U.S. Department of Health and Human Services
National Institutes of Health

National Institute of Allergy and Infectious Diseases (NIAID)

RFP-NIH-NIAID-DAIT-BAA-05-11

Immune Function and Biodefense in Children, Elderly, and Immunocompromised Populations

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

SECTION A – SOLICITATION/CONTRACT FORM -- PURCHASE AUTHORITY: FAR 1.602-1

NOTE: The issuance of this solicitation does not commit the government to an award.

1. Issue Date:	2. Due Date: January 20, 2005 **Time :** 4 :00 PM	**3. Small Bus. Set-Aside:** [ ]Yes [X] No 8(a) Set-Aside: [ ]Yes [X] No NAICS #: 541710 (See Part IV, Section L.)
October 5, 2004		

4. Just In Time:	5. Number of Awards:	6. Technical Proposal Page Limits:
[X] No [ ] Yes (See Part IV, Section L.)	[ ] Only 1 Award [X] Multiple Awards	Number of Copies: See SECTION J Page Limitations: 100 Electronic File Size: 5 mega-bytes

7. Issued By:	8.	
Sharon M. Kraft Contracting Officer Contract Management Program, DEA NIH, NIAID, DHHS 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	[X] NIAID reserves the right to make awards without discussion.	
	9. Options: [X] No [ ] Yes (See Part IV, Section L.)	10. Period of Performance: Five (5) years beginning on or about September 30, 2005

11. Primary Point of Contact:	12. Secondary Point of Contact:	13. Protest Officer:
Name : Suzanne L. Dawkins Phone: 301-451-3698 Fax: 301-480-4675 E-Mail: sd33r@nih.gov	Name: Sharon M. Kraft Phone: 301-496-0195 Fax: 301-480-4675 E-Mail: sraft@niaid.nih.gov	Program Director, CMP Address (see block 7.)

14. COLLECT CALLS WILL NOT BE ACCEPTED. FACSIMILE SUBMISSIONS ARE NOT ACCEPTABLE.

15. Offers will be valid for 120 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)

DELIVERY ADDRESS INFORMATION

17. Hand Delivery or Overnight Service:	18. U.S. Postal Service or an Express Delivery Service
Suzanne L. Dawkins Contract Management Program, DEA NIAID, NIH, DHHS 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	Suzanne L. Dawkins Contract Management Program, DEA NIAID, NIH, DHHS 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612

19. The Official Point of Receipt for the purpose of determining timely delivery is the address provided in Block 17/18, above. The original paper copy with original signatures is the official copy for recording timely receipt. If the original 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.

Updated thru FAC 2001-24 (6/18/2004)

TABLE OF CONTENTS

BROAD AGENCY ANNOUNCEMENT DESCRIPTION

You are invited to submit a proposal in accordance with the requirements of this BROAD AGENCY ANNOUNCEMENT (BAA) (NIH-NIAID-DAIT-BAA-05-11) entitled "Immune Function and Biodefense in Children, Elderly, and Immuno-Compromised Populations." The Broad Agency Announcement is authorized by FAR 6.102 and further described in FAR 35.106 as well as the NIH Manual Issuance 6035, Broad Agency Announcements. A BAA is a general announcement of an agency's research interest and constitutes a solicitation. The intent of a BAA is to encourage the submission of creative and innovative approaches to specific research areas identified by the Government.

A proposal submitted in response to this BAA must present a detailed technical and cost proposal designed to meet the Research and Technical Objectives described in this announcement. The proposal must be signed by an official authorized to contractually commit the submitting organization.

The Statement of Work, including the specific work requirements and performance specifications, is developed and defined by the Offeror, not the Government. The Statement of Work should not exceed ten (10) single spaced-pages in length within the technical proposal, which is limited to one hundred (100) pages total.

Proposals are not evaluated against a specific Government need, as in the case of a conventional Request for Proposal (RFP), since they are not submitted in accordance with common Statement of Work issued by the Government. Instead, Research and Technical Objectives are provided in the BAA that describe the research areas in which the Government is interested. Proposals received as a result of the BAA are evaluated by a Scientific Review Group (SRG) in accordance with the Evaluation Criteria specified in the BAA.

There is no Source Selection Determination utilized under the BAA process. All the competing proposals are ranked on the basis of their respective relevance and scientific merit. The score assigned by the SRG is considered the final score. An Order of Merit Ranking is established by the Contracting Officer in lieu of a Competitive Range.

Negotiations are conducted with those Offerors selected from The Order of Merit Ranking based on their scientific merit and those specific considerations set forth in this solicitation under item 1of Section M, Evaluation Factors for Award. During negotiations, there is an opportunity to refine the proposed Statement of Work in consultation with the Project Officer, including the incorporation of the comments of the SRG, as appropriate. At the conclusion of negotiations with the Offerors selected from the Order of Merit Ranking, those Offerors are allowed the opportunity to submit a Final Proposal Revision (FPR) to address weaknesses in the proposal, based on issues identified by the SRG and to revise costs as may be appropriate.

It is anticipated that multiple awards will result from this announcement and these awards will be multi-year, cost-reimbursement, completion type contracts. The NIAID anticipates awarding 5-10 contracts. Awards are expected to be made on or about September 30, 2005. The NIAID estimates that the average annual total cost (direct and indirect cost combined) for these contracts is $1 million to $2 million per contract. However, it is anticipated that the total cost for each award may vary depending upon the scope of the project and the technical objectives of the award. The length of time for which funding is requested should be consistent with the nature and complexity of the proposed research. The maximum period of performance is five (5) years.

The award document will be tailored to the final negotiations with the selected Offeror(s) and modified as appropriate for the type of contractor organization, cost and/or fee arrangements, and other elements as negotiated prior to award.

BACKGROUND

The National Institute of Allergy and Infectious Diseases (NIAID) promotes and supports a broad range of research projects focused on basic mechanisms of immune function, including studies of innate and adaptive immunity and the immunological basis of vaccines, adjuvants, and immunotherapies. As part of its biodefense research mission, the Division of Allergy, Immunology and Transplantation (DAIT) of the NIAID announces a program to encourage research aimed at protecting immunosuppressed populations from potential bioterrorism agents (listed at http://www2.niaid.nih.gov/biodefense/bandc_priority.htm). The increased threat of bioterrorism and the emergence of potentially fatal diseases (such as SARS and West Nile virus) underscore the compelling need to develop improved treatments for protecting all segments of the human population, including immunocompromised individuals at high risk of acquiring infectious diseases. In addition to the very young and the elderly who have a natural sub-optimal immune capacity, there are a growing number of people receiving chemotherapy for cancer, or transplant recipients and patients with autoimmune disease receiving immunosuppressive drugs that must be protected. New methods must be developed that focus

on both innate and acquired immunity to provide better vaccines and immune-based therapeutic agents (such as adjuvants and passive immunoglobulins) to protect against infection and minimize harmful side effects for these populations.

On May 12th and 13th, 2004, an NIAID Biodefense Workshop titled "*Immunosuppression and Vaccination in Special Populations*" brought members of the medical research community together to consider the challenges that exist for vaccination of immunosuppressed groups. Workshop discussion focused on research needs in different populations:

- *Transplantation patients receiving immunosuppressive therapy*

New immunosuppressive drugs have decreased the rate of transplant rejection in this population. This success, however, has lead to a growing number of immunosuppressed patients who are more vulnerable to infectious disease and are unable to be treated safely with live virus vaccines. Until now, medical research has focused on the need to maintain a functional transplant. But little work has been done to study what specific immune components these drugs affect or how to enhance immune function after immunosuppressive therapy, while keeping rejection rates low.

