13,711,698	11,804,164	773,939	1,133,595	13,711,698
	%	2.1%	22.2%	9.9%	0.4%	56.0%	1.3%	8.1%	100.0%	86.1%	5.6%	8.3%	100.0%
2006	2005	141,567	3,463,202	1,251,339	38,460	7,089,017	321,554	1,200,541	13,505,680	11,308,244	1,054,313	1,143,123	13,505,680
	%	1.0%	25.6%	9.3%	0.3%	52.5%	2.4%	8.9%	100.0%	83.7%	7.8%	8.5%	100.0%

6D. New Form Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos EnrollSeudbt ottoa UDSatgeU (SCumulative)

FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian /Pacific Islander	White	More Than One Race	Unknown /Other	Total Hispanic or Latino**	Minority Categories (shaded): NEW FORM Parts A+B	Number of Protocols with Enrollment data (New Form):
2002	2001	4,867	1,305	13,066	101	159,252	7390	106,448	292,429	1,297,850	2,758

	%	1.7%	0.4%	4.5%	0.0%	54.5%	2.5%	36.4%	100.0%	29.5%	
2003	2002	5,400	1,953	14,566	679	350,439	28,088	210,516	611,641	3,859,622	5,313
	%	0.9%	0.3%	2.4%	0.1%	57.3%	4.6%	34.4%	100.0%	39.7%	
2004	2003	6,408	5,040	25,276	2,037	361,112	62,909	293,557	756,339	6,718,662	7,343
	%	0.8%	0.7%	3.3%	0.3%	47.7%	8.3%	38.8%	100.0%	43.3%	
2005	2004	22,739	7,816	19,446	1,981	388,874	51,166	281,916	773,938	5,603,876	8,447
	%	2.9%	1.0%	2.5%	0.3%	50.2%	6.6%	36.4%	100.0%	40.9%	
2006	2005	45,074	6,641	21,712	2,193	417,495	185,477	375,721	1,054,313	6,009,338	9,367
	%	4.3%	0.6%	2.1%	0.2%	39.6%	17.6%	35.6%	100.0%	44.5%	

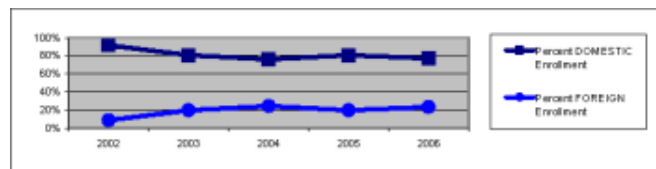
* These totals must agree.

**These totals must agree.

6E. Comparison of Domestic and Foreign Enrollment & Protocols with Total Enrollment for the period FY2002-2006											
ENROLLMENT							PROTOCOLS				
FY Reported	FY Funded	Total Enrollment	Total DOMESTIC	Percent DOMESTIC	Total FOREIGN	Percent FOREIGN	Number of Protocols	Number of	Percent Domestic	Number of	Percent Foreign

		data (Old + New Forms):	Enrollment	Enrollment	Enrollment	Enrollment	with Enrollment data (Old + New Forms):	DOMESTI C Protocols	Protocols	FOREIGN Protocols	Protocols
2002	2001	11,138,484	10,192,401	91.5%	946,083	8.5%	8,945	8,463	94.6%	482	5.4%
2003	2002	14,772,254	11,911,357	80.6%	2,860,897	19.4%	10,216	9,578	93.8%	638	6.2%
2004	2003	18,923,920	14,359,793	75.9%	4,564,127	24.1%	10,125	9,760	96.4%	365	3.6%
2005	2004	15,722,752	12,669,858	80.6%	3,052,894	19.4%	10,233	9,862	96.4%	371	3.6%
2006	2005	14,830,930	311,425,701	77.0%	3,405,229	23.0%	10,758	10,294	95.7%	464	4.3%

Percentage of Domestic and Foreign Enrollment



Number of Domestic and Foreign protocols

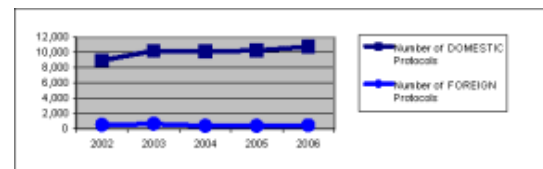


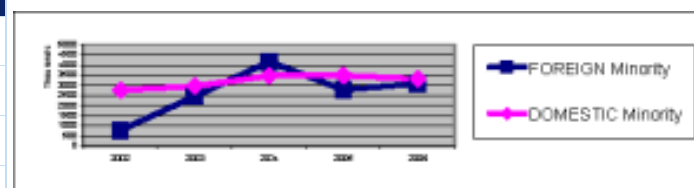
Table 6 E Comments:

1. The Total Enrollment, Total Domestic, and Total Foreign enrollment increase from FY2002-2006.
2. The Domestic enrollment decreased to approximately 80%, while the Foreign enrollment increased to approximately 20%.
3. The vast majority of protocols are domestic protocols (approximately 94-96%), while foreign protocols make up approximately 4-6% of total protocols.
4. Foreign enrollment was reported using the same race and ethnicity categories as domestic enrollment.

6F. Comparison of Domestic and Foreign Minority Participation for FY 2002-2006

FY Reported	FY Funded	FOREIGN Minority	Foreign Total	DOMESTIC Minority	Domestic Total
2002	2001	777,461	946,083	2,754,820	10,149,869
		82.2%	100.0%	27.1%	100.0%
2003	2002	2,452,329	2,860,897	2,935,363	11,911,357
		85.7%	100.0%	24.6%	100.0%
2004	2003	4,147,255	4,561,127	3,464,356	14,359,793
		90.9%	100.0%	24.1%	100.0%
2005	2004	2,776,565	3,052,894	3,468,864	12,669,858
		90.9%	100.0%	27.4%	100.0%

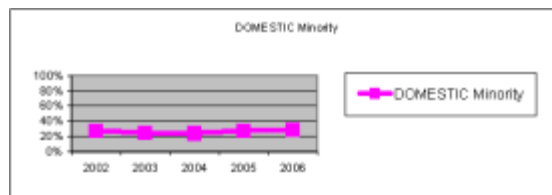
Number of Minority Participants for FY2002-2005



2006	2005	3,087,181	3,405,229	3,301,135	11,425,701
		90.7%	100.0%	28.9%	100.0%

NOTE MINORITY % WILL NOT ADD TO 100%

Percentage Comparison of Domestic Minority Enrollment to Total Domestic Enrollment for FY 2002-2006



Percentage Comparison of Foreign Minority Enrollment to Total Foreign Enrollment for FY 2002-2006

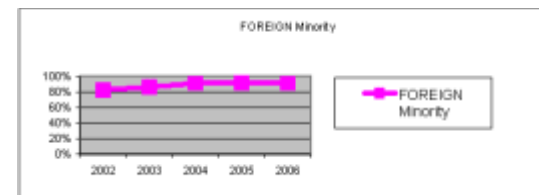


Table 6 F Comments:

1. Domestic Minority Enrollment has varied from 24.1% to 28.9% of Total Domestic Enrollment. research is done in countries that are within the OMB race and ethnicity origin categories that are included in the summary
2. The Total Minority Enrollment reported in FY2006 was 52% Domestic and 48 % Foreign (see Table 1). The small percentage of foreign protocols account for a significant proportion (48%) of the Total Minority Enrollment, as shown by comparing both domestic and foreign enrollment data.

