OMB No. 0990-0115

Electronic Request for Proposal

SECTION A – SOLICITATION/CONTRACT FORM

OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE CMB WEBSITE http://www.niaid.nih.gov/contract/default.htm FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.

Purchase Authority: Public Law 92-218, as amended.
NOTE: The issuance of this solicitation does not commit the government to an award.

RFP Number:	***Just In Time:***	Small Bus. Set-Aside [ ]Yes [X]No 8(a) Set-Aside [ ]Yes [X]No NAICS Code: 54171 Size Standard: 500 Employees	***Level of Effort:***
NIH-NIAID-DMID-03-04	[ ] Yes [X] No		[ ] Yes [X] No

TITLE: Food and Waterborne Diseases Integrated Research Network

Issue Date: July 29, 2002	***Due Date: November 18, 2002*** ***Time:*** **4:00 PM, EST**	***Technical Proposal Page Limits:*** [X] Yes *(see "How to Prepare and Submit Electronic Proposals")* [ ] No

ISSUED BY:	[X] ***We reserve the right to make awards without discussion.***	
Lawrence M. Butler Contracting Officer Contract Management Branch, DEA NIH, NIAID 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, MD 20892-7612	***NO. OF AWARDS:*** [ ] Only 1 Award [X] Multiple Awards	***PERIOD OF PERFORMANCE:*** 7 years beginning on or about 07/01/2003

Offers will be valid for 240 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See SECTION J - Attachments)

The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

POINT OF CONTACT **-- Kristen Mistichelli** ***--COLLECT CALLS WILL NOT BE ACCEPTED--***

Telephone: ***Direct*** **301-496-0384** ***Main*** **301-496-0612**	***Fax*** **301-402-0972**	***E-Mail*** **KMistiche@NIAID.NIH.GOV**

Updated thru FAC 97-25 (05/02/01)

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Food and Waterborne Diseases Integrated Research Network
RFP DMID-03-04

BACKGROUND

Each year in the United States, the CDC estimates 76 million persons experience food borne illnesses. Waterborne disease outbreaks associated with drinking water or recreational water occur annually. Vaccines, therapeutics and diagnostics for these infectious diseases are limited. Challenge studies requiring specialized clinical facilities are necessary for some of the vaccine studies. The development of antibiotic resistance and its relationship to the food supply is an important public health issue. The Food and Waterborne Diseases Integrated Research Network will support activities critical to filling gaps in food and water safety and enteric diseases research.

INTRODUCTION

This RFP solicits proposals from offerors who wish to participate as research units in the Food and Waterborne Diseases (FWD) Integrated Research Network (IRN). The FWD IRN will facilitate the integration of research programs to develop products to rapidly identify, prevent, and treat food and waterborne diseases that threaten public health.

The NIAID research agenda in Food and Waterborne Diseases will be implemented at the direction of the Project Officer. This inter-disciplinary consortia will address food and waterborne pathogens (bacteria, viruses, and protozoa included in the NIAID Category A, B, C priority organisms list http://www.niaid.nih.gov/dmid/biodefense/bandc_priority.htm.
It is likely that some of these agents will be more pertinent to the work of the different research units.

The FWD IRN will: 1) evaluate vaccines, therapeutics, and rapid detection methods; 2) integrate human mucosal immunity with clinical research; 3) increase research and product development activities, and 4) include the ecology and microbiology of food- and water-borne zoonoses as well as drug-resistant pathogens.

This RFP consists of four (4) parts (A-Microbiology Research Units, B- Immunology Research Units, C-Zoonoses Research Units, and D-Clinical Research Units). Offerors are not required to submit proposals for all parts; however, Offerors may submit proposals for only one part, or for any combination of the four parts (A, B, C, and D). Proposals must be separated so that each part is able to stand on its own. Each proposal must have a unique Principal Investigator. When appropriate, Offerors may employ subcontractors to provide the capacity/expertise in the full range of activities requested. An important feature of the network is the synergy that results from collaborative efforts. NIAID encourages flexibility throughout the contract period regarding use of collaborators and choice of projects in order to continually incorporate new ideas and projects of the highest scientific merit. NIAID anticipates up to eight awards under this RFP. Two awards are anticipated in each of the four parts of this RFP, as follows:

Part A Microbiology Research Units. These units shall have capacity and expertise in, but not be limited to microbiology, genetics, molecular biology, infectious diseases, and the use of advanced technologies such as genomics and proteomics. Each Offeror is required to address their capability with each of the agents in the NIAID Category A, B, C priority organisms list which are transmissible through food and/or water. Access to facilities with the appropriate biosecurity necessary to properly handle highly contagious or dangerous samples is a requirement.

Part B Immunology Research Units. These units shall have capacity and expertise in, but not be limited to innate, humoral and cell-mediated immunology in the context of infectious diseases research. Each Offeror is required to address their capability with each of the agents in the NIAID Category A, B, C priority organisms list which are transmissible through food and/or water. Access to facilities with the appropriate biosecurity necessary to properly handle highly contagious or dangerous samples is a requirement.

Part C Zoonoses Research Units. These units shall have capacity and expertise in, but not be limited to veterinary and water microbiology, disease ecology, environmental microbiology, epidemiology, and veterinary and comparative medicine. Each Offeror is required to address their capability with each of the agents in the NIAID Category A, B, C priority organisms list which are transmissible through food and/or water. Access to facilities with the appropriate biosecurity necessary to properly handle highly contagious or dangerous samples is a requirement.

Part D Clinical Research Units. These units shall have capacity and expertise in, but not be limited to Phase I and II clinical trials to evaluate candidate prophylactic and/or therapeutic vaccines, biologicals and drugs, new vaccine or therapy strategies, e.g., adjuvants, delivery vehicles, routes of administration, induction of specific innate and/or

adaptive immune response. Offerors must have the facilities to conduct enteric challenge studies in which infections with or without symptoms are experimentally induced under carefully controlled and monitored conditions.

Research units are encouraged to develop a broadly based and flexible approach to their area of responsibility. Multidisciplinary research will be achieved through interactive research projects with the other units of the FWD IRN. The research interactions will be facilitated through the FWD IRN Executive Committee and the Coordinating and Biostatistics Center. The Project Officer(s), the Principal Investigator of each Research Unit, and the PI of the Coordinating and Biostatistics Center will form the FWD IRN Executive Committee. The FWD IRN Executive Committee will participate in review of proposed research projects and make recommendations to the Project Officer as to those that should be conducted in the FWD IRN. Ad Hoc consultants will provide advice to the NIAID regarding research priorities and projects in food and waterborne diseases.

The Coordinating and Biostatistics Center will provide each FWD IRN with statistical support and administrative support (administrative core) for the Research Unit activities and integration with other FWD IRN activities. The FWD IRN investigators will be required to work with the Coordination and Biostatistics Center in the capacities we outline (RFP NIH-NIAID-DMID-03-28). The Project Officer will effect the NIAID research priorities in food and waterborne diseases through the research activities of the interactive units. Administrative and Biostatistical support will be provided by the Coordinating and Biostatistics Center currently being competed under RFP NIH-NIAID-DMID-03-28.

In the event of a public health threat, each unit will be required to respond and research will be re-directed at the direction of the Project Officer. Therefore, it is envisioned that these units will implement, staff and maintain coordinated groups that can provide activities needed to enhance the U.S. capacity to better prevent, treat and control food and waterborne diseases, especially those associated with agents on the NIAID Category A, B, C priority organisms list. The ability to enhance and facilitate response and research efforts with the efforts of local, state and federal public health and regulatory agencies in a coordinated biodefense response is an essential part of this contract activity. The Offeror shall develop a proactive plan for this integrated response. NIAID anticipates that a final plan will be developed by the FWD IRN and approved by the FWD IRN Executive Committee, within the first 6 months of the awards.

Independently and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional and technical personnel, volunteer populations, access to farm animals and/or wildlife, food supply chain, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract as needed to conduct the studies as set forth below and as approved by the Project Officer.

Part A. Microbiology Research Unit (MRU)

These units shall have capacity and expertise in, but not be limited to: microbiology, genetics, molecular biology, infectious diseases, and the use of advanced technologies such as genomics and proteomics. Research units are encouraged to develop a broadly based and flexible approach to their area of responsibility. Multidisciplinary research will be achieved through interactive research projects with the other units of the FWD IRN. The research interactions will be facilitated through the FWD IRN Executive Committee and the Coordinating and Biostatistics Center. Each Offeror is required to address their capability with each of the agents in the NIAID Category A, B, C priority organisms list which are transmissible through food and/or water. Access to facilities with the appropriate biosecurity necessary to properly handle highly contagious or dangerous samples is a requirement. The Contractor is required to work with the Coordinating and Biostatistics Center. The Coordinating and Biostatistics Center will provide each RWD IRN with statistical support and administrative support (administrative core) for the Research Unit activities and integration with other FWD IRN activities. See Notes to the Offeror (1), (2) and (8).

*Specifically, the Contractor shall**:***

1. Establish and/or maintain a focused and coordinated research group with expertise in, but not limited to, microbiology, molecular biology, genetics, infectious diseases and the use of advanced technologies such as genomics and proteomics.

2. Interact with the Immunology Research Units, the Zoonoses Research Units and the Clinical Research Units as directed by the Project Officer and work collaboratively and participate fully in development, performance and reporting of multi-disciplinary studies.

3. Identify at least one person to interact with and facilitate interactions for clinical trials and other studies. The contractor shall develop a plan for this activity.

4. Maintain the ability to assess genetic strain variation (including antibiotic resistance plasmids) and correlate these changes with factors influencing pathogenesis or emergence.

5. Develop and critically evaluate novel technologies to rapidly detect food and waterborne pathogens in food and/or water samples.

6. Develop diagnostic tests for rapid and simultaneous screening of multiple clinical specimens for multiple foodborne pathogens (including bacteria, viruses and parasites). Develop molecular methods for confirmation of etiologic agents; for simultaneous characterization of serotype, bacteriophage type, antimicrobial resistance, specific virulence factors, and other appropriate identifying markers; and subtyping for epidemiologic purposes. These tests will ultimately be validated and integrated into the laboratory-based public health surveillance activities conducted by the Center for Disease Control and Prevention (CDC) in collaboration with the state local public health laboratories. The developed methods should enable CDC and the state and local public health laboratories to rapidly and appropriately respond to incidents of bioterrorism affecting the nation's food supply.