- *Elderly populations*

Experimental results from animal models and clinical studies have described some types of immune deficiencies that occur during aging. For example, there is evidence that T cell immunity and innate immune system function decrease with age. It is also known that elderly populations do not respond to new antigens as well as younger populations. Characterization of the aging immune system is not complete, however, and very little is known about how to increase immune responsiveness in this growing population.

- *Neonates*

It is known that neonatal immune function is deficient in all immune compartments, and neonates represent another population in which vaccination with live virus is not considered safe. Much more research is needed to understand what specific immunodeficiencies exist as the neonate matures, and when each of these components becomes fully functional. Treatments that are designed to boost immunity of neonates must consider that this immune system is continuously changing and maturing. Therapies that enhance the immune response to vaccination must not only be properly targeted, but must also be appropriate for the stage of immune development in order to avoid unwanted effects, such as an ineffective response, development of tolerance to introduced antigens, or induction of autoimmunity.

The "*Immunosuppression and Vaccination in Special Populations*" workshop revealed the need for research in two primary areas: 1) a better understanding of the biological mechanisms that cause immunosuppression in all immunocompromised groups, and 2) new methods and treatments to enhance the immune response of these populations to vaccinations and immune-based therapeutic strategies. Quantitative information on the status of the immune system as it develops and senesces in normal individuals is clearly incomplete, as is information on the immune capabilities of individuals who are immunocompromised. Given the enormous breakthroughs in knowledge of the genes, receptors, signaling pathways, local cellular interactions, and systemic networks that comprise the immune system, comparative analyses between normal healthy adults and immunocompromised individuals should be a fruitful approach for uncovering critical differences between the groups.

The NIAID is using the contract mechanism in order to obtain the descriptive, hypothesis-generating research that is needed to develop novel methods and treatments to enhance the immune response of immune-suppressed populations to vaccinations and immune-based therapeutic strategies against NIAID Category A, B or C pathogens (listed at http://www2.niaid.nih.gov/biodefense/bandc_priority.htm).

INTRODUCTION

The Division of Allergy, Immunology and Transplantation (DAIT) of the NIAID seeks to improve the immune response of immunocompromised individuals to vaccines and immunotherapies that defend against NIAID Category A, B, or C priority pathogens (listed at http://www2.niaid.nih.gov/biodefense/bandc_priority.htm). The purpose of this BAA, entitled " Immune Function and Biodefense in Children, Elderly, and Immunocompromised Populations," is to solicit proposals for research programs that focus on either: 1) the discovery of basic biological mechanisms that cause these immune deficits (Research Area 1); or 2) testing of treatments that are designed to increase the safety and efficacy of such vaccines and immunotherapies in immunocompromised populations (Research Area 2). The ultimate goal of this research program is to protect the human population from potential bioterrorism agents. Therefore, it is expected that research results will provide information that ultimately contributes to the development of new or improved vaccines and/or immunotherapeutic treatments that target the human population, with a focus on immunocompromised individuals.

Through this BAA, research contracts will be awarded to identify, analyze, and modify specific immune parameters that prevent effective and safe vaccination or immunotherapy in immunocompromised populations, in the context of protecting them against one or more of the NIAID Category A, B, or C pathogens. Inclusion of immunological research that is not directed specifically at NIAID Category A, B and C pathogens or their products is responsive to this solicitation only if it addresses improving the effectiveness of vaccination or immunotherapies in immunocompromised populations against infection by those pathogens. Proposals submitted in response to this BAA should include at least one of the following immunocompromised populations:

- Neonates and/or children (for the purposes of this BAA, are defined as individuals under 5 years of age)
- Pregnant women
- Elderly populations (for the purpose of this BAA, are defined as individuals over 50 years of age)
- Individuals with primary immunodeficiency disease (e.g., severe combined immunodeficiency, etc.)
- Transplant patients receiving immunosuppressive therapy
- Cancer patients receiving chemotherapy
- Patients with autoimmune disorders receiving immunosuppressive therapy.

Offerors must submit complete and separate proposals for Research Area 1 or Research Area 2. Separate proposals to both Research Areas are acceptable but are not required. NIAID may establish separate Scientific Review Groups to evaluate proposals and will establish separate order of merit rankings for Research Area 1 and Research Area 2.

Research Area 1: Identify one or more biological mechanisms responsible for the immunosuppression in one or more of the populations listed above.

Research Area 2: Develop one or more treatments to improve the immune response of one or more of the populations listed above to vaccination or immunotherapy against NIAID Category A, B or C pathogens.

Examples of research and approaches that are responsive to Research Area 1 include (but are not limited to) the following:

- Characterization of expression patterns, densities, and signaling capabilities of innate or adaptive immune receptors, ligands, and cell types that are different in an immunocompromised population than in normal healthy adults.
- Comparative analyses between normal healthy adults and immunocompromised individuals to identify differences between the groups with respect to genes, receptors, signaling pathways, local cellular interactions, or systemic networks that comprise the immune system.
- Characterization of changes in the components of the innate immune system that affect adaptive immune responses to vaccination.
- Elucidation of alterations in antigen processing and presentation events in immunocompromised individuals following vaccination.
- Characterization of differences in T cell or B cell activation and maintenance in immunocompromised groups in response to immunotherapy.
- Genetic studies using animal models that are directly relevant to the human immune response, such as:
  a. Application of genetic homologies to guide discovery and characterization of human immune molecules and activation pathways; and
  b. Investigation of transgenic expression of human receptors or other molecules in animal models.

Examples of research and approaches that are responsive to Research Area 2 include (but are not limited to) the following:

- Application of knowledge of differences in gene expression patterns and immune signaling capabilities in an immunocompromised population compared to healthy adults to the development of new treatments to induce more effective immune responses to vaccines and immunotherapies, such as: enhancing phagocytosis, innate immunity, cytokine production, T and NK cell-mediated cytotoxicity, antibody production, or long-term T and B cell memory.
- Development of new treatments to stimulate or inhibit components of defective intracellular signaling pathways or networks for the purpose of boosting the host response to vaccination.
- Development of a new drug or cytokine therapy that targets specific immune mechanisms in immunocompromised populations to improve vaccine efficacy.
- Use of human *in vitro* studies or animal *in vivo* studies to test a new treatment to enhance immune cell activation after vaccination.
- Development of new drugs or therapeutics that enhance innate immune function (e.g. macrophage antimicrobial activity, or production of antimicrobial peptides).

The following types of research proposals are not responsive to this initiative:

- Proposals involving animal models for mechanism discovery that are not directly relevant to the human immune system (e.g., human molecules are not used or correlations to the human immune system are not clearly defined).
- Proposals involving clinical trials, although clinical research that uses human samples and/or clinical data obtained from independent clinical trials or studies is strongly encouraged (see the NIH definition of a clinical trial vs. clinical research at http://grants1.nih.gov/grants/funding/phs398/section_3.html).
- Proposals limited to further clinical testing of drugs, adjuvants, or other treatments that are already advanced in the product development process, such as:
    a. Treatments presently or previously in clinical testing; and
    b. Re-evaluation of existing treatments in the context of biodefense.

Although the above mentioned research areas are not responsive to this solicitation, they may be relevant to other NIAID Biodefense research programs. A listing of these programs can be found on the NIAID Biodefense funding website: http://www2.niaid.nih.gov/biodefense/research/funding.htm .