Table 7: Twelve Year Minority Enrollment Summary of NIH Extramural and Intramural Phase III Clinical Research Reported in FY1995-2006: Enrollment by Race and Ethnicity.

7A. Phase III TWELVE YEAR SUMMARY TOTALS: ENROLLMENT BY SEX/GENDER IN ALL PROTOCOLS (Old + New Forms)

FY Reported	FY Funded	Females	Males	Unknown	Total All Subjects (Old + New Forms)	Subtotal: All Subjects Enrolled by US Minority Categories	Number of Protocols with Enrollment data (Old + New Forms):
1995	1994	171,181	108,324	19,818	299,323	80,562	560
	%	57.2%	36.2%	6.6%	100.0%	26.9%	
1996	1995	264,755	203,698	21,210	489,663	110,669	608
	%	54.1%	41.6%	4.3%	100.0%	22.6%	
1997	1996	264,755	203,698	21,210	489,663	110,000	608
	%	54.1%	41.6%	4.3%	100.0%	22.5%	
1998	1997	228,417	74,389	2,705	305,511	69,599	320
	%	74.8%	24.3%	0.9%	100.0%	22.8%	
1999	1998	339,533	163,950	1,446	504,929	141,449	578
	%	67.2%	32.5%	0.3%	100.0%	28.0%	
2000	1999	313,952	180,705	1,086	495,743	120,339	589

	%	63.3%	36.5%	0.2%	100.0%	24.3%	
2001	2000	412,379	168,085	1,273	581,737	117,873	645
	%	70.9%	28.9%	0.2%	100.0%	20.3%	
2002	2001	278,876	195,090	781	474,747	111,269	754
	%	58.7%	41.1%	0.2%	100.0%	23.4%	
2003	2002	294,950	239,403	1,914	536,267	132,302	852
	%	55.0%	44.6%	0.4%	100.0%	24.7%	
2004	2003	301,353	242,913	1,101	545,367	150,456	573
	%	55.3%	44.5%	0.2%	100.0%	27.6%	
2005	2004	290,977	197,300	4,723	493,000	154,191	547
		59.0%	40.0%	1.0%	100.0%	31.3%	
2006	2005	314,066	179,975	5,389	499,430	167,446	624
		62.9%	36.0%	1.1%	100.0%	33.5%	
Total Phase III Enrollment by Year Reported				Sex/Gender Phase III Enrollment by Year Reported			

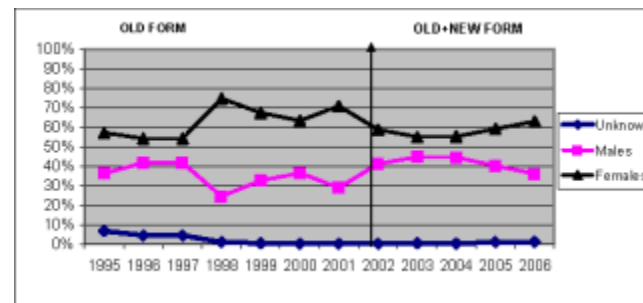
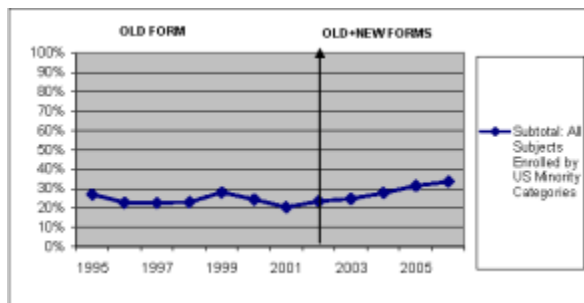


Table 7A Comments:

1. Table 7A summarizes enrollment by sex/gender and minority race/ethnicity categories for the twelve year reporting period (1995-2006). The data are compiled from Tables 7B, 7C and 7D below, which provide the detailed distributions by sex/gender and race/ethnicity using the OLD Enrollment Form (Table 7B) and the NEW Enrollment Form (Tables 7C and 7D).
2. The Race and Ethnicity data in the OLD FORM and the NEW FORM cannot be combined by individual race and ethnicity categories because the categories reflect the different OMB Formats used based on the 1977 OMB standards (OLD FORM) and the 1997 OMB Standards (NEW FORM).

NOTE: Trend data varies over time because the data for each year represent the net total of data resulting from: (1) studies continuing from the prior year; (2) the addition of new studies reported; (3) and the subtraction of studies that are no longer reported.

Notes Tables 7B-D

NOTE 1: The shaded portions of the Tables B, C and D below show the race/ethnicity categories that are identified as minority categories. The Data Reported in FY 2002 and later are from the new Population Tracking System that was deployed with data reported in FY 2002 and later, and allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

NOTE 2: Data from Tables 7B, 7C and 7D are combined to provide the summary data in Table 7A.