7. Maintain basic research focused on the causes of enteric food and water-borne diseases and mechanisms of pathogenesis. One or more of the following activities shall be maintained:
   a. Provide capacity to translate basic research findings to applications, e.g., vaccine and adjuvant candidates for testing in animal models/human clinical protocols under production conditions compatible with eventual scale-up for phase II human trials.

b. Develop, standardize and use state-of-the-art assays, including but not limited to micro-array analyses and quantitative gene expression.
c. Perform genetic modifications to support basic and clinical research, pathogenesis and immune response studies with live, attenuated vaccines.
d. Emphasize new technologies and development of new vaccine and therapeutic candidates.

8. Pursue the identification of food and waterborne pathogens in infectious etiologies of chronic human disease, e.g., Crohn's Disease, at the direction of the Project Officer.

9. Obtain, isolate, grow, and preserve organisms from the environment, animal or human sources, at the specific request of the Project Officer. These shall be sent, at the direction of the Project Officer, to another contractor, research unit or grantee that may perform additional experiments with, or analysis on, them. Relevant information shall also be sent.

10. Attend a start-up meeting of the FWD IRN investigators in Bethesda, MD to be held within 2 months of the award. Include subcontractors and 4-5 MRU investigators in the contract budget for travel costs to attend the meeting.

11. Attend annual meeting of the FWD IRN investigators in Bethesda, MD. Discuss results of projects and provide study proposals. Include subcontractors and 4-5 MRU investigators in the contract budget for travel costs to attend the meetings.

12. The PI of each MRU shall participate as a member of the FWD IRN Executive Committee. The member shall participate in regular FWD IRN Executive Committee conference calls.

13. The Contractor shall develop Standard Operating Procedures and shall forward these procedures to the Coordinating Biostatistics Center.

14. In the event of a public health threat, each unit shall be required to respond, and research will be re-directed, at the direction of the Project Officer.

15. Within six months of contract award, the Contractor shall develop a proactive plan to implement, staff and maintain coordinated groups that can provide activities needed to enhance the U.S. capacity to better prevent, treat and control food and waterborne diseases. The ability to enhance and facilitate an integrated response and research effort with the local, state and federal public health and regulatory agencies is an essential part of this contract activity. The plan will be approved by the FWD IRN Executive Committee.

16. Prepare for an orderly transition to a subsequent Contractor by developing and submitting to the Project Officer at least 120 days prior to Contract completion a written transition plan outlining the secure and orderly transfer of this project to a designated Contractor, if other than the incumbent, that includes but is not limited to provision for transferring files, computer programs, and all written documentation for any studies. The Contractor shall carry out the plan as approved by the Project Officer by providing detailed instructions for employees of the new Contractor on the operation of the data management system as well as on particular study records and data sets.

17. Upon completion of this contract all data and specimens (including all source codes) collected and/or analyzed under this contract shall be delivered to the Government and/or subsequent contractors, if any.

Independently and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional and technical personnel, volunteer populations, access to farm animals and/or wildlife, food supply chain, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract as needed to conduct the studies as set forth below and as approved by the Project Officer.

Part B. Immunology Research Unit (IRU)

These units shall have capacity and expertise in, but not be limited to: innate, humoral and cell-mediated immunology in the context of infectious diseases research. Research units are encouraged to develop a broadly based and flexible approach to their area of responsibility. Multidisciplinary research will be achieved through interactive research projects with the other units of the FWD IRN. The research interactions will be facilitated through the FWD IRN Executive Committee and the Coordinating and Biostatistics Center. Each Offeror is required to address their capability with each of the agents in the NIAID Category A, B, C priority organisms list which are transmissible through food and/or water. Access to facilities with the appropriate biosecurity necessary to properly handle highly contagious or dangerous samples is a requirement. The Contractor is required to work with the Coordinating and Biostatistics Center. The Coordinating and Biostatistics Center will provide each RWD IRN with statistical support and administrative support (administrative core) for the Research Unit activities and integration with other FWD IRN activities. See Notes to the Offeror (1), (2) and (8).

Specifically, the Contractor shall:

1. Establish and/or maintain a focused and coordinated research group with expertise in, but not limited to, innate, humoral, mucosal and cell-mediated immunology in the context of infectious diseases research.

2. Interact with the Microbiology Research Units, the Zoonoses Research Units and the Clinical Research Units as directed by the Project Officer and work collaboratively and participate fully in development, performance and reporting of multi-disciplinary studies.

3. Provide expertise in and capacity for performing research and development that includes, but is not limited to:
   a. immunological assays to assess innate, humoral, cell-mediated immune responses in blood, tissues and mucosal compartments in both animal and human samples;
   b. development, standardization and application of: new, sensitive, and reproducible state-of-the-art tools for specific evaluation, characterization, and quantitation of the human immune response to pathogens, vaccines and therapies;
   c. development, standardization and use state-of-the-art immunological assays including, but not limited to: ELISA, ELISpot, flow cytometry, tetramer analysis, micro-array analysis, quantitative gene and protein expression;
   d. translation of immunological knowledge from animal studies to development and evaluation of vaccines and/or immune therapies in human subjects
   e. development and evaluation of strategies including novel vaccines, adjuvants and immunomodulators to optimize the protective immune responses and maintain immunological memory;
   f. development and evaluation of immune-based therapies (e.g., monoclonal antibodies, cytokines, anti-toxins, etc.)

4. Provide capacity and expertise to perform gene expression profiling in order to identify:
   a. host cellular signatures indicative of initial infection and unique for each pathogen;
   b. immune responses to pathogen sub-components (e.g., virulence factors);
   c. genetic polymorphisms of specific loci associated with host resistance and susceptibility to infection as well as its subsequent disease; and
   d. new targets for drugs or vaccines for therapeutic intervention and clinical management.

5. Conduct appropriate immunologic assays to determine volunteer eligibility baseline levels on entry into a study and response to the candidate vaccines/therapies in support of clinical trials.

6. Identify at least one individual responsible for facilitating the interactions between the IRU and CRU. Provide a plan for the cooperative interactions, specimen transfer etc., between the CRU and the IRU to achieve this task.

7. Develop and implement with the Project Officer's approval ancillary studies that use clinical specimens to develop additional information.

8. Identify and assess new targets for disease prevention and treatment based on innate and adaptive immune responses to food and waterborne pathogens.

9. Collect, manage and analyze immunological data with assistance from the Coordinating and Biostatistics Unit and interpret results.

10. Use animal studies/models to demonstrate proof of concept relating to immunogenicity of new vaccines, adjuvants, delivery methods, development of assays, etc.

11. Lead developments in translating pre-clinical immunogenicity studies to induction and maintenance of protective immunity in healthy adults, the elderly, children, infants, and the immune-compromised.

12. Obtain samples for immunologic assessment from animal or human sources, at the specific request of the Project Officer. These shall be sent, at the direction of the Project Officer, to another contractor, research unit or grantee that may perform additional experiments with, or analysis on them. Relevant information shall also be sent.

13. Attend a start-up meeting of the FWD IRN investigators in Bethesda, MD to be held within 2 months of the award.

14. Attend annual meeting of the FWD IRN investigators in Bethesda, MD. Discuss results of projects and provide study proposals. Include subcontractors and 4-5 IRU investigators in the contract budget for travel costs to attend the meetings.

15. The Principal Investigator of the IRU shall participate as a member of the FWD IRN Executive Committee. The member shall participate in regular FWD IRN Executive Committee conference calls.

16. The Contractor shall develop Standard Operating Procedures and shall forward these procedures to the Coordinating Biostatistics Center.

17. In the event of a public health threat, each unit shall be required to respond, and research shall be re-directed, at the direction of the Project Officer.

18. Within six months of contract award, the Contractor shall develop a proactive plan to implement, staff and maintain coordinated groups that can provide activities needed to enhance the U.S. capacity to better prevent, treat and control food and waterborne diseases. The ability to enhance and facilitate an integrated response and research effort with the local, state and federal public health and regulatory agencies is an essential part of this contract activity. The plan will be approved by the FWD IRN Executive Committee.

19. Prepare for an orderly transition to a subsequent Contractor by developing and submitting to the Project Officer at least 120 days prior to Contract completion a written transition plan outlining the secure and orderly transfer of this project to a designated Contractor, if other than the incumbent, that includes but is not limited to provision for transferring files, computer programs, and all written documentation for any studies. The Contractor shall carry out the plan as approved by the Project Officer by providing detailed instructions for employees of the new Contractor on the operation of the data management system as well as on particular study records and data sets.

20. Upon completion of this contract all data and specimens (including all source codes) collected and/or analyzed under this contract shall be delivered to the Government and/or subsequent contractors, if any.

Independently and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional and technical personnel, volunteer populations, access to farm animals and/or wildlife, food supply chain, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract as needed to conduct the studies as set forth below and as approved by the Project Officer.

Part C. Zoonoses Research Unit (ZRU)

These units shall have capacity and expertise in, but not be limited to: veterinary and water microbiology, disease ecology, environmental microbiology, epidemiology, and veterinary and comparative medicine. Research units are encouraged to develop a broadly based and flexible approach to their area of responsibility. Multidisciplinary research will be achieved through interactive research projects with the other units of the FWD IRN. The research interactions will be facilitated through the FWD IRN Executive Committee and the Coordinating and Biostatistics Center. Each Offeror is required to address their capability with each of the agents in the NIAID Category A, B, C priority organisms list which are transmissible through food and/or water. Access to facilities with the appropriate biosecurity necessary to properly handle highly contagious or dangerous samples is a requirement. The Contractor is required to work with the Coordinating and Biostatistics Center. The Coordinating and Biostatistics Center will provide each RWD IRN with statistical support and administrative support (administrative core) for the Research Unit activities and integration with other FWD IRN activities. See Notes to the Offeror (1) and (2).