RESEARCH AND TECHNICAL OBJECTIVES

This section presents the technical objectives that the Government seeks to achieve through this BAA. Proposals should explain how the Offeror will contribute to these overall objectives. In contracts awarded as a result of this BAA, the Statement of Work will be the Statement of Work proposed by the Offeror and negotiated and accepted by the Government.

When preparing proposals in response to this BAA, offerors must review the "Technical Proposal Instructions for Broad Agency Announcements" included in Section L and the "Evaluation Factors for Award" included in Section M of this RFP for additional information.

Offerors may submit proposals for a coordinated program that encompass either Research Area 1 or Research Area 2. Offerors may submit multiple proposals; however, each proposal should address one research area and stand alone. The experimental objectives, approaches, methodology, possible outcomes and alternatives, as well as the personnel, percent of effort, specific duties, work location, supervision, lines of authority, and available equipment, facilities, and other resources should be described separately for each of the research areas: discovery of immunological defects responsible for insufficient host response to vaccination or immunotherapy against one or more NIAID Category A, B, or C pathogens (Research Area 1), or development of targeted treatments to enhance the host response to vaccination or immunotherapy (Research Area 2) against these pathogens. Proposals for Research Area 1 or Research Area 2 shall focus on one or more of the following immunocompromised populations:

- Neonates and/or children (for the purposes of this BAA, are defined as individuals under 5 years of age.)
- Pregnant women
- Elderly populations (for the purposes of this BAA, are defined as individuals over 50 years of age)
- Individuals with primary immunodeficiency disease (e.g., severe combined immunodeficiency, etc.)
- Transplant patients receiving immunosuppressive therapy
- Cancer patients receiving chemotherapy
- Patients with autoimmune disorders receiving immunosuppressive therapy

Offerors should comply with the following parameters in developing proposals for Research Area 1 and/or Research Area 2:

Research Area 1

Offerors shall identify, define, and analyze at least one biological mechanism that is the underlying cause of immunosuppression and the inadequate or adverse response of a specific immunocompromised population to vaccination/immunotherapy against NIAID Category A, B, or C pathogens or relevant model systems. Offerors not specifically addressing NIAID Category A, B, or C priority pathogens or their products shall justify how the proposed studies are applicable to immune responses against the listed agents. Studies of biological mechanisms shall be achieved in at least one of the following ways: (1) by analyzing human tissue samples or other clinical data obtained in conjunction with a clinical trial (although the NIH will not fund clinical trials under this contract); or (2) by analyzing human cells, *ex vivo*, that were obtained by another means. Animal models that have direct application to human immune systems may be included, with clear justification of how these models shall advance understanding of human immune responses. Studies shall include

both characterization of the biological mechanisms underlying immune suppression and identification of potential targets for vaccine or immunotherapeutic development to correct the defect.

Research Area 2

The Offeror shall develop at least one new treatment to enhance immune responsiveness against NIAID Category A, B, or C pathogens or relevant model systems, for at least one of the targeted populations listed in paragraph 3 of the Research and Technical Objectives section above. The treatment may involve the use of drugs, cytokines, hormones, biological proteins, adjuvants, or other molecules. Since it is possible that the underlying mechanisms of immunosuppression may be common to more than one of the immunocompromised groups listed in paragraph 3 above, the treatment that is developed may also affect the immune response in more than one of these groups. The Offeror shall evaluate potential efficacy of the treatment using *in vitro* human cell culture systems or animal models to demonstrate safety and a more efficacious host response to vaccination or immunotherapy. The purpose of this research will be to provide preclinical data to show that the chosen treatment is a valid approach for further development.

For both Research Areas, Offerors shall provide the following information as part of their technical proposal:

- *Experimental Design*. A detailed description of the experimental design (including the design of any human tissue sample studies), the rationale for experimental approaches, and a description of alternative approaches to be employed if these methods do not achieve the defined goals.

- *Project Plan and Milestones.* A project plan shall be developed that includes scientific, technical and administrative expertise to achieve the goals of the contract. The Plan shall include milestones of the research program and time-line implementation of milestones for aims/goals/ data and their intermediates. Milestones will be used to show progress in determining the biological mechanisms of immunosuppression or developing new treatment(s), and the expected timelines for achieving each milestone. The first year of the Project Plan shall be in sufficient detail to allow for monitoring the success of the research project. Years two, three, four and five may be less specific. The Plan shall detail participation in the Program Meeting (see below for description of Program Meetings). An update to the Plan is required semi-annually and annually as indicated under Section 2 under Reporting Requirements.

- *Animal Model Studies*. The rationale for proposed animal model studies and a detailed description of their relevance to human infection or vaccination (if applicable). Offerors proposing an animal model shall comply with all NIH guidelines for animal welfare (http://grants1.nih.gov/grants/funding/phs398/section_1.html#f_vertebrate_animals).

- *Tissue Samples/Clinical Data*. Descriptions of any human tissue samples and/or other clinical data to be used in the proposed studies, including how human subjects shall be protected from research risks and justification for the ethnic, gender, and age compositions of the human populations chosen for analysis. Offerors shall comply with all NIH guidelines for human subjects research (http://grants1.nih.gov/grants/funding/phs398/section_1.html#e_humansubs). Additional information on human subjects requirements may be found in Sections L and M of this announcement. Descriptions shall be sufficiently detailed to allow the Scientific Review Group to determine the feasibility and appropriateness of the proposed experimental approaches.

- *Data Management System*. Data from this contract shall be stored and managed at the Contractor's site in a Laboratory Management System designed and maintained by the Contractor, in consultation with the Project Officer. The Database management system shall be commercially available, documented, and supported relational database management system. The Contractor shall provide security systems, firewalls, and computer virus detection systems to be used to ensure database integrity and security. The local database at each Contractor site will contain, at a minimum: a) raw data and original results, and b) detailed experimental protocols. To ensure database integrity and interoperability, the contractor shall include bioinformatics experts in the research team. Key bioinformatics team members shall participate in the annual meetings (described below) in special sessions to define and execute standard operating procedures for data management and analysis among the funded contracts. Additionally, during the life of the contract, the Contractor may be required to submit data to a centralized database developed and maintained through the NIAID Bioinformatics Support Contract (BISC; see http://www.niaid.nih.gov/contract/archive2002.htm for the most recent RFP solicitation). After contract award, the project officer and a BISC representative will work with successful offerors to develop a process for data submission to the database.

- *Data Sharing Plan*. A plan for sharing data with the scientific research community, including any drugs or treatments developed under the contract. The NIH policy on the sharing of reagents and data can be found at http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html. Stating that results will be published may not be an adequate plan. Additional information about data sharing, including examples, can be found at http://grants.nih.gov/grants/policy/data_sharing/. The plan will be evaluated by the Scientific Review Group with respect to its feasibility and appropriateness.