7B. Phase III OLD FORM: Total of All Subjects Reported Using the 1977 OMB Standards in a Combined Race/Ethnicity Format

FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown /Other	Total	Subtotal Using US Minority Categories (shaded): OLD FORM	Number of Foreign Protocols with Enrollment data (Old Form):
1995	1994	5,358	2,740	52,433	20,031	172,773	45,988	299,323	409	560
	%	1.8%	0.9%	17.5%	6.7%	57.7%	15.4%	100.0%	26.9%	
1996	1995	4,235	40,126	46,838	19,470	321,445	57,549	489,663	110,669	608
	%	0.9%	8.2%	9.6%	4.0%	65.6%	11.8%	100.0%	22.6%	
1997	1996	4,235	40,126	46,838	19,470	321,445	57,549	489,663	110,669	608
	%	0.9%	8.2%	9.6%	4.0%	65.6%	11.8%	100.0%	22.6%	
1998	1997	5,030	5,324	42,805	16,440	229,534	6,378	305,511	69,599	215
	%	1.6%	1.7%	14.0%	5.4%	75.1%	2.1%	100.0%	22.8%	
1999	1998	3,685	20,276	76,921	40,567	336,703	26,777	504,929	141,449	578
	%	0.7%	4.0%	15.2%	8.0%	66.7%	5.3%	100.0%	28.0%	

2000	1999	3,726	24,017	62,512	30,084	335,824	39,580	495,743	120,339	589
	%	0.8%	4.8%	12.6%	6.1%	67.7%	8.0%	100.0%	24.3%	
2001	2000	4,079	11,132	70,110	32,552	422,802	41,062	581,737	117,873	645
	%	0.7%	1.9%	12.1%	5.6%	72.7%	7.1%	100.0%	20.3%	
2002	2001	1,645	20,560	51,991	29,636	315,543	12,228	431,603	103,832	660
	%	0.38%	4.8%	12.0%	6.9%	73.1%	2.8%	100.00%	24.1%	
2003	2002	1,689	20,038	49,255	29,066	337,654	16,615	454,317	100,048	656
	%	0.4%	4.4%	10.8%	6.4%	74.3%	3.7%	100.0%	22.0%	
2004	2003	1,505	18,807	45,285	32,974	265,764	14,050	378,385	98,571	296
	%	0.4%	5.0%	12.0%	8.7%	70.2%	3.7%	100.0%	26.1%	
2005	2004	1,319	17,740	39,402	21,829	231,492	4,507	316,289	80,290	210
	%	0.4%	5.6%	12.5%	6.9%	73.2%	1.4%	100.0%	25.4%	
2006	2005	1,012	16,800	20,355	9,524	175,724	6,348	229,763	47,691	215
	%	0.4%	7.3%	8.9%	4.1%	76.5%	2.8%	100.0%	20.8%	

ORIENTATION TO TABLES 7C and 7D.

1. The New Form consists of Parts A and B (Tables 7C and 7D) for reporting years 2002-2006. This Form is provided as part of the annual progress report.
2. Table 7C displays the New Form Part A for reporting separate race and ethnicity data.
3. Table 7D displays the New Form Part B, which is the Distribution of Hispanics reported by race, using the totals from the “Hispanic or Latino” column in Part A.

7C. Phase III New Form: Total of All Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity													
		Total of All Subjects by Race								Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Hawaiian/ Pacific Islander	White	More Than One Race	Unknown /Other	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
2002	2001	159	799	4,647	52	34,654	560	2,273	43,144	36,224	1,629	5,291	43,144
	%	0.37%	1.85%	10.77%	0.12%	80.32%	1.30%	5.27%	100.00%	83.96%	3.78%	12.26%	100.00%
2003	2002	484	2,609	21,641	220	47,869	989	8,138	81,950	64,295	7,831	9,824	81,950
	%	0.6%	3.2%	26.4%	0.3%	58.4%	1.2%	9.9%	100.0%	78.5%	9.6%	12.0%	100.0%
2004	2003	1,396	4,385	43,721	611	106,793	4,419	5,657	166,982	145,742	13,435	7,805	166,982
	%	0.8%	2.6%	26.2%	0.4%	64.0%	2.6%	3.4%	100.0%	87.3%	8.0%	4.7%	100.0%

2005	2004	2,164	9,192	50,338	462	101,238	3,063	10,254	176,711	156,650	10,397	9,664	176,711
	%	1.2%	5.2%	28.5%	0.3%	57.3%	1.7%	5.8%	100.0%	88.6%	5.9%	5.5%	100.0%
2006	2005	4,630	32,360	50,780	535	126,670	4,246	50,446	269,667	202,358	31,034	36,275	269,667
	%	1.7%	12.0%	18.8%	0.2%	47.0%	1.6%	18.7%	100.0%	75.0%	11.5%	13.5%	100.0%

7D. Phase III Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

FY Reported	FY Funded	American Indian/Alaska Native	Asian	Black or African American	Hawaiian/Pacific Islander	White	More Than One Race	Unknown/Other	Total	FSubtotal Using US Minority Categories (shaded): NEW	Number of Protocols with Enrollment data(New Form):
2002	2001	49	22	31	4	660	304	560	1,630	7,437	94
	%	3.0%	1.3%	1.9%	0.2%	40.5%	18.7%	34.4%	100.0%	17.2%	
2003	2002	37	70	186	23	2,115	203	5,197	7,831	32,254	196
	%	0.5%	0.9%	2.4%	0.3%	27.0%	2.6%	66.4%	100.0%	39.4%	
2004	2003	269	59	193	26	7,264	3,052	2,572	13,435	54,405	277
	%	2.0%	0.4%	1.4%	0.2%	54.1%	22.7%	19.1%	100.0%	32.6%	
2005	2004	759	42	446	45	3,667	423	5,015	10,397	73,901	337

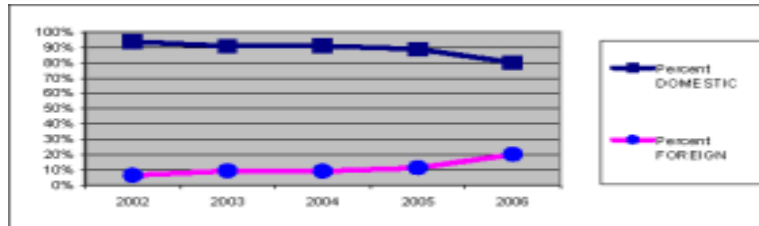
	%	7.3%	0.4%	4.3%	0.4%	35.3%	4.1%	48.2%	100.0%	41.8%	
2006	2005	2,307	50	720	40	6,872	713	20,332	31,034	119,755	409
	%	7.4%	0.2%	2.3%	0.1%	22.1%	2.3%	65.5%	100.0%	44.4%	

* These totals must agree

** These totals must agree

7E. Comparison of Domestic and Foreign Phase III Enrollment and Protocols with Enrollment for the period FY2002-2006											
ENROLLMENT							PROTOCOLS				
FY Reported	FY Funded	Total Enrollment data (Old + New Forms):	Total DOMESTIC	Percent DOMESTIC	Total FOREIGN	Percent FOREIGN	Number of Protocols with Enrollment data (Old + New Forms)	Number of DOMESTIC Protocols	Percent Domestic Protocols	Number of FOREIGN Protocols	Percent Foreign Protocols
2002	2001	474,747	444,436	93.6%	30,311	6.4%	754	582	77.2%	172	22.8%
2003	2002	536,267	486,857	90.8%	49,410	9.2%	852	643	75.5%	209	24.5%
2004	2003	545,367	496,241	91.0%	49,126	9.0%	573	549	95.8%	24	4.2%
2005	2004	493,000	437,902	88.8%	55,098	11.2%	547	517	94.5%	30	5.5%
2006	2005	499,430	400,297	80.2%	99,133	19.8%	624	564	90.4%	60	9.6%