Specifically, the Contractor shall:

1. Establish and/or maintain a focused and coordinated research group with expertise in, but not limited to, veterinary and water microbiology, disease ecology, environmental microbiology, epidemiology, and veterinary and comparative medicine.

2. Interact with the Microbiology Research Units, the Immunology Research Units and the Clinical Research Units as directed by the Project Officer and work collaboratively and participate fully in development, performance and reporting of multi-disciplinary studies.

3. Establish partnerships with State or Federal Veterinary Diagnostic Laboratories as well as State and Local Public Health Laboratories in order to form linkages, share information and specimens, and apply advanced technologies to pathogen identification and antibiotic resistance. Be able to perform standard identification technology (e.g., PULSENET, www.cdc.gov\pulsenet) so as to form a common basis for these partnerships as well as the basis for evaluating new technologies.
   a. Perform additional subtyping and molecular characterization of isolates of interest, e.g., use a model pathogen like Salmonella and the subtypes Salmonella enterica subtype typhimurium and S. newport.
   b. In the first year develop a program for sharing real time the subtype results in human and animals within the FWD IRN.
   c. In the second year develop a program for participation in a national effort to form bridges or partnerships outside of the FWD IRN.

4. At the direction of the Project Officer, establish multiple study site capabilities, e.g., on-farm (e.g., dairy, feed-lot, etc), wildlife, near-by environment (e.g., stream, packing plant, water reservoir) and human population (e.g., hospital patients, schools, retirement communities) to include, but not be limited to:
   a. Collection of specimens;
   b. Characterization/identification, quantitation, and preservation of organisms;
   c. Study of infection, disease, and microbial emergence applying advanced technologies such as genomics and proteomics when appropriate.

5. Perform studies of epidemiological and ecological factors/characteristics such as:
   a. Determine the prevalence of E. coli O157 H:7, and design and conduct studies to determine why some farms have a high prevalence of E. coli O157 H:7 and others a low prevalence;
   b. Design and conduct studies of the emergence, spread, and persistence of single and multi-drug resistant

organisms (e.g., multi-drug resistant Salmonella enterica subtype typhimurium DT104) in animals, the environment, and humans;

c. Design and conduct studies of the dissemination and transfer of resistance genes from one bacterial pathogen to other pathogens, (e.g., Salmonella enterica subtype typhimurium DT104 and S. newport , etc.).
d. Identify mutations and mechanisms of resistance as well as mechanisms of persistence.

6. Evaluate:
   a. Methods to prevent spread of these organisms from vertebrate animals including domestic and wild, to one another, or to water and other ecological systems and hence to humans, e.g., chemical or other decontamination, vaccination of animals, therapeutics.
   b. Strategies to diminish emergence and spread of resistance while maintaining animal health.
   c. New detection and diagnostic methods.
   d. Risk of public health threat of a food and waterborne incident. Specifically, establish and enhance existing collaborations with other government agencies, e.g., USDA, FDA, CDC, local and state public health and or animal health departments and laboratories.

7. Obtain, isolate, grow, and preserve organisms from the environment, animal or human sources, at the specific request of the Project Officer. These shall be sent, at the direction of the Project Officer, to another contractor, research unit or grantee that may perform additional experiments with, or analysis, on them. Relevant information shall also be sent.

8. Attend a start-up meeting of the FWD IRN investigators in Bethesda, MD to be held within 2 months of the award. Include subcontractors and 4-5 ZRU investigators in the contract budget for travel costs to attend the meeting.

9. Attend annual meeting of the FWD IRN investigators in Bethesda, MD. Discuss results of projects and provide study proposals. Include subcontractors and 4-5 ZRU investigators in the contract budget for travel costs to attend the meetings.

10. The Principal Investigator of the ZRU shall participate as a member of the FWD IRN Executive Committee. The member shall participate in regular FWD IRN Executive Committee conference calls.

11. The Contractor shall develop Standard Operating Procedures and shall forward these procedures to the Coordinating Biostatistics Center.

12. In the event of a public health threat, each unit shall be required to respond, and research shall be re-directed, at the direction of the Project Officer.

13. Within six months of contract award, the Contractor shall develop a proactive plan to implement, staff and maintain coordinated groups that can provide activities needed to enhance the U.S. capacity to better prevent, treat and control food and waterborne diseases. The ability to enhance and facilitate an integrated response and research effort with the local, state and federal public health and regulatory agencies is an essential part of this contract activity. The plan will be approved by the FWD IRN Executive Committee.

14. Prepare for an orderly transition to a subsequent Contractor by developing and submitting to the Project Officer at least 120 days prior to Contract completion a written transition plan outlining the secure and orderly transfer of this project to a designated Contractor, if other than the incumbent, that includes but is not limited to provision for transferring files, computer programs, and all written documentation for any studies. The Contractor shall carry out the plan as approved by the Project Officer by providing detailed instructions for employees of the new Contractor on the operation of the data management system as well as on particular study records and data sets.

15. Upon completion of this contract all data and specimens (including all source codes) collected and/or analyzed under this contract shall be delivered to the Government and/or subsequent contractors, if any.

Independently and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional and technical personnel, volunteer populations, access to farm animals and/or wildlife, food supply chain, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract as needed to conduct the studies as set forth below and as approved by the Project Officer.

Part D. Clinical Research Units (CRU)

These units shall have capacity and expertise in, but not be limited to: Phase I and II clinical trials to evaluate candidate prophylactic and/or therapeutic vaccines, biologicals and drugs, new vaccine or therapy strategies, e.g., adjuvants, delivery vehicles, routes of administration, induction of specific innate and/or adaptive immune response. Offerors shall have the facilities to conduct enteric challenge studies in which infections with or without symptoms are experimentally induced under carefully controlled and monitored conditions. The Contractor is required to work with the Coordinating and Biostatistics Center. The Coordinating and Biostatistics Center will provide each RWD IRN with statistical support and administrative support (administrative core) for the Research Unit activities and integration with other FWD IRN activities. See Notes to the Offeror (1), (3), (4), (5), (6), (7) and (8).

Specifically, the Contractor shall:

1. Establish and/or maintain a focused and coordinated research group with expertise in, but not limited, to performance of Phase I and II clinical trials to evaluate candidate prophylactic and/or therapeutic vaccines, biologicals and drugs, new vaccine or therapy strategies, e.g., adjuvants, delivery vehicles, and routes of administration.

2. Interact with the Microbiology Research Units, Immunology Research Units, and the Zoonoses Research Units as directed by the Project Officer and work collaboratively and participate fully in development, performance and reporting of multi-disciplinary studies.

3. Conduct Phase I and II clinical studies of potential new vaccine candidates or vaccination strategies using technology or information developed in pre-clinical or early clinical studies. Per DMID policy, adhere to Good Clinical Practice Standards (GCP) throughout the management/performance of all clinical trials. GCP standards apply to all aspects of trials, from ethical and scientific study design and oversight to maintenance of accurate records and diligent data recording.

4. Participate in multi-site trials and/or Phase III clinical trials as directed by the Project Officer.

5. Provide a plan to coordinate protocol development and monitoring activities with the Coordinating and Biostatistics Center. At least one person shall be identified to interact with and facilitate interactions between the CRU and the Coordinating and Biostatistics Center.

6. Coordinate protocol sampling with the MRUs and the IRUs. Engage the expertise of the MRUs and the IRUs to identify the appropriate studies, assays, samples and sampling time points for studying the immunologic and microbiologic responses. At least one person shall be identified to interact with and facilitate interactions between the CRU, the IRUs, and the MRUs. Provide a plan for the cooperative interactions, specimen transfer etc., between the CRU and the IRUs and the MRUs to achieve this task.

7. Conduct challenge studies in which infections with or without symptoms are experimentally induced under carefully controlled and monitored conditions. Pathogens for which challenge studies have been performed and are anticipated include cholera, E. coli, Shigella and Norwalk. Both vaccines and controls shall be challenged with pathogens to assess protection.

8. Conduct clinical studies in human volunteers. Clinical study activities will include, but are not limited to the following tasks:
    a. Recruitment of appropriate number and type of volunteers as required for all approved studies.
    b. Lead in the development of protocols, consent forms, case report forms. Prepare protocols, consent forms, and data collection forms for the clinical trials with assistance from the Coordinating and Biostatistics Center. The Coordinating and Biostatistics Center has the responsibility for the administrative tasks associated with protocol, consent and case report form development including but not limited to such activities as: circulation of protocols for review, collating comments, preparing redline documents, protocol tracking, and entering and keeping current FWD IRN studies in DMID's database e.g., HSROAD, and collecting and tracking all records required for IND studies by the U.S. FDA and for studies involving human subjects research by the Office of Human Subjects Protection. The Coordinating and Biostatistics Center will modify protocol documents as requested by the CRU protocol principal investigator.
    c. Provide responses to FDA IND questions and provide these to the Coordinating and Biostatistics Center to be included in the response prepared by the Center.
    d. Work with the Coordinating and Biostatistics Center to collect, store, and track distribution of sera and other clinical specimens from study participants.
    e. Determine the safety, immunogenicity, and trends for efficacy of vaccine candidates or prevention strategies by developing an effective study design. Safety reports will be prepared by the Coordinating and Biostatistics Center based on the protocol and safety monitoring committee requests.

9. Obtain and preserve samples of agents, animal or human tissue, at the specific request of the Project Officer. Samples shall be sent, at the direction of the Project Officer, to another contractor, research unit or grantee that may perform additional experiments with, or analysis on, the samples. Information relevant to the specimens shall be sent with the specimens at the request of the project officer. The Contractor shall cooperate or collaborate with other investigators as requested. Isolate, grow, and preserve these organisms and clinical specimens from which they are derived (if appropriate).

10. Attend a start-up meeting of the FWD IRN investigators in Bethesda, MD to be held within 2 months of the award. Include subcontractors and 4-5 ZRU investigators in the contract budget for travel costs to attend the meeting.

11. Attend annual meeting of the FWD IRN investigators in Bethesda, MD. Discuss results of projects and provide study proposals. Include subcontractors and 4-5 CRU investigators in the contract budget for travel costs to attend the meetings.