- *Clinical Studies and Associated Clinical Trials.* Although clinical trials will not be funded under this program, the IRB-approved protocol and the investigators' brochure for any parent or core clinical trial that is a source for data or materials for the proposed studies shall be included with the proposal as part of the human subjects section. Informed consent form(s) shall also be included as part of this section. While drafts of the consent forms at participating sites are not required, it would be useful to include them if they are available. NIH will treat as confidential any scientific, preclinical, clinical, or formulation data and information that the sponsor deems to be proprietary and confidential. In order to ensure coordination between the proposed studies and any parent or core clinical trial, the Offeror and the sponsor of the parent or core clinical trial shall have a written agreement regarding the conduct of the studies presented in this proposal. Prior to award, the Offeror shall provide to NIAID a memorandum of understanding signed by the Offeror, an appropriate representative of the applicant institution, the principal investigator of the parent or core clinical trial, and an appropriate representative of the sponsor of the parent or core clinical trial. The memorandum shall outline the specifics of the agreement between the parties with respect to the following areas:

    - Nature of the biological specimens and the manner of access;

    - Timing and manner of access to data produced by the parent or core clinical trial that will be used in the proposed studies, including procedures for the prevention of unblinding of the parent trial;

    - Ownership, analysis, and release of data resulting from the proposed studies;

    - Documentation of quality assurance procedures for both the parent trial and the proposed studies;

    - Documentation of data and safety monitoring procedures for the parent trial, especially for efficacy trials;

    - Ownership of intellectual property developed during the proposed studies; and

    - Publication of the results of the proposed studies.

Additionally, after the contract is awarded, the following shall be required:

- *Program Meetings.* Each Contractor shall participate in Program meetings organized by the NIAID Project Officer to foster collaborations and the exchange of ideas among the participating researchers. These Program meetings will be held twice in the first year of the contract and once a year thereafter in or near Bethesda, Maryland, unless otherwise determined by the Project Officer. The Principal Investigators and other Key Personnel (maximum of two individuals per contract in addition to the Principal Investigators, with prior approval by the Project Officer) shall attend the meetings, which will also involve Project Officers, Contracting Officers, and other relevant NIH staff. Included in this meeting will be a bioinformatics session that will be attended by up to two key bioinformatics staff members (additional to the two key research personnel). The purpose of the bioinformatics session will be to facilitate data sharing between different contractors and to share possible solutions to common problems that may occur with data management.

- *Intellectual Property Rights.* Contractors shall provide plans to protect their intellectual property rights arising from work performed under this contract, that will not conflict with the goal of this BAA, which is to make project-generated data, reagents, and protocols widely accessible and available to the research community in a timely manner to encourage new discovery and innovation leading to long term health benefits to the human population. Contractors are strongly encouraged to protect new discoveries in a timely manner and to ensure their availability to the research community. A general plan shall be submitted to the Project Officer and Contracting Officer two months after award. An update shall be provided in Semi-Annual Reports as stated in Section 1.E. under Reporting Requirements and Deliverables.

Disclosures of any and all patents and copyrights or patent and copyright applications of drugs, biological therapies or procedures filed in or outside the U.S. by the Offeror and/or listed personnel or collaborators must be made at the time of proposal submission and must be updated in progress reports. Individual and institutional intellectual property rights and rights to inventorship under United States patent law will not be affected by participation in this BAA. The involvement of the NIH in the performance of this contract will not affect ownership rights of the participating parties beyond U.S. Government rights under any funding agreement as specific under 35 U.S.C. #202.

It is expected that the Offeror will administer its patent rights in a manner that will not conflict with the central goal of this BAA, which is to make the project generated drugs or treatments widely available to the research community. All licensing agreements entered into by the Contractor for completion of any or all of the research listed in this BAA and included in the negotiated Statement of Work shall be transferable to the Government.

NOTES TO THE OFFEROR

NOTE 1

Subcontracting agreements are allowable and encouraged to accomplish the work outlined in this solicitation. For each proposed subcontract, the technical proposal must describe in detail the subcontract research plan and contribution to the overall proposal, as well as include a complete description of the facilities and resources, professional training, background, experience and availability of proposed personnel, and associated direct and indirect (total) costs.

NOTE 2

For budget estimating purposes, the Offeror should assume the following:

The Program Meeting cost estimates should include annual travel costs (transportation, meals, hotel, etc.) for the Principal Investigator and no more than two other key personnel. Cost estimates should also include travel costs for the same personnel to attend an additional Kickoff Meeting that will be held in the first year. Offerors should assume the meetings will be held in Bethesda, Maryland, for 1.5 days per meeting.

The Offeror shall budget travel for up to three key personnel to attend two scientific meetings per year, not including the Program Meeting.

REPORTING REQUIREMENTS AND DELIVERABLES

The Contractor shall prepare and deliver the following reports throughout the period of performance. The exact submission schedule will be established in the contract document.

1. *Semi-Annual Reports*

The Contractor shall submit two (2) copies of the Semi-Annual Report on the15th of the month following the end of each 6 months (180 calendar days) of the performance period. The original shall be submitted to the Contracting Officer, with one copy submitted to the Project Officer. Each Semi-Annual Report shall include the following:

A. Face page, to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address, and submission date.

B. Executive summary, to include:

- An overview of the status of the project, including adherence to timelines, since the previous reporting period and specific milestones achieved;
- An overview of the activities conducted during the current reporting period, including any problems that occurred (technical or financial) and justification for any failure to complete the intended work, as well as any work that was performed beyond that initially planned, and;
- The extent to which the goals and specific objectives set forth in the Statement of Work were fulfilled.

C. Progress Report, to include a detailed description of:

- The work performed during the reporting period, including progress toward, for Research Area 1, the characterization of one or more mechanisms responsible for the immunosuppression in a particular population, or, for Research Area 2, the development of one or more treatments for improving immune response;
- A full disclosure of the results obtained and their relevance, explanations of any differences between planned and actual progress, and, if necessary, what corrective steps are planned or have been implemented to achieve the goals and objectives of the contract;
- An update to the Project Plan. The Contractor shall update the milestones of the research program and time-line implementation of milestones for aim/goal/ data and their intermediates for the upcoming 2 quarters, highlighting (in color, bold, italic, etc.) any changes in the previously reported Plan. Alterations in the Plan shall be sufficiently outlined and justified;

D. Copies of manuscripts (published or unpublished) derived from research performed under the contract and copies of all abstracts, manuscripts, preprints, and publications that resulted from work conducted, as well as any protocols and methods developed specifically under this contract during the performance period; and

E. A full disclosure of intent to file patent applications or copyrights within or outside of the U.S. on procedures utilized, derived, or established by the work supported under this contract; and full disclosure of any patent applications or copyrights filed, as well as copies of patent or copyright applications.

F. An update to the Intellectual Property Rights Plan.

A Semi-Annual Report is not required for the period in which a Final Report is due.

2. *Annual Update to the Project Plan*

The Contractor shall submit two (2) copies of the Annual Report on the15th of the month following the end of each 12 month performance period. The original shall be submitted to the Contracting Officer, with one copy submitted to the Project Officer.

The Contractor shall update the Project Plans milestones of the research program and time-line implementation of milestones for aim/goal/ data and their intermediates for the upcoming 4 quarters, highlighting (in color, bold, italic, etc) any changes in the previously reported Plan. Alterations in the Plan shall be sufficiently outlined and justified. Additionally, the Contractor shall update any changes in milestones and plans for the remaining years of the project.

3. *Final Report*

The Contractor shall submit two (2) copies of the Final Report one week prior to the completion date of the contract. The original shall be submitted to the Contracting Officer, with one copy submitted to the Project Officer. The Final Report shall include the following:

A. Face page, to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address, and submission date;

B. Introduction covering the purpose and scope of the contract effort, including a summary of salient results obtained during the entire performance period. The summary shall not exceed 200 words;

C. Executive summary, to include an overview of the activities conducted during the contract period and the extent to which the goals and specific objectives set forth in the proposal were fulfilled; and

D. A detailed description of the work performed, results obtained, relevance of the results, relation between the results and work in the research area being conducted by other groups, and impact of the findings on the scientific community (based on annual meetings, training sessions, and community feedback).

