NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NIH, DHHS

Electronic Request for Proposal

SECTION A – SOLICITATION/CONTRACT FORM

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

<table>
<tr><td colspan="4">Purchase Authority: Public Law 92-218, as amended.
NOTE: The issuance of this solicitation does not commit the government to an award.</td></tr>
<tr><td>RFP Number:

NIH-NIAID-DAIT-04-39</td><td>Just In Time:

[ ] Yes
[X] No</td><td>Small Bus. Set-Aside [ ]Yes [X]No
8(a) Set-Aside [ ]Yes [X]No
NAICS Code: 54171
Size Standard: 500 employees</td><td>Level of Effort:
[ ] Yes [X] No
Total Effort:
[N/A]</td></tr>
<tr><td colspan="4">TITLE: Large Scale Antibody and T Cell Epitope Discovery Program</td></tr>
<tr><td colspan="2">Issue Date:
October 10, 2003</td><td>Due Date: January 15, 2004
Time: 4:00 PM, EST</td><td>Technical Proposal Page Limits:
[ ] Yes (see “How to Prepare and Submit Electronic Proposals”)
[X] No</td></tr>
<tr><td colspan="2" rowspan="2">ISSUED BY:
Paul D. McFarlane
Contracting Officer
Contract Management Branch, DEA
NIH, NIAID
6700-B Rockledge Drive
Room 2230, MSC 7612
Bethesda, MD 20892-7612</td><td colspan="2">[X] We reserve the right to make awards without discussion.</td></tr>
<tr><td>NO. OF AWARDS:

[ ] Only 1 Award
[X] Multiple Awards</td><td>PERIOD OF PERFORMANCE:

5 years beginning on or about 09/04/2004</td></tr>
<tr><td colspan="4">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)</td></tr>
<tr><td colspan="4">The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.</td></tr>
<tr><td colspan="4">POINT OF CONTACT -- Yvette Brown --COLLECT CALLS WILL NOT BE ACCEPTED--

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Main 301-496-0612</td></tr>
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Updated thru FAC 97-25 (05/02/01)

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INTRODUCTION

As a part of its research program to improve biodefense, the National Institute of Allergy and Infectious Diseases (NIAID) announces a Large-Scale Antibody and T Cell Epitope Discovery Initiative. This program is an expansion of NIAID RFP NIH-NIAID-DAIT-03-43, Large-Scale Antibody and T Cell Epitope Discovery Program. The purpose of both RFPs is identical and is outlined below. NIAID plans to award 5-10 contracts under NIH-NIAID-DAIT-03-43 and a similar number of contracts under this acquisition. All contract awardees will participate in an annual workshop, with the goals of fostering collaborations and improving milestone achievements among the groups.

Recent bioterrorist attacks underscore the urgency for protective immunotherapies and vaccines, as well as diagnostics, against agents of bioterrorism. In addition, emerging and re-emerging infectious diseases continue to pose major health threats to the worldwide population. The production of antibodies and development of active vaccines and rapid diagnostic tools for the prevention, treatment and detection of such infections requires new knowledge about antigenic epitopes recognized by antibodies and T cells. In regard to T cell epitopes, an understanding of the molecular basis of MHC-peptide/ligand selection and binding characteristics that lead to T cell activation will aid vaccine design. In addition, the epitope discovery initiative is an important component of NIAID-supported research projects focused on elucidation of the basic mechanisms of immune function.

PURPOSE OF THE CONTRACT

A. The primary purpose of this initiative is to establish and support several highly interactive, multi-disciplinary teams focused on large-scale discovery of novel antibody (B cell) and/or T cell epitopes associated with microorganisms responsible for emerging and re-emerging infectious diseases, including potential agents of bioterrorism and their toxins (listed as NIAID category A-C agents at www.niaid.nih.gov/dmid/bioterrorism/bandc_priority.htm). It is anticipated that the multi-disciplinary teams minimally will include immunologists with the appropriate expertise and microbiologists with expertise in the study pathogen(s). These teams shall use state-of-the-art technological advances, such as, but not limited to, computer-based epitope prediction algorithms, genome-wide scanning, structural genomics, mass spectrometry, phage-display libraries, and combinatorial library screens to conduct epitope identification. All newly discovered epitopes shall be evaluated for their reactivity *in vitro* and *in vivo* in appropriate animal models and/or in human studies, where feasible. Research conducted under this initiative may include one or more type of epitope discovery, for example:

   - Discovery of linear and/or conformational antibody epitopes;
   - Discovery of cytotoxic and/or helper T cell epitopes presented by MHC class I and class II molecules, respectively; and
   - Discovery of epitopes/ligands presented by nonclassical MHC and/or MHC-related molecules.