12. Principal Investigator of the CRU shall participate as a member of the FWD IRN Executive Committee. The member shall participate in regular FWD IRN Executive Committee conference calls. The Contractor shall develop Standard Operating Procedures and shall forward these procedures to the Coordinating Biostatistics Center.

13. In the event of a public health threat, each unit shall be required to respond, and research shall be re-directed, at the direction of the Project Officer.

14. Within six months of contract award, the Contractor shall develop a proactive plan to implement, staff and maintain coordinated groups that can provide activities needed to enhance the U.S. capacity to better prevent, treat and control food and waterborne diseases. The ability to enhance and facilitate an integrated response and research effort with the local, state and federal public health and regulatory agencies is an essential part of this contract activity. The plan will be approved by the FWD IRN Executive Committee.

15. Prepare for an orderly transition to a subsequent Contractor by developing and submitting to the Project Officer at least 120 days prior to Contract completion a written transition plan outlining the secure and orderly transfer of this project to a designated Contractor, if other than the incumbent that includes but is not limited to provision for transferring files, computer programs, and all written documentation for any studies. The Contractor shall carry out the plan as approved by the Project Officer by providing detailed instructions for employees of the new Contractor on the operation of the data management system as well as on particular study records and data sets.

16. Upon completion of this contract all data and specimens (including all source codes) collected and/or analyzed under this contract shall be delivered to the Government and/or subsequent contractors, if any.

Notes To Offerors

Food and Waterborne Diseases Integrated Research Network
DMID-03-04

NOTE (1) TO OFFEROR: Statistical support for the proposals and administrative support for the Research Unit activities and integration with other FWD IRN activities will be provided through the Coordinating and Biostatistics Center currently being competed under RFP NIH-NIAID-DMID-03-28. Such activities should not be included in your proposal.
The CoBC will also function as an administrative, operations, and regulatory support office to accomplish the objectives of the FWD IRN research agendas.

NOTE (2) TO OFFEROR: Identify and describe the details for a specific activity in collaboration with at least one of the following: FDA Centers for Excellence, CDC, USDA, state or local veterinary or public health department and or laboratory.

NOTE (3) TO OFFEROR: The offeror should assume that volunteers will need to be studied as inpatients, and a detailed outline of the design of such a study including a description of patient isolation facilities and containment procedures, the time required for completion, types of specimens to be collected, assessment of safety and efficacy, and the follow-up of patients should be included. Examples of the types of vaccines for enteric pathogens that have been evaluated in the past include: Norwalk virus like particle (VLP) vaccine; transgenic potatoes expressing *Escherichia coli* heat labile toxin; transcutaneous immunization with a *Helicobacter pylori* recombinant urease plus *E. coli* heat labile toxin adjuvant (NIAID DMID 00-001), and *Shigella flexneri* auxotrophic mutants (NIAID DMID 00-096). Summaries of the ongoing studies (NIAID DMID 00-001 and NIAID DMID 00-096) are available through the NIAID Clinical Trials Database website which can be found at: http://www.niaid.nih.gov/clintrials/ntest.asp.

NOTE (4) TO OFFEROR: It is estimated that a minimum of 100 subjects/year will be required for initial studies aimed at examining comparability with animal data. For these preliminary studies, assume 10 subjects would be needed for each of 10 vaccine/delivery system evaluations.

NOTE (5) TO OFFEROR: Following preliminary evaluation, expanded capability to conduct placebo controlled studies will require at least 100 subjects/year, minimum. Assume that 20 patients will be enrolled as vaccinees or controls to test safety and immunogenicity of 5 vaccines or delivery systems per year. It is likely that some of these trials will also need to be performed as inpatient studies.

NOTE (6) TO OFFEROR: Depending on the vaccine candidate, evaluation of safety and immune response may also include the need to measure reactogenicity, infectivity, degree of virulence or attenuation, transmissibility, antibiotic resistance, optimal dose/schedule, genetic stability, interference with other vaccines, effect of pre-existing or maternal antibodies, and booster responses.

NOTE (7) TO OFFEROR: The NIAID will assume responsibility for filing all Investigational new drug applications. All submissions are coordinated through the Coordinating and Biostatistics Center.

NOTE (8) TO OFFEROR: Offerors should check the links below for Guidance for activities involving human subjects:

Office for Human Research Protections, http://ohrp.osophs.dhhs.gov/

Monitoring of clinical trials and studies policy, http://grants.nih.gov/grants/guide/notice-files/NOT-AI-00-003.html

NIH policy on reporting race and ethnicity data: subjects in clinical research, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-053.html

Title 45--Public Welfare, Subtitle A –Department of Health and Human Services, Part 46—Protection of Human Subjects, http://www.access.gpo.gov/nara/cfr/waisidx_99/45cfr46_99.html

It is NIH policy that children (i.e., individuals under the age of 21) must be included in all human subjects research conducted or support by NIH, unless there are scientific or ethical reasons not to include them.

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

OER implementation of inclusion of children, http://odoerdb2.od.nih.gov/oer/policies/children.htm

NIH Guide notice on inclusion of children in studies, http://grants.nih.gov/grants/guide/notice-files/not98-024.html

All applicants participating in clinical research must document that they have completed training in the protection of human research participants by sending us a letter stating they have done so.

PHS Policy on Instruction in the Responsible Conduct of Research (RCR), http://ori.dhhs.gov/html/programs/finalpolicy.asp

NIH Guide notice, September 5, 2001, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-061.html

NIH Guide notice, December 5, 2000, http://grants.nih.gov/grants/guide/notice-files/NOT-OD-01-007.html

NIAID *Council News* article, December 21, 2000, http://www.niaid.nih.gov/ncn/newsletters/nl122100/nl122100.htm#6

NIAID *Council News* article, October 12, 2000, http://www.niaid.nih.gov/ncn/newsletters/nl101200/nl101200.htm#1

OER research training site, http://grants.nih.gov/training/index.htm

Sample letter to document research training, http://www.niaid.nih.gov/ncn/newsletters/nl090700/sample.htm

OHSR computer based training for researchers, Protection of Human Subjects, http://ohsr.od.nih.gov/cbt/

Document library, Office for Human Research Protections, http://ohrp.osophs.dhhs.gov/polasur.htm

NIAID Council News roadmap for human subjects policies, http://www.niaid.nih.gov/ncn/tools/humansubjects/default.htm

Human subject regulations decision charts, http://ohrp.osophs.dhhs.gov/humansubjects/guidance/decisioncharts.htm

http://ohrp.osophs.dhhs.gov/irbasur.htm

Reporting Requirements and Deliverables
Food & Waterborne Diseases Integrated Research Network
RFP DMID-03-04

The Contractor shall submit to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during each reporting period. These reports shall be brief and factual and prepared in accordance with the format specified below. The reports and deliverables shall be prepared by the Principal Investigator of the FWD IRN Research Unit Project with the administrative and biostatistical support of the CoBC.

Project Officer technical progress reports covering the work accomplished during each reporting period. These reports are subject to the technical inspection and requests for clarification by the Project Officer. These shall be brief and factual and prepared in accordance with the following format:

1. **Semi-Annual Technical Progress Reports** - by the fifteenth working day of the month following the end of each six month period, the Contractor shall submit four (4) copies of a semi-annual Technical Progress Report, comprising three (3) copies to the Project Officer and one (1) copy to the Contracting Officer. The CoBC will provide the support to develop this report. Such reports shall include the following specific information:

    a. A cover page that lists the contract number and title, the period of performance being reported, the contractor's names and address, the author(s), and the date of submission;

    b. SECTION I - An introduction covering the purpose and scope of the contract effort;

    c. SECTION II - A description of overall progress plus a separate description for each task or other logical segment of work on which effort was expended during the report period. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project;

    d. SECTION III - Substantive performance; a description of current technical or substantive performance and any problems encountered and/or which may exist along with proposed corrective action. Each clinical study should be reported separately according to the number assigned by the Project Officer. An explanation of any difference between planned progress and actual progress, why the differences have occurred, and if behind planned progress what corrective steps are planned.

    e. An anticipated work plan for the following six months.

    f. Preprints, reprints, and abstracts shall be submitted along with the report.

    g. Budget information including spent this period (six months), spent to date, balance, and proposed spending plan for the next six-month period.

Semi-annual Technical Progress Reports are not due for periods in which an annual or final report is due.

2. **Annual Reports -** On the anniversary date of the contract, the Contractor shall submit four (4) copies of an Annual Technical Progress Report, as above, comprising three (3) copies to the Project Officer and one (1) copy to the Contracting Officer. Such reports shall detail, document, and summarize the results of the entire contract work for the period covered. These reports shall be in sufficient detail to explain comprehensively the results achieved. Also to be included in the report is a summary of work proposed for the next reporting period. Specific requirements, if any, are set forth in the Work Statement. A one page summary of each ongoing and completed protocol shall be submitted at this time. An annual report will not be required for the period when the final report is due. The CoBC will provide the support to develop this report. Preprints and reprints of papers and abstracts not submitted in the semi-annual report shall be submitted.

3. **Final Report** - By the expiration date of the contract, the Contractor shall submit four (4) copies of a comprehensive Final Report, as above, comprising three (3) copies to the Project Officer and one (1) copy to the Contracting Officer. This final report shall detail, document and summarize the results of the entire contract work for the period covered. This report shall be in sufficient detail to explain comprehensively the results achieved. Additional specific requirements are set forth in the Work Statement. Preprints and reprints not included previously submitted shall be submitted.

4. **Summary of Salient Results** - With the annual/final reports the Contractor shall submit a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

5. **Other Reports** - The Contractor shall submit five (5) copies of: a) a one page summary of each ongoing and completed protocol one year and thirty days after an individual IND goes into effect and b) yearly IRB approvals and supporting documents.

If the Contractor becomes unable to deliver the reports specified hereunder within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of anticipated delays with reasons, therefore.