Other Deliverables

As Directed by the Project officer or the contracting officer, the contractor shall return to the government or deliver to a successor Contractor all data, protocols, and publications generated during the period of the contract. During the contract's performance and upon its delivery, this information may be made freely available to the research community. In addition, all licensing agreements entered into by the contractor for completion of any or all of the research listed in this contract and proposed by the contractor in its Statement of Work, as well as all data and protocols generated by the contractor under this contract shall be transferable to the government upon completion of the contract.

Deliverable Reports	No. of Copies	Addressee/Distribution	Due Dates
Intellectual Property Rights Plan	1 1	Contracting Officer NIAID 6700-B Rockledge Drive Bethesda, MD 20892 Project Officer NIAID 6610 Rockledge Drive Bethesda, MD 20892	General Plan to be submitted two (2) months after award; updates are required semi-annually and are included in the Semi-Annual Reports
Semi-Annual Reports	1 1	Contracting Officer NIAID 6700-B Rockledge Drive Bethesda, MD 20892 Project Officer NIAID 6610 Rockledge Drive Bethesda, MD 20892	The 15th of the month following the end of each semi-annual reporting period
Annual Update to the Project Plan	1 1	Project Officer NIAID 6610 Rockledge Drive Bethesda, MD 20892 Contracting Officer NIAID 6700-B Rockledge Drive Bethesda, MD 20892	The 15th of the month following the end of each annual performance period
Final Report	1 1	Contracting Officer NIAID 6700-B Rockledge Drive Bethesda, MD 20892 Project Officer NIAID 6610 Rockledge Drive Bethesda, MD 20892	One week prior to the completion date of the contract

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

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

http://rcb.cancer.gov/rcb-internet/wkf/sample-contract.htm

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF 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.

ARTICLE I.1. GENERAL CLAUSES

The complete listing of these clauses may be accessed at: http://rcb.cancer.gov/rcb-internet/clauses/clauses.html

The following General Clause Listing will be applicable to most contracts resulting from this RFP. However, the organizational structure of the successful offeror(s) will determine the specific General Clause Listing to be contained in the contract(s) awarded from this RFP:

General Clauses for a Cost-Reimbursement Research and Development Contract

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

ITEM 9: **Alternate II** (OCTOBER 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (JANUARY 2002) is added.

See I.2 Authorized Substitutions of Clauses of SECTION I at http://rcb.cancer.gov/rcb-internet/wkf/sectioni.pdf for the general listing of Authorized Substitutions of Clauses.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

ITEM 34: FAR Clause **52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns** (JUNE 2003), is applicable to this solicitation as follows:

"(b) Evaluation adjustment. (1) The Contracting Officer will evaluate offers by adding a factor of 10 percent to the price of all offers, except--…"

Offerors will be evaluated by adding a factor of 10 percent to the price of all offers, except offers from disadvantaged business concerns that have not waived the adjustment.

ITEM 47: FAR Clause **52.227-16, Additional Data Requirements** (JUNE 1987), is applicable to this solicitation.

ITEM 48: FAR Clause **52.227-17, Rights in Data--Special Works** (JUNE 1987), is applicable to this solicitation.

ITEM 49: FAR Clause **52.227-18, Rights in Data--Existing Works** (JUNE 1987), is applicable to this solicitation.

ITEM 50: FAR Clause **52.227-19, Commercial Computer Software--Restricted Rights** (JUNE 1987), is applicable to this solicitation.

ITEM 51: FAR Clause **52.227-23, Rights to Proposal Data (Technical)** (JUNE 1987), is applicable to this solicitation.

Excluded pages from the proposal dated *, are identified as follows:

*Information to be determined during negotiations.

See I.3 Additional Contract Clauses of SECTION I at http://rcb.cancer.gov/rcb-internet/wkf/sectioni.pdf for the general listing of Additional Contract Clauses.

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT:

No additional or supplemental Additional FAR Contract Clauses Included in Full Text are applicable to this solicitation. See I.4. Additional FAR Contract Clauses Included in Full Text of SECTION I at http://rcb.cancer.gov/rcb-internet/wkf/sectioni.pdf for the general listing of Additional FAR Contract Clauses Included in Full Text.

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: (http://www.niaid.nih.gov/contract/eproposal.htm#pack)

HOW TO PREPARE AN ELECTRONIC PROPOSAL: (http://www.niaid.nih.gov/contract/eproposal.htm#electronic)

PROPOSAL INTENT RESPONSE SHEET DUE ON/BEFORE: December 13, 2004 (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 CMP'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):

- Targeted/Planned Enrollment Table
- NIH-1688-1, Project Objectives
- Technical Proposal Cost Information
- Summary of Related Activities
- Government Notice for Handling Proposals
- Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption, OMB No. 0990-0263 (formerly OF-310)

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

- NIH-2043, Proposal Summary and Data Record
- Small Business Subcontracting Plan Format *[if applicable]*
- Summary of Proposed Estimated Cost (plus fee) and Labor Hours
- Offeror's Points of Contact
- OMB Form SF-LLL, Disclosure of Lobbying Activities

INFORMATIONAL ATTACHMENTS:

- 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)
- Safety and Health, HHSAR Clause 352.223-70
- Report of Government Owned, Contractor Held Property
- Government Property – Schedule I-A
- Inclusion Enrollment Report
- OMB Form SF-LLL, Disclosure of Lobbying Activities

PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

Please refer to **http://www.niaid.nih.gov/contract/eproposal.htm** for 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.

ELECTRONIC SUBMISSION: In addition to the paper submission, you are requested to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided at the above-referenced weblink. You must certify that both the original paper and electronic versions of the proposal are identical.

The electronic submission is solely for the benefit of the Agency. Such submission is still in a "test" stage, and the electronic submissions may or may not be utilized, at the sole discretion of the Agency.

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.
SUBMISSION OF ONLY ELECTRONIC PROPOSALS WITHOUT PAPER COPIES IS NOT ACCEPTABLE.

WARNING: You are advised to read and carefully follow the instructions listed in this RFP. Failure to adhere to these instructions and to the specified limitations for size of paper and electronic proposals may result in the rejection of your proposal.

NUMBER OF COPIES:

Document	Number of Copies	Page Limits	File Size
Technical Proposal	One (1) unbound SIGNED ORIGINAL. One (1) unbound COPY Twenty (20) bound copies.	Limited to not-to-exceed 100 pages.	Limited to not-to-exceed 5 mega-bytes
Technical Proposal Appendices All materials not available electronically (i.e. SOPs, Pertinent Manuals, Nonscannable Figures or Data, and Letters of Collaboration/Intent).	One (1) unbound SIGNED ORIGINAL. One (1) unbound COPY Twenty (20) bound copies.	This information is included in the total page limitation of 100 pages.	N/A
Business Proposal	One (1) unbound SIGNED ORIGINAL. One (1) unbound COPY Ten (10) bound copies.	N/A	Limited to not-to-exceed 5 mega-bytes
Representations and Certifications	One (1) Original required to be submitted with the Original Business Proposal. (Extra copies are optional.)	N/A	N/A
All offerors are required to submit three (3) CDs that each contain electronic versions of all proposal information (both technical and business – clearly named). If information appended to the paper version is not available electronically, the CD shall contain a file listing all documents that are submitted in paper format only. The offeror shall include certification that the documents provided electronically match the paper version of those same documents.		Technical Proposal: 2 Compact Discs (CDs) Business Proposal: 1 Compact Disc (CD)	

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

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

PAGE LIMITS -- THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 100 PAGES. PAGES THAT ARE 2-SIDED WILL COUNT AS 2 PAGES. [THIS PAGE LIMIT INCLUDES: Statement of Work, Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc.]. ANY PORTIONS OF YOUR TECHNICAL PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS TECHNICAL PROPOSAL PAGE LIMITATION WILL BE REMOVED FROM THE TECHNICAL 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 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.