B. The initiative also promotes the development of novel or improved high-throughput screening methods for antibody and/or T cell epitope identification, with an emphasis on novel methods for the identification of antibody epitopes, T helper cell epitopes, or epitopes and ligands that bind to non-classical MHC or MHC-related molecules. Methods may include the design of novel technologies and/or development of robust algorithms/mathematical models for predicting antigenic antibody or T cell epitopes, as well as improved algorithms for predicting host responses to antigens.

   Development of technologies or algorithms without direct application to antibody and/or T cell epitope discovery is excluded from this acquisition.

   Through the Large-Scale Antibody and T Cell Epitope Discovery Initiative, the NIAID plans to fund multiple proposals that address one or both of the research areas listed in the Statement of Work. Therefore, it is important that the funded research teams interact to exchange ideas and share information on technical objectives, progress, and impediments, and where appropriate, establish collaborations. To encourage collaboration among the teams, the NIAID will organize an annual workshop attended by the Principal Investigator of each funded project, key personnel from each project, a small number of investigators from related research areas, and NIAID staff (including the Project Officer, Contracting Officer, and other program staff).

BACKGROUND

The main function of the immune system is to protect the host from infection. The effectiveness of immune responses is related to both antigen specificity and the diverse functions of B and T cells. B cells secrete antibodies with different functions and T cells differentiate into groups that lyse infected target cells [cytotoxic T cells (CTL)], promote CTL development [T helper 1 (Th1) cells], or promote powerful antibody responses [T helper 2 (Th2) cells]. The antigen specificity of the immune system depends upon B and T cell receptor molecules that bind strongly to specific regions, termed epitopes, of target pathogen molecules.

An antibody epitope, also called a B cell epitope, consists of a molecular region on the surface of a foreign pathogen that is directly contacted by the antibody produced by the B cell. There are two types of structures that are recognized by antibodies and are therefore referred to as antibody epitopes: linear and conformational. Linear epitopes are formed by a continuous sequence of amino acids in a protein, whereas conformational epitopes are composed of amino acids that are discontinuous in the primary sequence but are brought together upon protein folding. Generally, antibodies raised against whole proteins or non-protein molecules recognize conformational epitopes and those raised against molecular fragments recognize linear epitopes. There are exceptions to this general rule, however, making it possible to use antigen fragments or synthetic molecules in vaccines to induce antibodies that can recognize a particular type of antigen molecule.

Methods for antibody epitope identification generally fall into two categories, reflecting the two types of epitopes: linear and conformational. Linear epitopes can be identified by screening of expression libraries derived from organisms or tissues, or screening of combinatorial synthetic peptide libraries. Conformational epitopes can be identified by X-ray crystallographic studies of antigen-antibody complexes. Linear and conformational epitopes as targets of neutralizing antibodies may be determined by analyzing pathogen mutants that are resistant to antibody neutralization. Antibody epitopes can also be identified by analyzing proteolytic cleavage products of protein antigens, using polyacrylamide gel electrophoresis followed by Western blotting to study antibody-protein interactions. However, these techniques are of limited use in analyzing epitopes that are denatured under such conditions.

T cell epitopes are displayed on the surface of antigen-presenting cells (APC), and most often consist of short protein segments, termed peptides, held in a pocket-like groove of Major Histocompatibility Complex (MHC) class I or class II molecules. In addition to peptides, T cell epitopes may be derived from carbohydrates, lipids, or modified peptides. For the purpose of this solicitation, these epitopes will be referred to as “ligands.” T cells recognize MHC-peptide and MHC-ligand complexes through their T cell antigen receptors (TCRs) and respond by initiating and regulating immune responses and aiding the clearance of foreign or aberrant material. The three-dimensional structures of MHC-peptide complexes show intimate contact between the backbone/side chain amino acids of the peptides and the variable region amino acids of the MHC molecule. Therefore, each distinct MHC molecule has its own rules for peptide binding, but can bind a large number of peptides derived from foreign or self proteins. Given that there are at least 1500 different MHC alleles in the human population, and an enormous number of possible peptides derived from foreign or self proteins, the number of potential peptide-MHC complexes is very large.