6. Data Submission to CoBC - The contractor must supply within an appropriate time frame, the data required for the Reports of the CoBC specifically:

A. **Accrual And Site Registration Repor**t

At specified time points to be determined by the Protocol Team and approved by the Project Officer, the Contractor shall submit a report for each open clinical protocol sponsored by the FWD IRN summarizing:

a. For each clinical site enrolling study participants in open clinical protocols: projected overall accrual at each site; date of first enrollment; actual accrual to date; summary of all eligible patients per month and to date; and, reasons for non-entry of eligible patients.

b. For each clinical site in the process of registering and obtaining approval to participate in open clinical protocols: outstanding requirements for approval; anticipated date of approval; projected accrual; and, any anticipated problems with protocol approval/implementation.

c. Summary of the projected versus actual accrual to date for all approved clinical sites, and reasons for non-entry of eligible patients.

The CoBC will assemble and distribute the Accrual and Site Registration Reports. Three (3) copies shall be provided to the NIAID Project Officer; additionally, one (1) copy of the report shall be provided to the Principal Investigators of the FWD IRN CRUs.

B. **Quarterly Technical Progress Report**

The Contractor shall submit a report to the CoBC summarizing the activities undertaken during the reporting period, as follows:

1.) Status of Protocol Development

a. Pending protocols for proposed clinical trials, including: lead investigator(s); stage of development; step within the NIAID review process; actions required for final approval, modification or disapproval, including unresolved issues, questions or problems; and, time frame for completion of review, approval, modification or disapproval.

b. A summary of issues or problems encountered with respect to the NIAID and/or the Protocol Team review and decision-making process, including recommendations for modifications and improvements to enhance the timeliness, efficiency or thoroughness of the review processes.

2.) Status of FWD IRN Research Unit Projects and Project Proposals

a. Pending projects, including: lead investigator(s); stage of development; step within the NIAID review process; actions required for final approval, modification or disapproval, including unresolved issues, questions or problems; and, time frame for completion of review, approval, modification or disapproval.

b. A summary of issues or problems encountered with respect to the NIAID and/or the FWD IRN review and decision-making process, including recommendations for modifications and improvements to enhance the timeliness, efficiency or thoroughness of the review processes.

c. A table charting the progress of FWD IRN approved projects including progress on milestones.

The CoBC shall have responsibility for assembling and distributing three (3) copies of the Quarterly Techincal Progress Report to the NIAID Project Officer; additionally, one (1) copy shall be provided to the Principal Investigators of each of the FWD IRN Research Units and one (1) copy to the Contracting Officer.

C. Semi Annual Technical Progress Report

Semi-annually and at the completion of each Project, the Contractor shall submit a summation of the work performed and the results obtained. This report shall be prepared by the Principal Investigator of the FWD IRN with the administrative and biostatistical support of the CoBC. The report should be in sufficient detail to explain comprehensively the tasks accomplished and the results achieved, and shall summarize data analyses performed in text, tabular and graphical form. This report shall include, but not be limited to, a summary of all relevant descriptive information for all research units, and for the clinical studies include accrual data, attrition, number of forms received, number of data edits, clinical site monitoring reports, adverse events, and safety information.

The CoBC shall have responsibility for assembling and distributing the semi-annual report. Each semi-annual report shall be due on or before 30 days following the end of each 6-month period beginning with the start of the contract. Three (3) copies of all reports shall be provided to the NIAID Project Officer and one (1) copy to the Contracting Officer.

D. Annual Technical Progress Report

On an annual basis, the Contractor shall submit a report summarizing the results of the entire contract work for the period covered, with separate reports prepared for each Project and/or Protocol for the components as specified below. These Annual Reports shall be in sufficient detail to explain comprehensively the status of these activities and results achieved, if applicable. Annual Reports shall be submitted thirty (30) days after the anniversary date. Three (3) copies of these reports shall be provided to the Project Officer and one (1) copy to the Contracting Officer.

Standard Operating Procedures, including:
a. Development, review and implementation of approved projects, including criteria for evaluation and prioritization.
b. Clinical site monitoring and training with respect to adherence to protocol requirements, data collection and quality assurance, and adherence to regulatory requirements.
c. Review and approval of publications, abstracts, reports and presentations.

E. Final Report And Deliverables

At the completion of the contract, the Contractor shall deliver to the Contracting Officer a cleaned, edited, documented public use data set containing all study data, on media to be determined at the time of delivery, as specified by the Project Officer, and copies of all data management tools, including, but not limited to, data documentation and data dictionaries, data entry software and editing programs to allow reading and analysis of the data. The Contractor shall provide to the Government appropriate computer programs capable of: (1) reading and manipulating all data, and (2) creating SAS compatible databases. Additionally, at the completion of the contract, the Contractor shall deliver to the Project Officer an audit trail of all raw data corrections, hard copies of the original data collected from study participants from all studies supported by this contract, and all logs, other records, and source codes related to data collection, entry, editing, analysis and transfer.

F. Other Deliverables

1. Prepare a plan for activation of the Food and Waterborne Diseases Integrated Research network at the direction of the Project Officer in response to a bioterrorist event. Submit within first 6 months of the award date. This will be one of the first tasks of the FWD IRN Executive Committee. This plan must include contact information and a mechanism for rapidly connecting all persons named on the Emergency Response Team. This plan will be prepared with the support of the CoBC

2. Provide the Project Officer and/or FWD IRN Research Unit investigators with information or reports as requested regarding any project. Such information may include, but not be limited to:

   a. Preparation of reports, analyses and recommendations for the Executive Committee and assistance in implementing necessary modifications approved by this body, including revised clinical protocols or Research Unit Projects.

   b. Preparation of materials such as tables, text, graphs, and diagrams as needed in collaboration with investigators and NIAID staff for presentation at study meetings or professional meetings and other special reports concerning study findings.

   c. Preparation of reports with custom formats and selection groups summarizing data for monitoring study progress or product safety or for use by separate site monitoring Contractor, if requested.

   d. Preparation of abstracts/protocol summaries for NIH clinical trials database and other databases specified by the Project Officer.

3. Design and conduct interim and final statistical analyses of study data as defined in the protocol. Prepare reports as directed by the Project Officer in collaboration with the NIAID Data Safety Monitoring Boards, Safety Monitoring Committees, or Safety Monitor. The reporting frequency and distribution of reports should be consistent with the requirements specified by the Safety Monitor, Safety Monitoring Committee or Data Safety Monitoring Board for each FWD IRN clinical protocol. The reports should include: interim analyses of data on the safety, toxicity, and efficacy of interventions and shall also include analyses of data on accrual, retention, loss to follow-up and other status indicators relevant to the conduct of the studies. Respond to requests for additional analyses from the FWD IRN investigators, Safety Monitor, Safety Monitoring Committee, Data Safety Monitoring Board and NIAID.

4. Prepare study status and site-specific performance reports including, but not limited to, accrual and retention of study participants, timeliness of data submission, and adherence to protocol specifications at least quarterly for Executive Committee for review, the appropriate Data Safety Monitoring Board or Safety Monitoring Committee, and the NIAID with recommendations for improvements and modifications to resolve such study issues and problems.

5. Participate in the preparation of scientific manuscripts and reports of the studies for publication in the peer-reviewed literature and presentation of the study results at relevant scientific meetings in collaboration with the protocol chairs, other FWD IRN investigators, Coordinating and Biostatistics Center, NIAID staff, and others, as appropriate.

6. Prepare for an orderly transition to a subsequent Contractor by developing and submitting to the Project Officer at least 120 days prior to Contract expiration a written transition plan outlining the secure and orderly transfer of this project to a designated Contractor, if other than the incumbent that includes but is not limited to provision for transferring files, computer programs, and all written documentation for any studies and for general Operating Center operating procedures. The Contractor shall carry out the plan as approved by the Project Officer by providing detailed instructions for employees of the new Contractor on the operation of the data management systems as well as on particular study records and data sets.

7. Upon completion of this contract, all data and specimens (including all source codes) collected and/or analyzed under this contract shall be delivered to the Government and/or subsequent contractors, if any.

Report Distribution

Item	Type of Deliverable	Initial Report Due	Recipients & Number of Copies	Subsequent Reports Due
1.	Semi-Annual Technical Progress Report	7 Months after Effective Date of Contract (EDOC)	3 Copies to PO 1 Copy CO	Semi Annually; due on or before 30 days following the end of each 6 month period beginning with the start of the contract. Semi-annual Technical Progress Reports are not due for periods in which an annual or final report is due.
2.	Annual Report	Anniversary Date of Contract	3 Copies to PO 1 Copy to CO	Annually; submitted 30 days after the anniversary date.
3.	Final Report	On the expiration date of the project.	3 Copies to PO 1 Copy to CO	
4.	Summary of Salient Results	With Annual/Final Reports	3 Copies to PO 1 Copy to CO	Annually; submitted 30 days after the anniversary date.
5.	Other Reports (IND Summary & IRB Approvals	1 year and 30 days after initial IND goes into effect; Anniversary date of the Contract	5 Copies to PO	1 year and 30 days after initial IND goes into effect; Anniversary date of the Contract

Data Submission to CoBC Summary

Item	Type of Deliverable	Initial Report Due	Recipient & Number of Copies	Subsequent Reports Due
A.	Accrual & Site Registration Report	TBD	1 Copy to Coordinating and Biostatistics Center (CoBC)	TBD
B.	Quarterly Technical Progress Report	4 Months after Effective Date of Contract (EDOC)	1 Copy to CoBC	Quarterly
C.	Semi Annual Technical Report	7 Months after EDOC	1 Copy to CoBC	Semi Annually; Due on or before 30 days Following the end of each 6 month period, beginning With the start of the contract.
D.	Annual Technical Report	Anniversary Date Of Contract	1 Copy to CoBC	Annually
E.	Final Report	By contract expiration	1 Copy to CoBC	
F.	Other Deliverables a. Plan for Bioterrorist Event b. Special Reports/Study Findings c. Study Progress Reports d. Abstracts/Protocols clinical trials	TBD	1 Copy to CoBC	TBD

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

A Sample Uniform Contract Format may be found at the following website:

http://www4.od.nih.gov/ocm/contracts/rfps/sampkt.htm

[Disregard SECTION I and J of this sample. Those SECTIONS have been incorporated as part of this RFP.]