Please note the two (2) electronic PDF files to be submitted are limited to the size of 5 MB. 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.
- Documents must be converted to a .pdf searchable format.
- 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 RESPONSE SHEET":

Upon receipt by the Contracting Officer of the "Proposal Intent Response Sheet", offerors will be provided, via e-mail correspondence, 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 via e-mail.
3. Log-in Password: Will be provided by the Contract Specialist via e-mail.
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-DAIT-BAA-05-11
RFP Title: Immune Function and Biodefense in Children, Elderly, and Immunocompromised Populations

Please review the attached Request for Proposal. Furnish the information requested below and return this page by December 13, 2004. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will also 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:
CMP, NIAID, NIH
Room 3214
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Suzanne L. Dawkins
RFP-NIH-NIAID-DAIT-BAA-05-11
FAX# (301)-480-4675
Email: sd33r@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).

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 AND SUBMIT ONE ORIGINAL OF THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT IT AS PART OF YOUR ORIGINAL BUSINESS PROPOSAL. ADDITIONALLY, A COMPLETED ORIGINAL MUST BE SUBMITTED FOR ANY PROPOSED SUBCONTRACTORS.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. Technical Proposal Instructions for Broad Agency Announcements

The technical proposal page limit is one hundred (100) pages total, including the Statement of Work. The Statement of Work should not exceed ten (10) single spaced pages in length within the technical proposal.

The Technical Proposal consists of two major sections:

SECTION ONE - The Statement of Work which delineates each step or task to be carried out after award of the contract in order to accomplish the proposed research.

SECTION TWO - The Detailed Proposal which consists of three parts:

(1) Part 1 - a separate Technical Plan which describes the proposed approach, methodology, and outcome in detail, including preliminary data and other documentation supporting the proposed research project;

(2) Part 2 - Personnel - a description of the experience and qualifications of proposed personnel and a discussion of how the project will be organized and managed; and,

(3) Part 3 - Other Considerations.

SECTION ONE - Offeror's Proposed Statement of Work *(Recommended limit-10 pages)*

In contracts awarded under this Broad Agency Announcement, the Statement of Work will be the Statement of Work proposed by the offeror and negotiated and accepted by the NIAID. This section of the offeror's Technical Proposal should outline the steps to be taken by the contractor during performance of the contract. The offeror's proposed Statement of Work should begin as follows:

"Independently, and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below. Specifically the Contractor shall:"

The opening paragraph should be followed by the Statement of Work describing each step that the contractor shall perform after the award of the contract, including: the tasks that will be performed to carry out the research project; how these tasks will be accomplished; and the time frame within which each task will be accomplished. Each step described in the Statement of Work will begin with the words "The Contractor shall...." Where appropriate, divide the Statement of Work into separate tasks and subtasks. An outline format should be used. Briefly describe the work related to each task and describe the tasks in the sequence in which they will be carried out. More in depth descriptions of the proposed work should be provided in SECTION TWO of your Technical Proposal. The Statement of Work should also include a description of all items to be delivered to the Government during performance of the contract, such as progress reports, financial reports, end products, and deliverables.

SECTION TWO - Part 1-Technical Plan *(recommended limit-25 pages)*

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and its relationship to comparable work in progress elsewhere or as part of your own studies. Review pertinent work already published which is relevant to this project and your proposed approach. Provide a list of references to document published work cited in the proposal. Place the list at the end of SECTION TWO, Part 1. This section of the Technical Plan should support the scope of the project as you propose it to be accomplished, and as outlined in your proposed Statement of Work.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly describe the general plan of work. Discuss phasing of research including rationale, experimental design, achievable milestones, and the possible or probable outcome(s) of the proposed approaches. Describe alternate approaches to be used if the primary approaches are unsuccessful. In addition, indicate the role of subcontractors in the plan of work, if applicable.

(3) Methods

Describe the methods 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 work and delivery of items specified in your proposed Statement of Work. Performance or delivery schedules should be indicated for phases or segments, as applicable, as well as for the overall project. Schedules should 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.

(5) Facilities

Describe facilities, equipment, and resources that will be used to perform all phases of the proposed project.

SECTION TWO - Part 2-Personnel - (*recommended limit-10 pages excluding letters of commitment and resumes*)

Describe the experience and qualifications of personnel who will be assigned for direct work on the project. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar research projects/programs and equipment/technologies. Special mention should be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for the project, as well as how the project will be organized and managed. If staff are to be hired, include a description of the qualifications that will be used to identify appropriate staff to fill the position(s). Include an organizational chart that clearly shows reporting relationships and lines of authority.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS AND OTHER SUPPORT FOR MORE THAN A TOTAL 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 who serves as the 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 contract awarded. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project(s), his or her proposed duties, and the areas or phases of work 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 of each individual. 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 directly responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time and part-time employment, or on a subcontract or consultant basis. Describe the technical areas, character, and extent of subcontract or consultant activity and specify anticipated sources for all such services. 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 each of the following items of information:

- The specific items or expertise they will provide

- Their availability to the project and the amount of time anticipate
- Willingness to act as a consultant; and
- How rights to publications and patents will be handled

Letters of commitment should be placed at the end of SECTION TWO, Part 2

(4) Resumes (recommended limit – 2 single-sided pages per person)

Resumes of all key personnel are required. Each resume must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant recent publications. Resumes should be placed as the last documents in SECTION TWO, Part 2 of the proposal.

SECTION TWO, Part 3- Other Considerations

Record and discuss specific factors, not included elsewhere, that support your proposal using specifically titled subparagraphs. Items may include:

(1) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how your Statement of Work will be accomplished within this working relationship and how intellectual property issues will be treated (if applicable).

(2) Unique arrangements, equipment, procedures, etc. that no or few organizations are likely to have which will be advantageous for effective implementation of the project.

(3) Equipment, training and unusual operating procedures established to protect personnel from any hazards associated with your project.

(4) Other factors you feel important to support your proposed research.

(5) For additional requirements to be addressed in your Technical Proposal, refer to the following Sections of this RFP, as applicable:

a. Section L, Part II (General Instructions)

- Care of Live Vertebrate Animals
- Possession, Use and Transfer of Select Biological Agents or Toxins
- Sharing Research Data

b. Section L, Part III (Technical Proposal Instructions)

- Protection of Human Subjects
- Required Education in the Protection of Human Research Participants
- Inclusion of Women and Minorities in Research Involving Human Subjects
- Inclusion of Children in Research Involving Human Subjects
- Data and Safety Monitoring in Clinical Trials
- Information Technology Systems Security

Discussion of these subjects should be placed at the end of SECTION TWO, Part 3 of the technical proposal.

2. Technical Evaluation

Proposals will be technically evaluated by an initial review panel in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (see Section M.). This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

The following information is specific to this solicitation and is provided to supplement and/or complete the associated ITEMS presented at the SECTION L website at **http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf**

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

The following information is specific to this solicitation and is provided to supplement and/or complete the associated ITEMS presented at the SECTION L website at http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf

I. GENERAL INFORMATION

ITEM 2: **Alternate I, of FAR Clause 52.215-1, INSTRUCTIONS TO OFFERORS-COMPETITIVE ACQUISTION**, is applicable to this solicitation.