In addition to MHC class I and class II molecules, non-classical MHC and MHC-related molecules likely present antigen to various types of T cells. At the present time, more than 50 non-classical genes have been identified in mice and more than 20 in humans, as well as an increasing number of MHC-related molecules. While the natural ligands for most of these molecules have not been defined, these molecules may present a variety of chemically distinct ligands (such as lipids and modified peptides) to T cells.

T cell epitopes can be identified by multiple approaches including peptide mapping, screening of synthetic peptide (or combinatorial) libraries, generation and screening of expression libraries derived from organisms or tissues of interest, and elution and sequencing of naturally occurring peptides from MHC molecules using high performance liquid chromatography coupled with mass spectrometry. Peptide mapping and the screening of synthetic peptide libraries provide critical information, but may not identify naturally occurring ligands. Elution and sequencing methods have the advantage of providing direct information about peptide generation and MHC selection *in vivo*. These methods are useful in identifying cytotoxic T cell epitopes, but are generally less effective in defining helper T cell epitopes due to the decreased binding affinity and target size of MHC class II-binding peptides.

Methods for predicting T cell epitopes are also available. One method derives from the identification of "peptide-binding motifs" for MHC alleles and uses this information to develop algorithms. These algorithms have been used successfully to predict T cell epitopes, although they tend to have a high failure rate. Recent evidence suggests that these algorithms can be improved by combining them with algorithms based on antigen processing and presentation events, such as degradation and transport.

Also, the recent use of artificial neural networks provides an opportunity to analyze amino acid preferences at specific sites within a peptide sequence that are influenced by the properties of amino acids at other sites. All of these predictive approaches rely on experimental methods (such as biochemical binding, 2m dissociation, and cell surface MHC expression/stabilization) to validate peptide specificity for MHC molecules. Antigenicity can be determined using methods such as *in vitro* CTL lysis assays, ELISpot or ELISA cytokine assays, intracellular cytokine staining coupled with flow cytometry, quantitative real-time RT-PCR, and MHC/tetramer detection of lymphocytes from blood or tissues samples.

Individual and institutional intellectual property rights and rights to inventorship under U.S. patent law will not be affected by participation in this RFP. 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 their patent rights in a manner that will not conflict with the central goal of this RFP, which is to make the epitope data, protocols, algorithms, mathematical models, and technologies freely available to the research community. All licensing agreements entered into by the Contractor for completion of any or all of the tasks listed in the Statement of Work shall be transferable to the Government.

In summary, the discovery of novel antibody and T cell epitopes will greatly facilitate the design and development of improved immunotherapeutics and vaccines by providing critical information needed to select antibodies for passive treatments and MHC-peptide or MHC-ligand complexes that induce T cell activation for effective vaccine design. In addition, large-scale epitope discovery will facilitate the development of diagnostic tools and more robust algorithms and mathematical models that can be used to identify host responses to antigens *in vivo*, as well as predict antibody and T cell epitope antigenicity. The Large-Scale B and T cell Epitope Discovery Initiative will enable the design of more effective immunotherapeutics and vaccines, which target antibody, T helper, and cytotoxic T cell epitopes. Such targeted approaches may ultimately avoid the potential safety issues encountered using large proteins of pathogens and their toxins. In addition, the development and utilization of large-scale screening methods for epitope identification will provide a rapid method for determining which pathogen molecules (e.g., proteins, carbohydrates or lipids) contain immunostimulatory sequences that can serve as targets for immune interventions (e.g., immunotherapeutics or vaccine components) or diagnostics.

STATEMENT OF WORK

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the work set forth below. Specifically, the Contractor shall perform one or both of the two research areas described below (Task I. (A) or I. (B)) in a manner consistent with the approach specified in the Offeror's proposal (unless another approach is recommended by the Project Officer). The Contractor may choose to perform the tasks listed under sections I.(A), I.(B), or both. Separate technical and business proposals shall be submitted for sections I.(A) and I.(B) and each proposal shall address all of the tasks listed in the Statement of Work (I –IV), as described below.