Percentage of Phase III Domestic and Foreign Enrollment



Number of Phase III Domestic and Foreign protocols

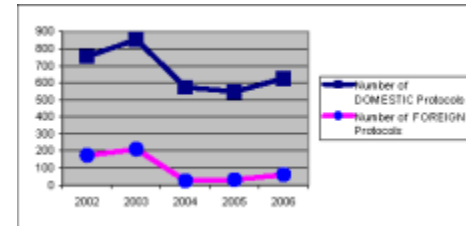


Table 7 E Comments:

1. The Total Enrollment, Total Domestic, and Total Foreign enrollment increase from FY2002-2006.
2. The Domestic enrollment decreased to approximately 80%, while the Foreign enrollment increased to approximately 20%.
3. The vast majority of protocols in FY2004-2006 are domestic protocols (approximately 90.4-95.8%), while foreign protocols make up approximately 4.2-9.6% of total protocols.
4. Foreign enrollment was reported using the same race and ethnicity categories as domestic enrollment.

7F. Phase III Foreign and Domestic Minority Comparison for FY 2002-2006					
FY Reported	FY Funded	FOREIGN Phase III Minority	FOREIGN Phase III Total	DOMESTIC Phase III Minority	DOMESTIC Phase III Total
2002	2001	18,308	30,311	92,961	444,436

		60.4%	100.0%	20.9%	100.0%
2003	2002	23,927	49,410	109,376	486,857
		48.4%	100.0%	22.5%	100.0%
2004	2003	37,126	49,126	125,813	496,241
		75.6%	100.0%	25.4%	100.0%
2005	2004	44,281	55,098	109,910	437,902
		80.4%	100.0%	25.1%	100.0%
2006	2005	84,412	99,133	83,034	400,297
		85.2%	100.0%	20.7%	100.0%

Number of Minority Participants in Phase III Clinical Studies for FY2002-2006

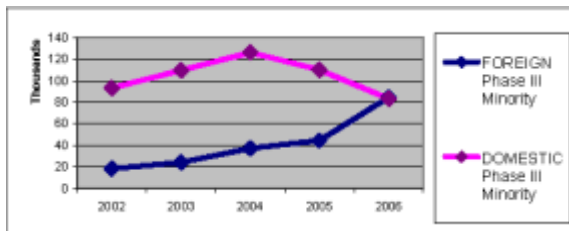


Table 7 F Comments:

1. Domestic Minority Enrollment has varied from 24.1% to 28.9% of Total Domestic Enrollment.
2. Foreign Minority Enrollment has varied from 82.2% to 90.9% of Total Foreign Enrollment, reflecting that most of the foreign research is done in countries that are within the OMB race and ethnicity origin categories that are included in the summary minority data used in this report.
3. The Total Minority Enrollment reported in FY2006 was 52% Domestic and 48 % Foreign (see Table 1). The small percentage of foreign protocols account for a significant proportion (48%) of the Total Minority Enrollment, as shown by comparing both domestic and foreign enrollment data.

8A. Five Year Summary Totals: Domestic Subjects in Domestic Protocols(Old + New Forms)							
FY Reported	FY Funded	Females	Males	Unknown	Total Domestic Subjects (Old + New Forms)	Subtotal: Domestic Subjects Enrolled by US Minority Categories	Number of Domestic Protocols with Enrollment data (Old +
2002	2001	6,583,087	3,506,787	59,995	10,149,869	2,754,820	8,425
	%	64.9%	34.6%	0.6%	100.0%	27.1%	
2003	2002	7,392,404	4,393,496	125,457	11,911,357	2,935,363	9,578
	%	62.1%	36.9%	1.1%	100.0%	24.6%	
2004	2003	8,881,299	5,199,765	278,729	14,359,793	3,464,356	9,760

	%	61.8%	36.2%	1.9%	100.0%	24.1%	
2005	2004	7,887,209	4,515,242	267,407	12,669,858	3,468,864	9,862
		62.3%	35.6%	2.1%	100.0%	27.4%	
2006	2005	7,684,453	3,566,577	174,671	11,425,701	3,301,135	10,294
		67.3%	31.2%	1.5%	100.0%	28.9%	

Table 8A Comments:

1. There were approximately an average of 63% females, 35% males and 2% of unknown sex enrolled in domestic protocols from 2002-2006.
2. There were approximately an average of 27% domestic minority subjects enrolled in domestic protocols from 2002-2006.
3. Total domestic enrollment ranged from 10.1M to 11.5M during these 5 years.
4. The number of domestic protocols increased from 8,425 to 10,294 in 2006.

NOTE on FY2002 Reported Data:

One domestic study had an enrollment of 540,833 subjects (Old Form).
One domestic study had an enrollment of 1,571,305 subjects (Old Form).

NOTE on FY2003 Reported Data:

One domestic study had an enrollment of 800,000 subjects (New Form).
One domestic study had an enrollment of 1,389,920 subjects (New form).
One domestic study had an enrollment of 1,799,820 subjects (New form).

NOTE on FY2004 Reported Data:

One domestic study had an enrollment of 540,833 subjects (New Form).

One domestic study had an enrollment of 800,000 subjects (New Form).
 One domestic study had an enrollment of 1,138,302 subjects (New form).
 One domestic study had an enrollment of 1,419,475 subjects (New form).
 One domestic study had an enrollment of 1,799,820 subjects (New form).

NOTE on FY2005 Reported Data:

One domestic study had an enrollment of 540,833 subjects (New Form).
 One domestic study had an enrollment of 800,000 subjects (New Form).
 One domestic study had an enrollment of 1,595,620 subjects (New form).
 One domestic study had an enrollment of 1,799,820 subjects (New form).

NOTE on FY2006 Reported Data:

One domestic study had an enrollment of 875,010 subjects (New Form).
 One domestic study had an enrollment of 1,964,668 subjects (New Form).
 One domestic study had an enrollment of 540,833 subjects (New form).