ITEM 9: **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 NAICS Code is 541710.
(2) The small business size standard is 500 Employees.

ITEM 11: **NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS**

ITEM 12: **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 or about September 30, 2005.

It is anticipated that the award(s) from this solicitation will be a multiple-year COST REIMBURSEMENT type COMPLETION contract with a Period Of Five (5) YEARS, and that incremental funding will be used [see Section L, PART IV - Business Proposal Instructions].

ITEM 17: **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. 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.

ITEM 21: **LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70**, is applicable to this solicitation.

II. GENERAL INSTRUCTIONS

ITEM 24: **Potential Award Without Discussions**, is applicable to this solicitation.

ITEM 27: **Care of Live Vertebrate Animals**, is applicable to this solicitation.

ITEM 28: **Possession, Use and Transfer of Select Biological Agents or Toxins**, is applicable to this solicitation.

ITEM 30: **Sharing Research Data**, is applicable to this solicitation.

ITEM 31: **Sharing of Model Organisms for Biomedical Research**, is applicable to this solicitation.

ITEM 34: **Small Business Subcontracting Plan**, is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation:

Identified below are the DHHS subcontracting goals. Offerors are encouraged to the greatest extent possible to identify subcontract dollars to these types of businesses.

23 % for Small Business; 5 % for Small Disadvantaged Business; 3 % for Women-Owned Small Business; 5 % for HUBZone Small Business; and 3 % for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

ITEM 36: **Extent of Small Disadvantaged Business Participation**, is applicable to this solicitation.

ITEM 38: **Salary Rate Limitation in Fiscal Year 2004**, is applicable to this solicitation.

ITEM 50: **Prohibition on Contractor Involvement with Terrorist Activities**, is applicable to this solicitation.

ITEM 51: **Solicitation Provisions Incorporated by Reference**: The following provisions are applicable to this solicitation.

Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).

Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).

Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).

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

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

III. TECHNICAL PROPOSAL INSTRUCTIONS

ITEM 53: **Project Objectives, NIH-1688-1**, is applicable to this solicitation.

ITEM 56: **Information Technology Systems Security**, is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation.

(a) Sensitivity and Security Level Designations.

The Statement of Work require the successful offeror to develop or access a Federal Automated Information System (AIS). Based upon the security guidelines contained in the *Department of Health and Human Services (DHHS) Automated Information Systems Security Program (AISSP) Handbook*, the Government has determined that the following apply:

(1) Category of Safeguarded Information

The safeguarded agency information that the successful offeror will develop or access is categorized as:

[X] Non Sensitive Information
[ ] Sensitive Information
[ ] Classified Information:
[ ] Confidential [ ] Secret [ ] Top Secret [ ] Special Access

(2) Security Level Designations

The information that the successful offeror will develop or access is designated as follows:
Level 1 applies to the sensitivity of the data.
Level 1 applies to the operational criticality of the data.

The overall Security Level designation for this requirement is Level 1C.

(3) Position Sensitivity Designations

Prior to award, the Government will determine the position sensitivity designation for each contractor employee that the successful offeror proposes to work under the contract. For proposal preparation purposes, the following designations apply:

[ ] Level 6C: Sensitive - High Risk (Requires Suitability Determination with a BI).
Contractor employees assigned to a Level 6C position are subject to a Background Investigation (BI).
[ ] Level 5C: Sensitive - Moderate Risk (Requires Suitability Determination with NACIC).
Contractor employees assigned to a Level 5C position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), or possibly a Limited Background Investigation (LBI).
[ ] Level 4C: Classified (Requires Special Access Clearance with an SSBI).
Contractor employees assigned to a Level 4C position are subject to a Single Scope Background Investigation (SSBI).
[ ] Level 3C: Classified (Requires Top Secret Clearance with an SSBI).
Contractor employees assigned to a Level 3C position are subject to a Single Scope Background Investigation (SSBI).
[ ] Level 2C: Classified (Requires Confidential or Secret Clearance with an LBI).
Contractor employees assigned to a Level 2C position shall undergo a Limited Background Investigation (LBI).
[X] Level 1C: Non Sensitive (Requires Suitability Determination with an NACI).
Contractor employees assigned to a Level 1C position are subject to a National Agency Check and Inquiry Investigation (NACI).

Contractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

(b) Information Technology (IT) System Security Program

The offeror's proposal must:

(1) Include a detailed outline (commensurate with the size and complexity of the requirements of the) of its present and proposed IT systems security program;

(2) Demonstrate that it complies with the AISSP security requirements, the Computer Security Act of 1987; Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems;" and the DHHS AISSP Handbook.

At a minimum, the offeror's proposed information technology systems security program must address the minimum requirements of a Security Level 1C identified in the DHHS AISSP Handbook, Exhibit III-A, Matrix of Minimum Security Safeguards.

(3) Include an acknowledgment of its understanding of the security requirements.

(4) Provide similar information for any proposed subcontractor developing or accessing an AIS.

(c) Required Training for IT Systems Security

DHHS policy requires that contractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each contractor employee has completed the following NIH Computer Security Awareness Training course prior to performing any contract work: http://irtsectraining.nih.gov/. The contractor will be required to maintain a listing of all individuals who have completed this training and submit this listing to the Government.

Additional security training requirements commensurate with the position may be required as defined in OMB Circular A-130 or NIST Special Publication 800-16, "Information Technology Security Training Requirements." These documents provide information about IT security training that may be useful to potential offerors.

(d) Prospective Offeror Non-Disclosure Agreement

The Government has determined that prospective offerors will require access to sensitive information described below in order to prepare an offer.

Any individual having access to this information must possess a valid and current suitability determination at the following level:

[ ] Level 6C: Sensitive - High Risk
[ ] Level 5C: Sensitive - Moderate Risk

To be considered for access to this sensitive information, a prospective offeror must:

(1) Submit a written request to the Contracting Officer identified in the solicitation;
(2) Complete and submit the "Prospective Offeror Non-Disclosure Agreement" provided as an attachment in Section J of this solicitation; and
(3) Receive written approval from the Contracting Officer.

Prospective offerors are required to process their requests for access, receive Government approval, and then access the sensitive information within the period of time provided in the solicitation for the preparation of offers.

Nothing in this provision shall be construed, in any manner, by a prospective offeror as an extension to the stated date, time, and location in the solicitation for the submission of offers.

(e) References

The following documents are electronically accessible:

(1) OMB Circular A-130, Appendix III: http://csrc.ncsl.nist.gov/secplcy/a130app3.txt
(2) DHHS AISSP Handbook: http://irm.cit.nih.gov/policy/aissp.html
(3) DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf
(4) NIH Applications/Systems Security Template: http://cit.nih.gov/security/secplantemp.html
(5) NIST Special Publication 800-16, "Information Technology Security Training Requirements:" http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf
(6) NIH CIT-Policies, Guidelines and Regulations:

Table 1 - Categories of Safeguarded Agency Information: http://irm.cit.nih.gov/security/table1.htm
Table 2 - Security Level Designations for Agency Information: http://irm.cit.nih.gov/security/table2.htm
Table 3 - Positions Sensitivity Designations for Individuals Accessing Agency Information: http://irm.cit.nih.gov/security/table3.htm

IV. BUSINESS PROPOSAL INSTRUCTIONS

ITEM 58: **Proposal Cover Sheet**, is applicable to this solicitation.

ITEM 61: **Cost and Pricing Data** is applicable to this solicitation.