I. The Contractor shall focus on large-scale identification of antibody and/or T cell epitopes from organisms listed as NIAID category A-C pathogens, but they may also include epitope identification for other antigens and/or diseases. Methods may include novel techniques as well as existing procedures. With appropriate justification, animal models or validation studies using human cells or tissues that enhance the identification and validation of epitopes are acceptable. It is presumed that a broad analysis of epitope generation and immunogenicity (i.e., the ability to elicit an adaptive immune response) will provide valuable insight regarding immune activation requirements and antigen processing and presentation mechanisms. Such insights will guide the development of more robust predictive algorithms for epitope identification and antigenicity determination. **See Notes 1, 2, 3, and 4 to the Offeror**.

(A) **Research Area A. Identify and validate antibody epitopes**. The Contractor shall:

1. Apply existing or develop novel methods, technologies, and other procedures to identify linear and conformational antibody epitopes from NIAID category A-C agents.

    a) Existing methods may include, but are not limited to:
        i. Expression, combinatorial peptide, or random peptide libraries;
        ii. X-ray crystallography and structural analysis of antigens and/or toxins;
        iii. Screening of pathogen or antigen mutants for antibody binding to these mutants; and
        iv. Algorithms or mathematical models to predict epitopes from genome and protein sequences, and lipid or carbohydrate structures.

    b) New or improved high-throughput screening methods may include, but are not limited to:
        i. Biochemical or genetic approaches that would be broadly applicable to the discovery of human antibody epitopes;
        ii. Screening assays that provide knowledge of epitope generation *in vivo* (e.g., post-translational modifications, processing, presentation, and recognition by appropriate antibodies);
        iii. Advanced algorithms and mathematical models for predicting epitope generation, epitope recognition by antibodies, and/or host immune responses to particular antibody epitopes; and
        iv. Development of algorithms, mathematical models, and artificial neural network programs based on specific biological, biochemical, or physical features of epitopes (such as their genomic sequence, amino acid sequence, *in vivo* processing and presentation events, and/or antigen or epitope structure).

    The developed methods shall be easily transferable to the broader scientific community, thus providing standardized methods for epitope discovery and validation.

2. Validate antigenicity or diagnostic potential of all newly defined antibody epitopes. This validation may be limited to the most promising epitopes (as determined by the Contractor in consultation with the Project Officer), using appropriate *in vivo* and/or *in vitro* methods (existing, novel, or improved methods), which may include, but are not limited to, one or more of the following:

    a) Enzyme-Linked ImmunoSorbent Assay (ELISA) to measure cytokine or antibody production, including antibody isotype;

    b) ELISpot to measure antibody or cytokine production;

    c) Pathogen neutralization (antibody blockade of pathogen infectivity); and

    d) *In vivo* challenge and protection studies, where appropriately justified by the Contractor and agreed to by the Project Officer.

(B) **Research Area B. Identify and validate T cell epitopes**. The Contractor shall:

1. Apply existing or develop novel methods, technologies, and other procedures to identify T cell epitopes from NIAID category A-C agents that bind MHC class I, MHC class II, non-classical MHC, and/or MHC-related molecules.

    a) Existing methods may include, but are not limited to:
        i. Screening of synthetic peptide libraries;
        ii. Elution and sequencing of peptide epitopes from MHC and MHC-related molecules;
        iii. Binding studies of peptides and ligands to MHC and MHC-related molecules;
        iv. Evaluation of antigen or pathogen mutants with respect to their ability to bind to MHC or MHC-related molecules or to stimulate T cell responses; and
        v. Algorithms or mathematical models to predict epitopes from genome and protein sequences, and lipid or carbohydrate structures.

    b) New or improved high-throughput screening methods may include, but are not limited to:
        i. Biochemical or genetic approaches that would be broadly applicable to the discovery of human T cell epitopes;
        ii. Screening assays that provide knowledge of epitope generation *in vivo* (e.g., post-translational modifications, processing, presentation, and recognition by appropriate T cells);
        iii. Advanced algorithms and mathematical models for predicting epitope generation, epitope recognition by T cells, MHC binding, and/or host immune responses to particular T cell epitopes; and
        iv. Development of algorithms, mathematical models, and artificial neural network programs based on specific biological, biochemical, or physical features of epitopes (such as their genomic sequence, amino acid sequence, *in vivo* processing and presentation events, and/or antigen or epitope structure).