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

BECAUSE THIS IS A STREAMLINED RFP, ARTICLES I.2. AND I.3., WHICH IDENTIFY ANY AUTHORIZED ADDITIONS, SUBSTITUTIONS AND/OR MODIFICATIONS TO THE GENERAL CLAUSES, WILL BE BASED ON THE TYPE OF CONTRACT/CONTRACTOR AND WILL BE DETERMINED DURING NEGOTIATIONS.

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CHAPTER 1) CLAUSES

FAR Clause No.	Date	Title
52.202-1	Dec 2001	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Covenant Against Contingent Fees (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printing/Copying Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000), Alternate II (Apr 1998)
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Feb 2002	Allowable Cost and Payment (Paragraph (a) is modified to delete the words Subpart 31.2 and to add the words Subpart 31.3)
52.216-11	Apr 1984	Cost Contract - No Fee

52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Jan 2002	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (NOTE: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	May 2002	Buy American Act - Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data - General, Alternate IV (Jun 1987)
52-232-9	Apr 1984	Limitation on Withholding of Payments
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Feb 2002	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	Dec 1998	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)

52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B., Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract), Alternate I (Jul 1985)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-5	Sep 1996	Termination for Convenience of the Government (Educational and Other Nonprofit Institutions)
52.253-1	Jan 1991	Computer Generated Forms

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES

HHSAR Clause No.	Date	Title
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.249-14	Apr 1984	Excusable Delays
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity
352.270-7	Jan 2001	Paperwork Reduction Act

[END OF GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS – Rev. 05/2002]

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

PACKAGING AND DELIVERY OF PROPOSALS (Attached to this listing)

HOW TO PREPARE AN ELECTRONIC PROPOSAL: (Attached to this listing)

PROPOSAL INTENT RESPONSE SHEET
SUBMIT ON or BEFORE: October 25, 2002 (Attached to this listing)

[NOTE: Your attention is directed to the "Proposal Intent Response Sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMB's coordination of the electronic submission and review of proposals.]

RFP FORMS AND ATTACHMENTS:

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE:

http://www.niaid.nih.gov/contract/ref.htm

APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):

- Summary of Related Activities
- Optional Form 310, Protection of Human Subjects Assurance Identification/Certification/Declaration

[When applicable, all institutions must have the form reviewed and approved by their Institutional Review Committee.]

- Government Notice for Handling Proposals
- Targeted/Planned Enrollment Table

APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):

- NIH-2043, Proposal Summary and Data Record
- Small Business Subcontracting Plan Format *[if applicable]*
- Offeror's Points of Contact

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

Inclusion Enrollment Report

- NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts
- NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)
- NIH(RC)-11: Research Patient Care Costs
- Safety and Health, HHSAR Clause 352.223-70
- Privacy Act System of Records
- Report of Government Owned, Contractor Held Property
- Government Property – Schedule ___
- Disclosure of Lobbying Activities, OMB Form LLL

PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

Listed below are delivery instructions for the submission of both PAPER and ELECTRONIC COPIES of your proposal.

PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals.
You are required to submit one original paper copy of your proposal along with the number of extra copies required below.

ELECTRONIC SUBMISSION:
In addition to the paper submission, you are required to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided below. If you experience difficulty or are unable to transmit, you should submit your proposal on a CD-Rom or ZipDisk by an express delivery service. We can then upload your proposal into the electronic system. You must certify that both the original paper and electronic versions of the proposal are identical.

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.

Shipment and marking of paper copies shall be as indicated below:

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:

"RFP NO. NIH-NIAID-DMID-03-04

TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. NUMBER OF COPIES:

The number of copies required of each part of your proposal are as specified below.

Technical Proposal: One (1) unbound signed original and five (5) unbound copies. Ten (10) copies of all material not available electronically (i.e. SOPs, Pertinent Manuals, Nonscannable Figures or Data, and Letters of Collaboration/Intent).

Business Proposal: One (1) unbound signed original and 5 unbound copies.

C. PAPER COPIES and CD-Rom or ZipDisk to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Kristen Mistichelli, MPA Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2242 Bethesda, Maryland 20817	Kristen Mistichelli, MPA Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive Room 2242, MSC 7612 Bethesda, Maryland 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with HHSAR 352.215-70, Late Proposals and Revisions (NOV 1986).

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

PAGE LIMITS -- THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 250 PAGES [INCLUDING: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc.]. ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.

Note that although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

ELECTRONIC SUBMISSION – To submit a proposal electronically under this RFP, offerors will need to prepare the proposal on a word processor or spreadsheet program (for the business portion) and convert them to Adobe Acrobat Portable Document Format (.pdf). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON SEPARATE FILES which must be identified as either TECHNICAL or BUSINESS and include some recognizable portion of the ORGANIZATION NAME.

Please note that the electronic submission does not replace the requirement to submit a signed, unbound original paper copy of both your Technical and Business Proposal, along with any required unbound duplicate copies. These paper originals should be mailed or hand-delivered to the address provided in this attachment and must be received on/before the closing date and time.

There is no limit to the size (MB) of the two electronic PDF files to be submitted; however, the size of the technical proposal is limited to the page limitation language outlined above. For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 4.0 (or higher).

Formatting Requirements:

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- Keep graphics embedded in documents as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly.
- Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.
- Paper size should not exceed 8-1/2 x 11. Larger paper sizes will be counted as 2 pages.
- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.
- Be aware of how large these graphics files become. Large files are discouraged.
- Limit scanned images as much as possible.
- Limit appendices and attachments to relevant technical proposal information (e.g., SOPs, pertinent manuals, non-scannable figures or data, resumes, letters of commitment/intent).

SUBMISSION OF "PROPOSAL INTENT TO RESPOND SHEET":

Approximately TWO weeks prior to the due date of the proposals, all offerors who submitted a "Proposal Intent Response Sheet" will be provided with specific electronic access information and electronic proposal transmission instructions. For this reason, it is imperative that all offerors who are intending to submit a proposal in response to this RFP contact the Contract Specialist identified in this RFP and complete and submit the attached "Proposal Intent Response Sheet" by the date provided on that Attachment.

CREATE ADOBE PDF ONLINE -- Adobe will allow you to create 5 documents on a trial for free. If you want to use the site regularly it costs $10/month or $100/year. Please link to the following URL for information:

https://createpdf.adobe.com/index.pl/3847995518.39272?BP=IE

LOG-IN / TRANSMISSION INSTRUCTIONS:

1. Log-in Site: Will be provided by the Contract Specialist after receipt of the "Proposal Intent Response Sheet"
2. Log-in Name: Will be provided by the Contract Specialist.
3. Log-in Password: Will be provided via telephone by the Contract Specialist after Log-in Name is provided.

4. Procedure -- When your proposal is completed and converted to a PDF file using Adobe Acrobat, it is ready to be transmitted electronically. You must upload separate Technical and Business Proposal Files. It is recommended that proposals be transmitted a few days before the due date so that you will have sufficient time to overcome any transmission difficulties.

- You must have Explorer 3.1 or higher.
- It is essential that you use antiviral software to scan all documents.
- Click on "Sign On" and enter your log-in name and password.
- Click on "Browse" to locate your saved files on your computer.
- Click on "Upload Proposal" after you have located the correct file.
- After a file is uploaded, a link to the file will appear under "Upload Files" at the bottom of the screen. Click on that link to view the uploaded file.
- If you experience difficulty in accessing your documents, please contact the appropriate NIH contracts office immediately.
- If you wish to revise your proposal before the closing date and time, simply log in again and re-post.

USER ACCESS TO THE POSTING SITE WILL BE DENIED AFTER THE RFP CLOSING DATE AND TIME PROVIDED WITH THIS RFP OR ITS MOST RECENT AMENDMENT(S).

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DMID-03-04
RFP Title: Food and Waterborne Diseases Integrated Research Network

Please review the attached Request for Proposal. Furnish the information requested below and return this page by October 25, 2002. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

[ ] DO INTEND TO SUBMIT A PROPOSAL
[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____
Address (print): _____
_____
_____
_____

Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (print clearly):
_____
_____

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____
Title: _____
E-Mail Address: _____
Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):

_____
_____
_____
_____
(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
CMB, NIAID, NIH
Room 2242
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Kristen Mistichelli, MPA
RFP-NIH-NIAID- DMID-03-04
FAX# (301) 480-5253
Email : KM359d@nih.gov

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).

1. REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following address:

http://rcb.cancer.gov/rcb-internet/forms/rcneg.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

a. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 54171.
(2) The small business size standard is 500 employees.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

b. **NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS**

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Section I.3., offerors will be evaluated by adding a factor of 10% percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment.

AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.

c. **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that MULTIPLE AWARD(S) will be made from this solicitation and that the award(s) will be made on/about June 30, 2003.

It is anticipated that the award(s) from this solicitation will be a multiple-year cost reimbursement type completion contract with a period of performance of seven (7) years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

d. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

e. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

f. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

g. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are [significantly more important than cost or price/approximately equal to cost or price/significantly less important than cost or price]. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

h. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

i. **SERVICE OF PROTEST** (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Brenda J. Velez
Contracting Officer
Contract Management Branch, DEA
National Institute of Allergy and Infectious Diseases
6700-B Rockledge Drive, Room 2230, MSC 7612
BETHESDA MD 20892-7612

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

j. **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors—Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

k. **AVAILABILITY OF THE "FEDERAL ADP AND TELECOMMUNICATIONS STANDARDS INDEX."**

Copies of the "Federal ADP and Telecommunications Standards Index" can be purchased from the U.S. Government Printing Office, Superintendent of Documents, Washington, DC 20402.

l. **USE OF INTERNET WEB SITE ADDRESSES (URLs) IN PROPOSALS**

Unless otherwise specified or required in NIAID solicitations, internet Web Site addresses (URLs) may not be used to provide information necessary to the conduct of the review of the proposal. Direct access to an internet site by a Reviewer who is examining and reviewing the proposal on behalf of the NIAID could compromise their anonymity during the review process. If a URL contains information pertinent to the proposal content, the offeror must provide access to the website via a temporary website portal which allow reviewers the capability to view and interact with the site.