NOTE 1: The shaded portions of the Tables B, C and D below show the race/ethnicity categories that are identified as minority categories. The Data Reported in FY 2002 and later are from the new Population Tracking System that was deployed with data reported in FY 2002 and later, and allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

NOTE 2: Data from Tables 8B, 8C and 8D are combined to provide the summary data in Table A.

8B. OLD FORM: Total of All Domestic Subjects Reported Using the 1977 OMB Standards in a combined race/ethnicity format										
FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown /Other	Total Domestic Enrollment (Old Form)	Domestic Subtotal Using US Minority ategories (shaded):	Number of Domestic rotocols with Enrollment data (Old Form):

									OLD FORM	
2002	2001	45,639	752,203	673,726	378,300	3,880,431	316,053	6,046,352	1,849,868	5,783
	%	0.8%	12.4%	11.1%	6.3%	64.2%	5.2%	100.0%	30.6%	
2003	2002	36,238	249,420	455,329	264,336	3,100,815	266,339	4,372,477	1,005,323	4,478
	%	0.8%	5.7%	10.4%	6.0%	70.9%	6.1%	100.0%	23.0%	
2004	2003	28,953	196,647	322,078	194,762	2,273,619	157,464	3,173,523	742,440	2,702
	%	0.9%	6.2%	10.1%	6.1%	71.6%	5.0%	100.0%	23.4%	
2005	2004	22,375	89,119	210,465	126,351	1,245,337	93,239	1,786,886	448,310	1,736
	%	1.3%	5.0%	11.8%	7.1%	69.7%	5.2%	100.0%	25.1%	
2006	2005	19,628	51,701	148,224	74,312	866,683	61,480	1,222,028	293,865	1,361
	%	1.6%	4.2%	12.1%	6.1%	70.9%	5.0%	100.0%	24.0%	

8C. NEW FORM PART A: Inclusion Enrollment Report (Total of All Domestic Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity Formats)

Part A: TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Total of All Subjects by Race										Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian/Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White	More Than One Race	Unknown or Not Reported	*Total of All Subjects by Racial Categories (New Form)	Not Hispanic	**Hispanic or Latino	Unknown/Not Reported	*Total of All Subjects by Ethnic Category
2002	2001	74,593	174,215	473,699	7,623	2,626,547	30,200	716,640	4,103,517	2,785,590	285,921	1,032,006	4,103,517
	%	1.8%	4.2%	11.5%	0.2%	64.0%	0.7%	17.5%	100.0%	67.9%	7.0%	25.1%	100.0%
2003	2002	61,526	295,061	897,518	23,068	5,161,965	94,138	1,005,604	7,538,880	6,003,326	602,018	933,536	7,538,880
	%	0.8%	3.9%	11.9%	0.3%	68.5%	1.2%	13.3%	100.0%	79.6%	8.0%	12.4%	100.0%
2004	2003	97,854	485,137	1,280,129	42,945	7,772,927	172,185	1,335,093	11,186,270	8,893,158	720,551	1,572,561	11,186,270
	%	0.9%	4.3%	11.4%	0.4%	69.5%	1.5%	11.9%	100.0%	79.5%	6.4%	14.1%	100.0%
2005	2004	291,044	655,959	1,232,957	42,993	7,485,193	164,096	1,010,730	10,882,972	9,120,293	721,138	1,041,541	10,882,972
	%	2.7%	6.0%	11.3%	0.4%	68.8%	1.5%	9.3%	100.0%	83.8%	6.6%	9.6%	100.0%
2006	2005	111,048	946,613	1,032,199	35,142	6,844,960	178,275	1,055,436	10,203,673	8,384,360	796,556	1,022,757	10,203,673
	%	1.1%	9.3%	10.1%	0.3%	67.1%	1.7%	10.3%	100.0%	82.2%	7.8%	10.0%	100.0%

8D. New Form Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White (Hispanic)	More Than One Race	Unknown or Not Reported	**Total of Hispanics or Latinos by Racial Categories	Domestic Subtotal Using US Minority Categories (shaded):NEW FORM Parts A+B	Number of Domestic Protocols with Enrollment data (New Form):
2002	2001	1,163	436	12,005	98	69,313	5,626	75,309	163,950	904,952	2,642
	%	0.7%	0.3%	7.3%	0.1%	42.3%	3.4%	45.9%	100.0%	22.1%	
2003	2002	3,756	1,950	13,345	678	349,844	23,560	208,885	602,018	1,930,040	5,100
	%	0.6%	0.3%	2.2%	0.1%	58.1%	3.9%	34.7%	100.0%	25.6%	
2004	2003	6,293	5,026	12,498	2,037	356,575	51,031	287,091	720,551	2,721,916	7,058
	%	0.9%	0.7%	1.7%	0.3%	49.5%	7.1%	39.8%	100.0%	24.3%	
2005	2004	22,057	7,810	19,282	1,981	362,707	36,503	270,798	721,138	3,020,554	8,126
	%	3.1%	1.1%	2.7%	0.3%	50.3%	5.1%	37.6%	100.0%	27.8%	
2006	2005	15,498	6,540	19,870	1,505	374,830	49,150	329,163	796,556	3,007,270	8,933
	%	1.9%	0.8%	2.5%	0.2%	47.1%	6.2%	41.3%	100.0%	29.5%	

* These Totals must agree

**These totals must agree

9A . Phase III Five Year Summary Totals: Domestic Subjects In Domestic Protocols(Old + New Forms)							
FY Reported	FY Funded	Females	Males	Unknown	Total DomesticSubjects (Old + New Forms)	Subtotal: Domestic Subjects Enrolled by US Minority Categories	Number of Domestic Protocols with Enrollment data (Old + New Forms):
2002	2001	264,517	179,179	740	444,436	92,961	582
	%	59.5%	40.3%	0.2%	100.0%	20.9%	
2003	2002	266,913	218,166	1,778	486,857	109,376	643
	%	54.8%	44.8%	0.4%	100.0%	22.5%	
2004	2003	277,333	217,890	1,018	496,241	125,813	549
	%	55.9%	43.9%	0.2%	100.0%	25.4%	
2005	2004	261,589	174,137	2,176	437,902	109,910	517
		59.7%	39.8%	0.5%	100.0%	25.1%	
2006	2005	258,467	137,621	4,209	400,297	83,034	564

		64.6%	34.4%	1.1%	100.0%	20.7%	
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Table 9A Comments:

1. There were approximately an average of 57% females, 42% males and 0.3% of unknown sex enrolled in domestic protocols from 2002-2005.
2. There were approximately an average of 23.5% domestic minority subjects enrolled in domestic Phase III protocols from 2002-2006.
3. Total domestic Phase III enrollment ranged from 400,297 to 496,241 during these 5 years.
4. The number of domestic Phase III protocols ranged from 517 to 564 in 2006.