    The developed methods shall be easily transferable to the broader scientific community, thus providing standardized methods for epitope discovery and validation.

2. Validate the antigenicity or diagnostic potential of all newly defined T cell epitopes shown to bind to MHC molecules using *in vivo* and/or *in vitro* methods, including, but not limited to:

    a) ELISA;
    b) ELISpot;
    c) Intracellular cytokine assays
    d) T cell proliferation assays;
    e) CTL assays (e.g., chromium release, measurement of perforin production, other methods of measuring cytotoxic activity);
    f) MHC class I or class II tetramer staining; and
    g) *In vivo* challenge and protection studies, where appropriately justified by the Contractor and agreed to by the Project Officer.

II. **Submit validated epitopes to the Immune Epitope Database and Analysis Resource**. Under a separate contract, the NIAID is supporting development of a comprehensive Immune Epitope Database and Analysis Resource to be populated with linear and conformational antibody and T cell epitopes, including peptides and other ligands that bind to MHC class I, class II, non-classical, and MHC-related molecules of human, non-human primate, and other animal origin. The database will be freely accessible to the scientific community through an Internet website. All Contractors supported by the Large-Scale Antibody and T Cell Epitope Discovery Initiative shall, within six months following the completion of verification/validation studies, submit detailed information to the Immune Epitope Database and Analysis Resource (as well as to the Project Officer of the present contract), describing each newly identified epitope along with the results of studies validating epitope antigenicity *in vitro* and *in vivo*, binding studies, and other relevant data. Submissions shall include all newly developed high throughput screening methods and other epitope identification software tools (such as predictive algorithms, mathematic models, and artificial neural network programs).

Specifically, The Contractor shall submit the following information to the Immune Epitope Database, as required by the Database Management, including but not limited to:

(A) For all Research Areas involving identification of antibody epitopes: Antibody epitopes and mimetopes (structural or functional antigen mimics) including linear and conformational sites, identifiable by their epitope sequence (i.e.,

amino acid, carbohydrate, or lipid composition for linear and conformational antibody epitopes) and or structure, as well as other key information currently available, such as their antibody isotype; pathogen, antigen or disease source; composition of natural, artificial, and modified amino acids as may occur during post-translational modifications of whole molecules or ligands); and haptens associated with the epitope/mimetope.

(B) For all Research Areas involving identification of T cell epitopes: T cell epitopes and mimetopes consisting of peptide and non-peptide ligands identifiable by their epitope sequence (i.e., amino acid, carbohydrate, or lipid composition) including the composition of natural, artificial, and modified amino acids as may occur during post-translational modifications of peptide ligands, as well as other key information currently available, such as their MHC binding motif; MHC molecule; pathogen, antigen or disease source; and haptens associated with the epitope/mimetope.

(C) For all Research Areas involving development of high-throughput screening methods for identification and/or validation of antibody and/or T cell epitopes: the complete protocols and list of reagents used for the high-throughput screening methods.

(D) For all Research Areas involving development and testing of algorithms, mathematical models and neural networks for predicting antibody and/or T cell epitopes and/or host immune responses to pathogens: the algorithms, mathematical models, and/or artificial neural networks shall be submitted in a format that allows the scientific community to use these tools in their individual research projects for epitope prediction or modeling/predicting host immune responses to pathogens.

(E) Extensive annotation of each antibody and T cell epitope, which shall minimally include, where feasible:

1. Background information about the epitope, including:
   a) identification methods;
   b) antibody/antigen binding;
   c) MHC binding affinity (T cell epitopes)
   d) methods used to test immune recognition of epitopes, where applicable, such as validation of immunogenicity, antigenicity, and/or diagnostic potential *in vivo* and *in vitro* (e.g, cytotoxicity, ELISA, ELISpot, pathogen neutralization, protection studies).