The proposal must clearly identify the URLs to be accessed and the procedure for accessing the temporary website portal. Access must not require the identity of the individual.

2. INSTRUCTIONS TO OFFERORS

GENERAL INSTRUCTIONS

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

(1) **Contract Type and General Clauses**

It is contemplated that a cost-reimbursement completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

(2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

(3) **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS).) However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or

amounts, fee amounts (if any)., and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

(7) **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

(8) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

(9) **Human Subjects**

IMPORTANT NOTE TO OFFERORS: The following 6 paragraphs [(9) through (14)] shall be addressed in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (JANUARY 2001)

a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office of Protection from Research Risks (OPRR), National Institutes of Health (NIH), Bethesda, Maryland 20892*. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR, Part 46.

c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The National Institutes of Health will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consideration with OPRR*, (telephone: 301-496-7014*), is recommended.

e) In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OPRR* an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR* and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.

f) It is recommended that OPRR* be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. (End of Provision)

**Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this provision. The phone number to reach this office is 301-496-7014. For more information, the OHRP website may be accessed at http://ohrp.osophs.dhhs.gov/ Copies of the DHHS Regulations for the Protection of Human Subjects, 45 CFR Part 46, are also available on line at http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html.*

- **Instructions to Offerors Regarding Protection of Human Subjects**

Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

(a) Risks to the subjects

Human Subjects Involvement and Characteristics:

- Describe the proposed involvement of human subjects in response to the solicitation.
- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
- Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.

Sources of Materials:

– Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks:

- Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.

- Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

- Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

Protection Against Risk:

- Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.

- Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.

- In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

(c) Potential Benefits of the Proposed Research to the Subjects and Others

- Discuss the potential benefits of the research to the subjects and others.

- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

(d) Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.

- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Note: If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

Collaborating Site(s)

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

(10) **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at http://ohsr.od.nih.gov/cbt/. You may download the information at this site at no cost and modify it, if desired. In addition, the University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at http://www.centerwatch.com/order/pubs_profs_protect.html. If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the contracting officer with the title of the education program and a one sentence description of the program that the replacement has completed.

(11) **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is NIH policy that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an Institute/Center Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43), ***and applies to research subjects of all ages***.

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(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" (http://www.nih.gov/news/crp/97report/execsum.htm).

Information Required for ALL Clinical Research Proposals

This solicitation contains a review criterion addressing the adequacy of: (1) the offeror's plans for inclusion of women and minorities in the research proposed; or (2) the offeror's justification(s) for exclusion of one or both groups from the research proposed.

Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic groups and provide a rationale for selection of such subjects in response to the requirements of the solicitation. The description may include (but is not limited to) information on the population characteristics of the disease or condition being studied in the planned research, and/or described in the statement of work, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned research.

The proposal must include the following information:

- A description of the subject selection criteria
- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group
- The proposed sample composition using the "Targeted/Planned Enrollment Table"(see Section J, Attachments)

NOTE 1: *For all proposals, use the ethnic and racial categories and complete the "Targeted/Planned Enrollment Table in accordance with the Office of Management and Budget (OMB) Directive No. 15, which may be found at: http://www.whitehouse.gov/OMB/fedreg/ombdir15.html*

.

NOTE 2: *If this is an Indefinite Delivery, Indefinite Quantity (IDIQ) or Requirements contract as defined in FAR 16.5, the proposal should describe in general terms how it will comply with each bulleted item above for each task order. When the Government issues a task order request for proposal, each of the bulleted information items must be fully and specifically addressed in the proposal.*

Standards for Collecting Data. When you, as a contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in OMB Directive No. 15. The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When you collect race and ethnicity separately, you must collect ethnicity first. You shall offer respondents the option of selecting one or more racial designations. When you collect data on race and ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple responses, you shall make available, at a minimum, the total number of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

In addition to the above requirements, solicitations for **NIH defined Phase III clinical trials**[1] require that*:* a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide:

[1]See NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, for the Definition of an "NIH-Defined Phase III clinical trial.

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference),

by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Also, the proposal must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups, OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Use the form in Section J, Attachments, entitled, "Targeted/Planned Enrollment Table," when preparing your response to the solicitation requirements for inclusion of women and minorities.

Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

Use the format for the Annual Technical Progress Report for Clinical Research Study Populations (See Section J - List of Documents, Exhibits and Other Attachments of the RFP) entitled, "Inclusion Enrollment Report," for reporting in the resultant contract.

(12) **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are *clear and compelling* reasons not to include them. **(See examples of Justifications for Exclusion of Children below).** For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

All offerors proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

http://www.nih.gov/grants/guide/notice-files/not98-024.html

Offerors also may obtain copies from the contact person listed in the RFP.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. The “Human Subjects” section of your technical proposal should

provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. This solicitation contains a review criterion addressing the adequacy of: (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

When children are included, the plan also must include a description of: (1) the expertise of the investigative team for dealing with children at the ages included; (2) the appropriateness of the available facilities to accommodate the children; and, (3) the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation.

Justifications for Exclusion of Children

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

- The objective of the solicitation is not relevant to children.

- There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.

- The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.

- A separate, age-specific study in children is warranted and preferable. Examples include:

- The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
- The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
- Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or
- Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or
- Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);
- Other special cases justified by the offeror and found acceptable to the review group and the Institute Director

Definition of a Child

For the purpose of this solicitation, a child is defined as an individual under the age of 21 years.

The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

(13) **Data and Safety Monitoring in Clinical Trials**

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

All offerors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusions of the monitoring reported to the Project Officer.

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for the monitoring, and the policies and procedures for adverse event reporting. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal. If the protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety monitoring plan must be submitted as part of the proposal.

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA). Also, in the plan you should describe the frequency of reporting of the conclusions of the monitoring activities. The overall elements of each plan may vary depending on the size and complexity of the trial. The NIH Policy for Data and Safety Monitoring at http://grants.nih.gov/grants/guide/notice-files/not98-084.html describes examples of monitoring activities to be considered.

The frequency of monitoring will depend upon potential risks, complexity, and the nature of the trial; therefore a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:

- Principal Investigator (required)
- Independent individual /Safety Officer
- Designated medical monitor
- Internal Committee or Board with explicit guidelines
- Data and Safety Monitoring Board (DSMB - required for multisite trials)
- Institutional Review Board (IRB - required)

For multi-site Phase I and Phase II trials, a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and IRBs should be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In this case, such organizations may include the IRB-approved monitoring plan as part of the proposal submission.

(14) **Care of Live Vertebrate Animals**

a. The following notice is applicable when contract performance is expected to involve care of live vertebrate animals:

Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects - (SEPTEMBER 1985)

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at http://www.grants.nih.gov/grants/olaw/olaw.htm.

b. If an Animal Assurance is already in place, the offeror's proposal shall include:

-The Animal Welfare Assurance number.
-The date last certified by OLAW. (i.e. assurance letter from OLAW)
-Evidence of recent AAALAC Accreditation.

(15) **Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a conditions of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://ott.od.nih.gov/NewPages/64FR72090.pdf.

(16) **Privacy Act (Treatment of Proposal Information)**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(17) **Selection of Offerors**

a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

(1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

(2) The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is this Institute's policy to conduct discussions with all offerors in the competitive range, the Institute reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected sources in accordance with HHSAR 315.370.

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The Institute reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet the Institute's requirements. Synopses of awards exceeding $25,000 will be published in the Commerce Business Daily and FedBizOpps.

(18) **Small Business Subcontracting Plan**

Specific instructions for the submission of this document are outlined in SECTION L.1.a. of this RFP.

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, Attachment _ to this RFP is an example of such a plan.

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.
(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.
(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

(6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.
(4) A description of the method used to develop the subcontracting goals.
(5) A description of the method used to identify potential sources for solicitation purposes.
(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
(8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.
(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.
(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

(19) **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

(20) **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: http://www.sba.gov/size

The Department of Commerce website for the annual determination is:
http://www.arnet.gov/References/sdbadjustments.htm

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	SDB Percentage of Total Contract Value	**SDB Dollars**
Total Contract Value- $1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	$150,000

***NOTE:** FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(21) **Salary Rate Limitation in Fiscal Year 2002** **

Offerors are advised that pursuant to P.L. 107-116, no NIH Fiscal Year 2002 (October 1, 2001 - September 30, 2002) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct

salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 107-116 applies only to Fiscal Year 2002 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 107-116 states in pertinent part:

> "None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or extramural mechanism at a rate in excess of Executive Level I."

Information regarding the FY-2002 rate can be found at: http://www.opm.gov/oca/02tables/ex.pdf

(22) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

INSTITUTIONAL MANAGEMENT OF CONFLICTING INTERESTS

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(23) **ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

(24) **Solicitation Provisions Incorporated by Reference**, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

b) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

(1) **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

a) **Statement of Work**

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

(3) Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

(4) Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

(2) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

(4) Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (SEE SECTION M).

(3) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d) Other factors you feel are important and support your proposed research.

e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Proposal Cover Sheet

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

(3) Information Other than Cost or Pricing Data

a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.

b) The information submitted shall be at the level of detail described below.

1. **Direct Labor**

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. **Materials**

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. **Subcontracted Items**

   Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $550,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. **Raw Materials**

   Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. **Purchased Parts**

   Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**

   Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

7. **Indirect Costs**

   Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. **Special Equipment**

   If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. **Travel**

   Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. **Other Costs**

    List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at: http://rcb.nci.nih.gov/forms/cpi.htm

(4) Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)]

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

Alternate I (October 1997). As prescribed in 15.408(l), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

(b) (1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

(5) Total Compensation Plan - Instructions

Specific instructions for the submission of this document are outlined in SECTION L.1.a. of this RFP.

a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors will submit, as part of their business

proposal, a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

(6) Total Compensation Plan - Evaluation

a) **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

b) **Cost (Professional Compensation)**

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

c) **Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

d) **Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

(7) Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(8) Other Administrative Data

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38** (MAY 1999)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232-34, Payment by Electronic Funds Transfer--Other than Central Contractor Registration.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

d) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

(9) Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

http://ocm.od.nih.gov/contracts/rfps/FDP/PDPclausecover.htm

(10) Proposer's Annual Financial Report

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

(11) Representations and Certifications

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(12) Travel Costs/Travel Policy

a) **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

The major evaluation factors for this solicitation include technical, cost/price factors, and Small Disadvantaged Business (SDB) Participation. Although technical factors are of paramount consideration in the award of the contract, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make award to the Offeror(s) whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposal based on the detailed criteria listed below.