NOTE 1: The shaded portions of the Tables B, C and D below show the race/ethnicity categories that are identified as minority categories. The Data Reported in FY 2002 and later are from the new Population Tracking System that was deployed with data reported in FY 2002 and later, and allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

NOTE 2: Data from Tables 9B, 9C and 9D are combined to provide the summary data in Table A.

9B. OLD FORM: Total of All Domestic Subjects Reported Using the 1977 OMB Standards in a combined race/ethnicity format										
FY Reported	FY Funded	American Indian/Alaska Native	Asian/Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown/Other	Total Domestic Enrollment (Old Form)	Domestic Subtotal Using US Minority Categories (shaded): OLD FORM	Number of Domestic Protocols with Enrollment data (Old Form):
2002	2001	1,586	8,291	49,184	27,912	305,964	10,670	403,607	86,973	494

	%	0.4%	2.1%	12.2%	6.9%	75.8%	2.6%	100.0%	21.5%	
2003	2002	1,612	7,610	48,975	25,567	322,600	8,538	414,902	83,764	468
	%	0.4%	1.8%	11.8%	6.2%	77.8%	2.1%	100.0%	20.2%	
2004	2003	1,504	6,739	45,233	31,967	262,671	6,447	354,561	85,443	286
	%	0.4%	1.9%	12.8%	9.0%	74.1%	1.8%	100.0%	24.1%	
2005	2004	1,319	5,488	39,401	20,646	229,235	4,493	300,582	66,854	205
	%	0.4%	1.8%	13.1%	6.9%	76.3%	1.5%	100.0%	22.2%	
2006	2005	996	4,505	20,325	9,512	171,191	5,673	212,202	35,338	207
	%	0.5%	2.1%	9.6%	4.5%	80.7%	2.7%	100.0%	16.7%	

9C. NEW FORM Part A: Inclusion Enrollment Report (Total of All Domestic Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity Formats)

Part A: TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

		Total of All Subjects by Race								Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian/	Asian	Black or African	Native Hawaiian	White	More Than	Unknown or Not	*Total of All	Not Hispanic	**Hispanic or	Unknown/Not	*Total of All

		Alaska Native		American or Pacific Islander			One Race	Reported	Subjects by Racial Categories (New Form)		Latino	Reported	Subjects by Ethnic Category
2002	2001	159	798	3,199	52	34,541	560	1,520	40,829	34,662	1,629	4,538	40,829
	%	0.4%	2.0%	7.8%	0.1%	84.6%	1.4%	3.7%	100.0%	84.9%	4.0%	11.1%	100.0%
2003	2002	477	2,586	14,031	220	46,774	989	6,878	71,955	55,575	7,828	8,552	71,955
	%	0.7%	3.6%	19.5%	0.3%	65.0%	1.4%	9.6%	100.0%	77.2%	10.9%	11.9%	100.0%
2004	2003	1,396	4,373	22,307	611	106,260	1,849	4,884	141,680	123,770	10,863	7,047	141,680
	%	1.0%	3.1%	15.7%	0.4%	75.0%	1.3%	3.4%	100.0%	87.4%	7.7%	5.0%	100.0%
2005	2004	1,775	4,920	24,390	462	93,662	3,063	9,048	137,320	118,528	9,773	9,019	137,320
	%	1.3%	3.6%	17.8%	0.3%	68.2%	2.2%	6.6%	100.0%	86.3%	7.1%	6.6%	100.0%
2006	2005	2,724	5,312	23,267	530	118,577	4,077	33,608	188,095	141,688	13,550	32,857	188,095
	%	1.4%	2.8%	12.4%	0.3%	63.0%	2.2%	17.9%	100.0%	75.3%	7.2%	17.5%	100.0%

9D. New Form Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date

FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White (Hispanic)	More Than One Race	Unknown or Not Reported	**Total of Hispanics or Latinos by Racial Categories	Domestic Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B	Number of Domestic Protocols with Enrollment data (New Form):
2002	2001	49	21	31	4	660	304	560	1,629	5,988	88
	%	3.0%	1.3%	1.9%	0.2%	40.5%	18.7%	34.4%	100.0%	14.7%	
2003	2002	37	70	186	23	2,113	203	5,196	7,828	25,612	175
	%	0.5%	0.9%	2.4%	0.3%	27.0%	2.6%	66.4%	100.0%	35.6%	
2004	2003	269	59	193	26	7,262	482	2,572	10,863	40,370	263
	%	2.5%	0.5%	1.8%	0.2%	66.9%	4.4%	23.7%	100.0%	28.5%	
2005	2004	371	42	446	45	3,663	423	4,783	9,773	43,056	312
	%	3.8%	0.4%	4.6%	0.5%	37.5%	4.3%	48.9%	100.0%	31.4%	
2006	2005	458	47	507	40	5,544	712	6,242	13,550	47,696	357
	%	3.4%	0.3%	3.7%	0.3%	40.9%	5.3%	46.1%	100.0%	25.4%	

* These totals must agree

**** These totals must agree**

10A . FIVE YEAR SUMMARY TOTALS: FOREIGN SUBJECTS IN FOREIGN PROTOCOLS (Old + New Forms)							
FY Reported	FY Funded	Females	Males	Unknown	Total Domestic Subjects (Old + New Forms)	Subtotal: Domestic Subjects Enrolled by US Minority Categories	Number of Domestic Protocols with Enrollment data (Old + New Forms):
2002	2001	553,056	379,294	13,833	946,083	777,461	482
	%	58.5%	40.1%	1.5%	100.0%	82.2%	
2003	2002	1,122,077	1,728,000	10,820	2,860,897	2,452,329	638
	%	39.2%	60.4%	0.4%	100.0%	85.7%	
2004	2003	2,007,798	2,542,127	14,202	4,564,127	4,147,255	365
	%	44.0%	55.7%	0.3%	100.0%	90.9%	
2005	2004	1,616,713	1,426,665	9,516	3,052,894	2,776,565	371
	%	53.0%	46.7%	0.3%	100.0%	90.9%	
2006	2005	1,788,820	1,605,628	10,781	3,405,229	3,087,181	464
	%	52.5%	47.2%	0.3%	100.0%	90.7%	

Table 10A Comments:

1. The percent females varied from 39.2% to 58.5% in foreign protocols from 2002-2005; the percent males varied from 40.1% to 60.4%.
2. The percent foreign subjects enrolled by U.S. Minority Categories in foreign protocols increased from 82.2% to 90.9% from 2002 to 2005.
3. Total foreign enrollment ranged from 777,461 to 4.15M during these 5 years.
4. The number of foreign protocols ranged from 638 in 2003 to 317 in 2005.