Subparagraph 3. Formats for Submission of Line Item Summaries:

[X] The format specified in SECTION L at http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf is applicable to this solicitation.
[ ] The following format shall be used in lieu of the one specified in SECTION L at http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf :*

** (Specify format) **
*It is noted that the format specified above is also applicable to Alternate I, of FAR Clause 52.215-20, Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data.

ITEM 67: **Incremental Funding**, is applicable to this solicitation.

ITEM 69: **Certification of Visa's for Non-U.S. Citizens**, is applicable to this solicitation.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against three (3) factors. The factors in the order of importance are: technical, cost, 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 an award(s) to that offeror whose proposal provides the best overall value to the Government.

All technical proposals will undergo evaluation by a peer review group also known as a Scientific Review Group (SRG).

The final state of the evaluation is the establishment of an Order of Merit Ranking in which all competing proposals are ranked on the basis of their respective relevance and scientific merit evaluations. Final selection of awards will depend upon the availability of funds, scientific priority, and program balance that the NIAID determines to exist at the time of award selection. A separate Order of Merit Ranking will be established for each of the two Research Areas.

The estimated cost of an offer must be reasonable for the tasks to be performed, and, in accordance with FAR 15.305, will be subject to a cost realism analysis by the Government.

Offerors must demonstrate in their proposals that they have the necessary expertise and capabilities for conducting the research as requested by this solicitation. Each proposal must document the feasibility of successful implementation of the requirements of the BAA.

2. EVALUATION OF DATA SHARING PLAN

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy.

If your proposal does not include a plan or if the plan in your proposal is considered "unacceptable," and the Government selects your organization from the Order of Merit Ranking, you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

3. EVALUATION OF PLAN FOR SHARING MODEL ORGANISMS FOR BIOMEDICAL RESEARCH

The offeror's proposal must address the plans for sharing model organisms OR state appropriate reasons why such sharing is restricted or not possible. Offerors must also address as part of the sharing plan if, or how, they will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. The discussion areas regarding intellectual property outlined in Section L should be addressed.

If your proposal does not include a plan, appropriate reasons for restricting sharing, or, if the plan in your proposal is considered "unacceptable," and the Government selects your organization from the Order of Merit Ranking, you will be afforded the opportunity to further discuss, clarify or modify your plan for sharing model organisms during discussions and in your Final Proposal Revision (FPR). If your plan for sharing model organisms is still considered "unacceptable," or your justification for restricting sharing is still considered inappropriate by the Government after discussions, your proposal may not be considered further for award.

4. 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 NIAID 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 selects your organization from the Order of Merit Ranking (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 trials 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 Research and Technical Objectives 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 selects your organization from the Order of Merit Ranking (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 selects your organization from the Order of Merit Ranking (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 "unnacceptable" (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 selects your organization from the Order of Merit Ranking (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.

5. 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 Order of Merit Ranking. 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) Extent of participation of SDB concerns in terms of the value of the total acqusition.

6. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the Scientific Review Group when reviewing the Technical Proposals, including the proposed Statement of Work. The criteria below are listed in relative order of importance with weights assigned for evaluation purposes.

A. CRITERIA FOR EVALUALTION OF RESEARCH AREA 1:

1. SCIENTIFIC RATIONALE AND TECHNICAL APPROACH **60 Points**

Appropriateness of the scientific and technical approach to determine one or more biological mechanisms of immune deficiency in a specific immunocompromised population against NIAID Category A, B, or C pathogens. Merit, feasibility, adequacy, and appropriateness of the proposed approach will be evaluated based on the following criteria:

a. Experimental methods for determining and defining the specific biological mechanisms underlying differences between one or more immunosuppressed populations and non-immunosuppressed populations, in relation to the host immune response to vaccination or immunotherapies against NIAID Category A, B or C

priority pathogens or relevant model systems. This should include the experimental design, the rationale for experimental approaches, and alternative approaches to be used if these methods do not achieve the defined goals. Also included will be the rationale for proposed animal model studies (and the plan for animal welfare) and a detailed description of their relevance to human infection or vaccination (if applicable). In addition, also to be evaluated will be any human tissue samples (including the design of human tissue sample studies), and/or other clinical data to be used in the proposed studies, including how human subjects will be protected from research risks as well as justification for the ethnic, gender and age compositions of the human populations chosen for analysis. (45 points)

b. Specific milestones that will be used to show progress in determining the biological mechanisms of immunosuppression and the expected timelines for achieving each milestone. (10 points)

c. The plan for sharing data with the scientific research community, including any drugs or treatments developed under the contract. (5 points)

2. OFFEROR'S QUALIFICATIONS AND CAPABILITIES **25 Points**

a. *Principal Investigator*. Documented training, related experience, expertise, commitment, and availability of the Principal Investigator necessary for planning, managing and directing the proposed studies. (15 points)

b. *Scientific and Technical Staff.* Documented training, related experience, expertise, commitment, and availability of the proposed professional and research technical and support staff, including any subcontractor staff proposed, and their documented capability to perform their roles in the proposed studies and expertise on similar projects. (10 points)

3. OFFEROR'S FACILITIES AND RESOURCES **15 Points**

Adequacy and documented availability of the organization (institution or business), facilities, equipment, and resources needed to carry out the proposed research and meet the goals and specific objectives of this solicitation.

TOTAL POINTS = 100

B. CRITERIA FOR THE EVALUATION OF RESEARCH AREA 2

1. SCIENTIFIC RATIONALE AND TECHNICAL APPROACH **60 Points**

Appropriateness of the scientific and technical approach to develop one or more treatments to induce in the targeted population an enhanced host response to vaccination or immunotherapies against NIAID Category A, B, or C pathogens. Merit, feasibility, adequacy, and appropriateness of the proposed approach with respect to:

a. Experimental methods for proposed testing of one or more drugs or other treatments that target biological mechanisms of immunosuppression. Appropriateness and feasibility of experimental methods used to address mechanisms of immunodeficiency. This should include the experimental design, the rationale for experimental approaches, and alternative approaches to be used if these methods do not achieve the defined goals. Also included will be the rationale for proposed animal model studies (and the plan for animal welfare) and a detailed description of their relevance to human infection or vaccination (if applicable). In addition, also to be evaluated will be any human tissue samples (including the design of human tissue sample studies), and/or other clinical data to be used in the proposed studies, including how human subjects will be protected from research risks as well as justification for the ethnic, gender and age composition of the human populations chosen for analysis. (45 points)

b. Specific milestones that will be used to show progress developing a safe and effective method that enhance the host response to vaccination or immunotherapies, and the expected timelines for achieving each milestone. (10 Points)

c. The Plan for sharing data and reagents with the broader research community, including any drugs or treatments developed under the contract. (5 points)

2. OFFEROR'S QUALIFICATIONS AND CAPABILITIES **25 Points**

a. *Principal Investigator*. Documented training, related experience, expertise, commitment, and availability of the Principal Investigator necessary for planning, managing and directing the proposed studies. (15 points)

b. *Scientific and Technical Staff*. Documented training, related experience, expertise, commitment, and availability of the proposed professional and research technical and support staff, including any subcontractor staff proposed, and their documented capability to perform their roles in the proposed studies. (10 points)

3. OFFEROR'S FACILITIES AND RESOURCES **15 Points**

Adequacy and documented availability of the organization (institution or business), facilities, equipment, and resources needed to carry out the proposed research and meet the goals and specific objectives of this solicitation.

TOTAL POINTS = 100