This research project involves human subjects. NIH Policy requires that women and members of minority groups and their subpopulations and children must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification is provided with respect to the health of the subjects or the purpose of the research.

Where inclusion of women, minority populations, and/or children is not feasible, a detailed rationale and justification for exclusion of one or both groups from the study population must be submitted with the technical proposal. The justification/rationale will be reviewed to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research. If the rationale is not considered acceptable by the Government and you are included in the competitive range, you will be afforded the opportunity to further discuss and/or clarify your position during discussions or include women, minorities and/or children in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

2. HUMAN SUBJECT EVALUATION

This research project involves human subjects. NIH Policy requires:

(a) Protection of Human Subjects from Research Risks

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by NCI that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal and provide a narrative with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable".

If your discussion regarding the protection of human subjects from research risks is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss and/or clarify your position during such discussions and in your Final Proposal Revision (FPR). If, after discussions, your proposed plan for the protection of human subjects from research risks is still found unacceptable, your proposal may not be considered further for award.

(b) **Data and Safety Monitoring**

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trails be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers should refer to the Statement of Work and Section L in the solicitation, as well as any further technical evaluation criteria in this Section M, as applicable, for the solicitations specific requirements for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will provide a narrative that describes the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the monitoring plan or no discussion can be found regarding the proposed monitoring plans) or "acceptable."

If the information provided regarding Data and Safety Monitoring is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss and/or clarify your plan during such discussions and in your Final Proposal Revision (FPR). If, after discussions, the plan is still considered "unacceptable," your proposal may not be considered further for award.

(c) **Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged), OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will address the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation

- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:
  - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
  - overriding factors dictate selection of subjects); or
  - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.
- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
  - inclusion of those groups would be inappropriate with respect to their health; or
  - inclusion of those groups would be inappropriate with respect to the purpose of the research.
- For NIH-defined Phase III clinical trials, reviewers will also address whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research

Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or "acceptable." See Section L of the solicitation for the requirements of women/minorities inclusion.

If the information you provide in your proposal regarding the inclusion of women and minorities is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify, or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion/exclusion of women/minorities is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

(d) **Children**

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them.
Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' narrative evaluation of the offeror's response to this evaluation criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance wit h NIH policy guidelines) or "acceptable."

If the information provided in your proposal about the inclusion of children is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further

discuss, clarify or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion of children is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

3. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

a. Extent to which SDB concerns are specifically identified
b. Extent of commitment to use SDB concerns
c. Complexity and variety of the work SDB concerns are to perform
d. Realism of the proposal
e. Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
f. Extent of participation of SDB concerns in terms of the value of the total acquisition.

4. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

SECTION M - EVALUATION FACTORS FOR AWARD

TECHNICAL EVALUATION CRITERIA

Part A: Microbiology Research Units

CRITERIA	WEIGHT

1. Technical Approach: Documented technical adequacy and feasibility of the technical approach for the project as a whole, and in the following areas:
   a) Research: This includes the methods and approaches for studying microbial pathogenesis including microbial physiology/biochemistry, genetics, molecular biology, and gene expression.
   b) Collaboration: Quality and depth of synergy of collaborations with public health resources including local and state public health laboratories and departments, local and state animal health departments and diagnostic laboratories and Federal agencies including USDA, FDA, and CDC. Proposed plans for collaborative research with these public health resources.
   c) Facilities: Plan to access to BSL2/3 or BSL 3 facilities as needed — 70 points

2. Personnel: Documented adequacy and relevance of expertise, experience, education, and availability of PI and other personnel for performing all the requirements of the work statement. The technical personnel should have documented training and experience to perform the assay and laboratory procedures. The administrative staff should possess the requisite experience to perform their duties related to program administration. — 20 points

3. Administration: Proposed plans for managing the microbiology research unit activities to ensure a cooperative, integrated and focused scientific effort. The ability to interact and coordinate with the Coordinating and Biostatistics Center and the other Research Units in the Food And Waterborne Diseases Integrated Research Network. Proposed plans to meet research needs recognized during course of award. — 10 points

Total possible points…….	100 points

SECTION M - EVALUATION FACTORS FOR AWARD

TECHNICAL EVALUATION CRITERIA

Part B: Immunology Research Units

CRITERA **WEIGHT**

a) Basic research: Documented technical adequacy and feasibility for the proposed methods and approaches for studying immune responses to microbial pathogens, vaccines, and therapies in humans and experimental animal models. This criteria also includes creating and evaluating new vaccines or vaccination strategies designed to deliver immunogens to maximally stimulate mucosal immunity, measuring the immune response (especially the mucosal immune response), and utilizing animal models to evaluate new vaccine paradigms, establish mechanisms of immune protection, or identify new targets for intervention. Lead developments in new strategies for the induction and maintenance of immunity in all populations representative of people affected by food and waterborne diseases. The use of state-of-the-art immunological assays and the proven ability to create and standardize new assays as required to support the clinical trials units.

70 points

b) Personnel: Documented adequacy and relevance of expertise, experience, education, and availability of the PI and other personnel for performing all the requirements of the work statement. The PI should have documented ability to collaborate and coordinate research activities with diverse partners. The PI should provide documented evidence of experience in animal model, vaccine strategy and mucosal immunology in the context of food and waterborne pathogens. The technical personnel should have documented training and experience to perform laboratory procedures. The administrative staff should possess the requisite experience to perform their duties related to program administration. 20 points

c) Administration: Proposed plans for managing the immunology research activities to ensure a cooperative, integrated focused scientific effort. The ability to interact and coordinate with the Coordinating Center and the other research units in the Food And Waterborne Diseases Integrated Research Network. Proposed plans to meet research needs recognized during course of award. 10 points

Total possible points…….	100 points

SECTION M - EVALUATION FACTORS FOR AWARD

TECHNICAL EVALUATION CRITERIA

Part C: Zoonoses Research Units

CRITERA **WEIGHT**

1. TECHNICAL APPROACH

a) Research: Documented technical adequacy and feasibility of the approach for the project as a whole, and for the plans, approach and strategy for research in ecology and epidemiology of food and waterborne diseases. This criteria includes methods for prevention and control in food production and approaches for studying anti-microbial resistance factors, food related molecular diagnostic and epidemiology methodologies, development of rapid diagnostic tests. Offerors should document access to field sites, food animals and wildlife, for the study of the ecology and epidemiology of food and waterborne diseases.

b) Collaboration: Quality and depth of synergy of collaborations with public health resources including local and state public health agencies, animal health agencies and Federal Agencies including USDA, FDA and CDC. The offerors proposed plans for collaborative research with these public health resources will be evaluated.

c) Facilities: Plan to access to BSL2/3 or BSL 3 facilities as needed.

80 points

2. PERSONNEL

Documented adequacy and relevance of expertise, experience, education, and availability of personnel for performing all the requirements of the work statement.

The PI should have a DVM degree and should provide documented evidence of experience in food and waterborne disease research, epidemiology. The team should have composite expertise in infectious diseases, zoonoses, epidemiology, molecular techniques, antimicrobials resistance issues. The technical personnel should have documented training and experience to perform the assay and laboratory procedures and animal work. The administrative staff should possess the requisite experience to perform their duties related to program administration.

20 points

Total possible points…….	100 points

SECTION M - EVALUATION FACTORS FOR AWARD

TECHNICAL EVALUATION CRITERIA

Part D: Clinical Research Units

CRITERA **WEIGHT**

A. Personnel

1. Demonstrated expertise of P.I. and professional staff with the FDA IND regulations and in designing, conducting, analyzing, interpreting, and publishing clinical trials of vaccines in adult and pediatric populations, including both genders and minorities, and in conducting appropriate laboratory evaluations. Appropriate quality assurance plan. (20 sub-points)

2. Documented success in managing and monitoring Phase I and II clinical trials. (20 sub-points)

3. Demonstrated training and expertise of supporting staff including staff for nursing, recruitment, laboratory evaluation, and data management, monitoring, analysis and reporting. Where appropriate, this includes experience with adult and pediatric populations of both genders and minorities. P.I.s commitment on this project (i.e., commitment to other projects is minimal). (10 sub-points)

50 points

B. Technical Approach: Documented technical adequacy and feasibility of the technical approach for the project as a whole, and in the following areas:

1. Adequacy and availability of appropriate pediatric and adult populations for vaccine studies. This includes an adequate availability of all populations representative of people affected by food and waterborne diseases.

2. Offerors should demonstrate the ability to recruit, retain, and following target populations. Documented adequacy and feasibility of the proposed plans for screening, recruiting, retaining and following target populations. This includes protection from research risks; and representation of genders, racial/ethnic and age groups appropriate to the research question and study complexity. Strategies for recruitment and retention should be presented. The recruitment plan should have specific plans for inclusion of minorities, women and children.

3. Adequacy and feasibility of proposed plans for conducting and managing clinical trials in relevant populations in inpatient and outpatient facilities using appropriate bio-safety precautions. This includes protection from research risks; data and safety monitoring and reporting; and valid analysis of data appropriate to the research question and study complexity.

4. Adequacy and feasibility of the proposed methods and procedures for determining vaccine virus or vaccine bacteria shedding and for detecting adventitious agents in vaccinated subjects.

40 points

C. Facilities

1. Adequacy and availability of adult and pediatric inpatient and outpatient facilities. Facilities should be accessible and acceptable to all study populations, including; women, minorities and child participants.

2. Adequacy and availability of laboratories to collect, process and store specimens for virologic, bacteriologic and immunologic evaluation of specimens

10 points

Total possible points…….	100 points