NOTE on FY2002 Reported Data:

One study in Vietnam had an enrollment of 302,381 subjects (Old Form).

NOTE on FY2003 Reported Data:

One study in Vietnam had an enrollment of 302,381 subjects (Old Form).

One study in China had an enrollment of 1,910,000 subjects (New form).

NOTE on FY2004 Reported Data:

One study in India had an enrollment of 2,000,000 subjects (New Form).

One study in China had an enrollment of 1,910,000 subjects (New form).

NOTE on FY2005 Reported Data:

One study in India had an enrollment of 2,200,000 subjects (New Form).

NOTE on FY2006 Reported Data:

One study in India had an enrollment of 2,200,000 subjects (New Form).

NOTE 1: The shaded portions of the Tables B, C and D below show the race/ethnicity categories that are identified as minority categories. The Data Reported in FY 2002 and later are from the new Population Tracking System that was deployed with data reported in FY 2002 and later, and allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

NOTE 2: Data from Tables 10B, 10C and 10D are combined to provide the summary data in Table A.

10B.OLD FORM: Total of All FOREIGN Subjects Reported Using the 1977 OMB Standards in a combined race/ethnicity format										
FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown /Other	Total Foreign Enrollment (Old Form)	Foreign Subtotal Using US Minority Categories (shaded): OLD FORM	Number of Domestic Protocols with Enrollment data (Old Form):
2002	2001	69	468,958	21,407	19,075	143,768	3,565	656,842	509,509	380
	%	0.0%	71.4%	3.3%	2.9%	21.9%	0.5%	100.0%	77.6%	
2003	2002	341	481,122	17,097	24,187	137,469	12,562	672,778	522,747	425
	%	0.1%	71.5%	2.5%	3.6%	20.4%	1.9%	100.0%	77.7%	
2004	2003	434	110,405	20,110	19,560	74,910	14,666	240,085	150,509	80
	%	0.2%	46.0%	8.4%	8.1%	31.2%	6.1%	100.0%	62.7%	
2005	2004	0	165,479	19,150	8,621	21,752	9,166	224,168	193,250	50
	%	0.0%	73.8%	8.5%	3.8%	9.7%	4.1%	100.0%	86.2%	
2006	2005	20	80,085	724	4,284	16,358	1,751	103,222	85,113	30

	%	0.0%	77.6%	0.7%	4.2%	15.8%	1.7%	100.0%	82.5%	
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10C. NEW FORM Part A: Inclusion Enrollment Report (Total of All FOREIGN Subjects Reported Using the 1997 OMB Standards for Separate Race and Ethnicity Formats)

Part A: TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

		Total of All Subjects by Race								Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White	More Than One Race	Unknown or Not Reported	*Total of All Subjects by Racial Categories (New Form)	Not Hispanic	**Hispanic or Latino	Unknown/ Not Reported	*Total of All Subjects by Ethnic Category
2002	2001	3,271	180,022	68,071	14,013	19,970	741	3,153	289,241	278,618	6,064	4,559	289,241
	%	1.1%	62.2%	23.5%	4.8%	6.9%	0.3%	1.1%	100.0%	96.3%	2.1%	1.6%	100.0%
2003	2002	2,018	1,842,941	62,572	14,501	253,745	5,324	7,018	2,188,119	2,158,933	9,623	19,563	2,188,119
	%	0.1%	84.2%	2.9%	0.7%	11.6%	0.2%	0.3%	100.0%	98.7%	0.4%	0.9%	100.0%
2004	2003	193	3,860,259	99,728	11,507	292,142	14,056	46,157	4,324,042	4,275,684	35,788	12,570	4,324,042
	%	0.0%	89.3%	2.3%	0.3%	6.8%	0.3%	1.1%	100.0%	98.9%	0.8%	0.3%	100.0%

2005	2004	1,171	2,390,404	125,305	10,293	187,697	18,857	94,999	2,828,726	2,683,871	52,801	92,054	2,828,726
	%	0.0%	84.5%	4.4%	0.4%	6.6%	0.7%	3.4%	100.0%	94.9%	1.9%	3.3%	100.0%
2006	2005	30,519	2,516,589	219,140	3,318	244,057	143,279	145,105	3,302,007	2,923,885	257,756	120,366	3,302,007
	%	0.9%	76.2%	6.6%	0.1%	7.4%	4.3%	4.4%	100.0%	88.5%	7.8%	3.6%	100.0%

10D. NEW FORM Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date												
FY Reported	FY Funded	American Indian/Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White (Hispanic)	More Than One Race	Unknown or Not Reported	**Total of Hispanics or Latinos by Racial Categories	FOREIGN Subtotal Using US Minority Categories (shaded): NEW FORM Parts A+B	Number of Foreign Protocols with Enrollment data (New Form):	
2002	2001	1,461	0	4	0	1,659	683	175	3,982	267,952	102	
	%	36.7%	0.0%	0.1%	0.0%	41.7%	17.2%	4.4%	100.0%	92.6%		
2003	2002	1,644	3	1,222	0	632	4,528	1,594	9,623	1,929,582	213	
	%	17.1%	0.0%	12.7%	0.0%	6.6%	47.1%	16.6%	100.0%	88.2%		
2004	2003	115	14	12,778	0	4,537	11,878	6,466	35,788	3,996,746	285	
	%	0.3%	0.0%	35.7%	0.0%	12.7%	33.2%	18.1%	100.0%	92.4%		

2005	2004	682	6	164	0	26,161	14,664	11,124	52,801	2,583,315	321
	%	1.3%	0.0%	0.3%	0.0%	49.5%	27.8%	21.1%	100.0%	91.3%	
2006	2005	29,576	101	1,842	688	42,665	136,326	46,558	257,756	3,002,068	434
	%	11.5%	0.0%	0.7%	0.3%	16.6%	52.9%	18.1%	100.0%	90.9%	

* These totals must agree

** These totals must agree

11A. Part A. Phase III FIVE YEAR SUMMARY TOTALS: FOREIGN SUBJECTS IN FOREIGN PROTOCOLS (Old + New Forms)							
FY Reported	FY Funded	Females	Males	Unknown	Total Foreign Subjects (Old + New Forms)	Subtotal: Foreign Subjects Enrolled by US Minority Categories	Number of Foreign Protocols with Enrollment data (Old + New Forms):
2002	2001	14,359	15,911	41	30,311	18,308	172
	%	47.4%	52.5%	0.1%	100.0%	60.4%	
2003	2002	28,037	21,237	136	49,410	23,927	209
	%	56.7%	43.0%	0.3%	100.0%	48.4%	
2004	2003	24,020	25,023	83	49,126	37,126	24