   And may also include, where available, such parameters as:

2. Size and three-dimensional structure of the antigen from which the epitope derives, as well as the MHC-ligand or antigen-antibody complexes; and

3. Epitope location on the whole antigen.

III. **Participate in an annual workshop**. Staff from each research team funded under the Large-Scale Antibody and T Cell Epitope Discovery Initiative shall participate in an annual workshop coordinated by NIAID. The primary goals of the workshop are to update NIAID program and contract staff and the other funded epitope discovery projects on each team's research progress; to exchange ideas and share information on technical objectives, progress, and impediments; to foster discussion and collaboration among researchers; to identify areas of scientific interest and community need; and to discuss/develop guidelines and milestones for each research team for the upcoming year. Workshop participants shall include the Principal Investigator of each research team along with up to 2 additional personnel approved by the Project Officer; a small number of investigators from related research areas recommended by the Contractors and approved by the Project Officer; the Scientific Advisory Committee (see below) and relevant NIAID staff, including the Project Officer, Contracting Officer, and program staff. In addition, the Offeror shall plan to travel the appropriate personnel to attend one domestic scientific meeting per year. **See Note 4 to the Offeror**.

IV. **In conjunction with the Project Officer, establish a Scientific Advisory Committee (SAC)**. Each Contractor shall provide to the Project Officer, within two weeks of contract award, a list of six (6) leading scientists knowledgeable in one or more research areas related to the contract including, but not limited to: immunology (B cell activation, T cell activation, antigen recognition, antigen processing,); microbiology and infectious disease; biochemistry; computational biology; and bioinformatics. The list shall include the scientist's full name, complete contact information (mailing address, phone number, fax number and email address), and a brief synopsis (2 page maximum) of their research interests and accomplishments. A single SAC will be established for the entire Epitope Discovery program. The total number of SAC members shall not exceed eight (8). Therefore, selection of members with expertise in more than one of the recommended scientific areas is encouraged, where possible. The SAC shall provide advice to the NIAID on the operations of all the programs supported by the Epitope Discovery program and future directions based on the state of epitope discovery technological and research advances, including those contributed by the programs funded under this contract. The composition of the advisory committee shall be proposed by the Contractors and will be subject to approval by the Project Officer prior to distribution of invitations by the Project Officer to proposed members. The Offeror shall not name any potential SAC members in the proposal or contact any potential members prior to Project Officer approval.

NOTES TO OFFERORS

NOTE 1:

Subcontracting agreements are acceptable and are encouraged in order to accomplish the work outlined in this solicitation. The proposal must describe in detail a management plan defining how the Contractor will coordinate the work of the subcontractor(s). The proposal must also define the subcontractor's contributions to the overall proposal, and include a complete description of all subcontractors' duties, facilities, professional background of personnel, and costs.

NOTE 2:

Disclosures of any and all patents and copyrights or patent and copyright applications of database design, analysis tools, or procedures filed in or outside the United States (U.S.) by the Offerors and/or listed personnel or collaborators must be made available to the Project Officer and Contracting Officer at the time of proposal submission and updated in quarterly progress reports. Individual and institutional intellectual property rights and rights to inventorship under U.S. patent law will not be affected by participation in this RFP. 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 their patent rights in a manner that will not conflict with the central goal of this RFP, which is to make the epitope data, protocols, algorithms, mathematical models, and technologies freely available to the research community.

All licensing agreements entered into by the Contractor for completion of any or all of the tasks listed in the Statement of Work shall be transferable to the Government.

NOTE 3:

General guidelines for preparation of Technical Proposals, regardless of which research area is chosen:

1. The Offeror shall submit an individual business and technical proposal for each research area (A and/or B) chosen. Each proposal shall address all of the tasks listed in the Statement of Work (I-IV), as each proposal will be reviewed separately. The Government reserves the right to combine awards for a single Offeror, in the event that multiple proposals from a single Offeror are chosen for award.

2. The Offeror shall specify the organisms that they plan to use for epitope discovery. The Government reserves the right to request redirection of epitope discovery efforts to a particular microorganism or toxin, in the unlikely event of a public health emergency or bioterrorism. For example, an outbreak of an emerging/re-emerging infectious disease or the needs of a pathogen-specific biodefense program may require the redirection of epitope discovery efforts in order to address public health and safety issues. In this case, the Government will make every effort to redirect a program with the proper expertise and facilities to address the need.