	%	48.9%	50.9%	0.2%	100.0%	75.6%	
2005	2004	29,388	23,163	2,547	55,098	44,281	30
	%	53.3%	42.0%	4.6%	100.0%	80.4%	
2006	2005	55,599	42,354	1,180	99,133	84,412	60
	%	56.1%	42.7%	1.2%	100.0%	85.2%	

Table 11A Comments:

1. The percent females varied from 47.4% to 56.7% in Phase III foreign protocols from 2002-2006; the percent males varied from 42.0% to 52.5%.
2. The percent foreign subjects enrolled by U.S. Minority Categories in Phase III foreign protocols increased from 60.4% to 85.2% from 2002 to 2006.
3. Total Phase III foreign enrollment increased from 30,311 to 99,133 during these 5 years.
4. The number of Phase III foreign protocols dropped from 209 in 2003 to 60 in 2006.

NOTE 1: The shaded portions of the Tables B, C and D below show the race/ethnicity categories that are identified as minority categories. The Data Reported in FY 2002 and later are from the new Population Tracking System that was deployed with data reported in FY 2002 and later, and allows separate reporting using the Old Form and the New Form, and separate reporting for Foreign and Domestic Data.

NOTE 2: Data from Tables 11B, 11C and 11D are combined to provide the summary data in Table A.

11B.OLD FORM: Total of All FOREIGN Subjects Reported Using the 1977 OMB Standards in a combined race/ethnicity format

FY Reported	FY Funded	American Indian/ Alaska Native	Asian/ Pacific Islander	Black or African American	Hispanic, Not White	White	Unknown /Other	Total Foreign Enrollment (Old Form)	Foreign Subtotal Using US Minority Categories (shaded): OLD FORM	Number of Foreign Protocols with Enrollment data (Old Form):
2002	2001	59	12,269	2,807	1,724	9,579	1,558	27,996	16,859	166
	%	0.2%	43.8%	10.0%	6.2%	34.2%	5.6%	100.0%	60.2%	
2003	2002	77	12,428	280	3,499	15,054	8,077	39,415	16,284	188
	%	0.2%	31.5%	0.7%	8.9%	38.2%	20.5%	100.0%	41.3%	
2004	2003	1	12,068	52	1,007	3,093	7,603	23,824	13,128	10
	%	0.0%	50.7%	0.2%	4.2%	13.0%	31.9%	100.0%	55.1%	
2005	2004	0	12,252	1	1,183	2,257	14	15,707	13,436	5
	%	0.0%	78.0%	0.0%	7.5%	14.4%	0.1%	100.0%	85.5%	
2006	2005	16	12,295	30	12	4,533	675	17,561	12,353	8
	%	0.1%	70.0%	0.2%	0.1%	25.8%	3.8%	100.0%	70.3%	

11C. NEW FORM Part A: Inclusion Enrollment Report (Total of All FOREIGN Subjects Reported Using the 1997 OMB Standards for Separate Race

and Ethnicity Formats)

Part A: Total Enrollment Report: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

		Total of All Subjects by Race								Total of All Subjects by Ethnicity			
FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White	More Than One Race	Unknown or Not Reported	*Total of All Subjects by Racial Categories (New Form)	Not Hispanic	**Hispanic or Latino	Unknown/ Not Reported	*Total of All Subjects by Ethnic Category
2002	2001	0	1	1,448	0	113	0	753	2,315	1,562	0	753	2,315
	%	0.0%	0.0%	62.5%	0.0%	4.9%	0.0%	32.5%	100.0%	67.5%	0.0%	32.5%	100.0%
2003	2002	7	23	7,610	0	1,095	0	1,260	9,995	8,720	3	1,272	9,995
	%	0.1%	0.2%	76.1%	0.0%	11.0%	0.0%	12.6%	100.0%	87.2%	0.0%	12.7%	100.0%
2004	2003	0	12	21,414	0	553	2,570	753	25,302	21,972	2,572	758	25,302
	%	0.0%	0.0%	84.6%	0.0%	2.2%	10.2%	3.0%	100.0%	86.8%	10.2%	3.0%	100.0%
2005	2004	389	4,272	25,948	0	7,576	0	1,206	39,391	38,122	624	645	39,391
	%	1.0%	10.8%	65.9%	0.0%	19.2%	0.0%	3.1%	100.0%	96.8%	1.6%	1.6%	100.0%
2006	2005	1,906	27,048	27,513	5	8,093	169	26,838	91,572	60,670	17,484	3,418	81,572

	%	2.1%	29.5%	30.0%	0.0%	8.8%	0.2%	29.3%	100.0%	74.4%	21.4%	4.2%	100.0%
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11D. New Form Part B: Hispanic Enrollment Report: Number of Hispanics or Latinos Enrolled to Date											
FY Reported	FY Funded	American Indian/ Alaska Native	Asian	Black or African American	Native Hawaiian or Pacific Islander	White (Hispanic)	More Than One Race	Unknown or Not Reported	**Total of Hispanics or Latinos by Racial Categories	FOREIGN Subtotal Using US Minority Categories (shaded):NEW FORM Parts A+B	Number of Foreign Protocols with Enrollment data (New Form):
2002	2001	0	0	0	0	0	0	0	0	1,449	6
	%	0.0%	0.0%	0.0%	0.0%	0.00%	0.0%	0.0%	0.0%	62.6%	
2003	2002	0	0	0	0	2	0	1	3	7,643	21
	%	0.0%	0.0%	0.0%	0.0%	66.7%	0.0%	33.3%	100.0%	76.5%	
2004	2003	0	0	0	0	2	2,570	0	2,572	23,998	14
	%	0.0%	0.0%	0.0%	0.0%	0.1%	99.9%	0.0%	100.0%	94.8%	
2005	2004	388	0	0	0	4	0	232	624	30,845	25
	%	62.2%	0.0%	0.0%	0.0%	0.6%	0.00%	37.2%	100.00%	78.3%	

2006	2005	1,849	3	213	0	1,328	1	14,090	17,484	72,059	52
	%	10.6%	0.0%	1.2%	0.0%	7.6%	0.00%	80.6%	100.0%	78.7%	

* These totals must agree

** These totals must agree