3. The Offeror shall provide detailed descriptions of the standard operating procedures for proposed methods, technologies, and other procedures to be utilized for epitope discovery and/or for the development of improved or novel high-throughput screening methods. The descriptions shall include, but are not limited to:
    a. Methods and technologies to be utilized for large-scale epitope discovery;
    b. Experimental or theoretical methods to identify actual epitopes from the potentially extensive pool of discovered epitopes, specifically those that are likely candidates for induction and/or maintenance of protective immunity; are candidate targets for passive antibody treatments; or are potential diagnostic tools
    c. The experimental methods for validating epitope recognition by antibodies or T cells *in vitro* and/or *in vivo*. Contractors will be responsible for validating all newly discovered epitopes using appropriate animal models (such as HLA transgenic animal models), tissue culture systems (animal and human), and/or human samples;
    d. The experimental methods for determining epitope antigenicity and ability to induce protective immunity *in vivo*, where applicable. Contractors will be responsible for determining the antigenicity or diagnostic potential of all newly discovered epitopes using appropriate animal models (such as HLA transgenic animal models) and/or tissue culture systems (animal and human);

e. For Offerors developing novel or improved high throughput screening procedures, the proposed methods and technologies for developing high throughput screening procedures and robust predictive algorithms and mathematical models for epitope identification and validation shall be described; and
f. The Offeror's rationale for using the proposed methods, technologies, and other procedures, including the relative flexibility of the proposed approach in identifying epitopes from a broad range of pathogens, such as those listed as NIAID category A-C microorganisms.
g. For all research areas proposed, Offerors must include: data sharing plans that provide access to data, reagents, protocols, technologies, predictive algorithms and/or mathematical models for the broader research community, or valid reasons for withholding information, reagents, and technologies from the community.

4. The Offeror shall provide specific descriptions of available equipment and facilities to conduct the work outlined in the contract proposal including: access to potential agents of bioterrorism; availability of appropriate containment facilities; security measures for conducting research with potential agents of bioterrorism; and compliance with current NIAID and CDC policies for research using NIAID category A-C pathogens and select agents.

5. It is anticipated that the multi-disciplinary teams minimally will include immunologists with the appropriate expertise and microbiologists with expertise in the study pathogen(s). The Technical Proposal should include documentation of the qualifications, knowledge, experience, education, competence, and decision-making skills of the proposed key personnel. In addition, similar documentation should be provided for technical and administrative staff proposed to carry out the requirements of this contract.

NOTE 4:

For budget estimating purposes, assume the following:

The annual workshop cost estimates should include travel costs (transportation, meals, hotel, etc.) for the Principal Investigator and up to four other personnel (1-2 personnel from the contractor's laboratory, recommended by the Contractor and approved by the Project Office, and 1- 2 additional personnel to be determined by the Project Officer {e.g., SAC members}) to attend the workshop. All cost estimates should be based on Government rates or University policy for per diem, hotel, and transportation (coach class). It should be assumed that the workshop will be held in Bethesda, Maryland, for 1.5 days.

The Offeror may budget travel for appropriate personnel to attend one domestic scientific meeting per year, not including the annual workshop. All cost estimates should be based on Government rates or University policy for per diem, hotel, and transportation (coach class).

The Government estimates that the performance of the activities presented in the Statement of Work, for conducting one of the research areas A or B described in the Statement of Work, is estimated to be 390-490% effort per year depending on research area chosen (e.g., Areas A, or B, using existing methods: 390%, area A or B, developing novel or improved methods: 490%), which includes Principal Investigator, Research Scientists, and Research Technicians, and 20% effort per year for administrative staff for either research area chosen. These estimates are for the Offerors' information only and are not to be considered restrictive for proposal purposes. As part of the business proposal (which is separate from the technical proposal) Offerors must provide a detailed cost proposal, containing detailed estimated expenditures, related to their chosen Research Area(s). A separate cost proposal must be submitted for each Research Area proposed.

REPORTING REQUIREMENTS

As part of the work to be performed under this contract, the Contractor shall prepare and deliver the following reports throughout the period of work. The Contractor shall submit electronic and hard copy versions of each report. The exact submission schedule will be negotiated and established in the contract document.

I. **Quarterly Progress Reports**

The Contractor shall submit three (3) copies of each Quarterly Progress Report document and summarizing the results of the contract work performed during the previous three (3) months. This report shall be due on the 15th of the month following the end of each quarterly performance period. The original shall be submitted to the Contracting Officer, with two copies to the Project Officer. Each Quarterly 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, E-mail address, and submission date.

(B) An executive summary to include, but not necessarily be limited to:

1) An overview of the status of the Contractor's large-scale epitope discovery program, including personnel and epitope discovery and technology development activities;
2) A brief overview of the work completed during the current reporting period and/or justification for failure to complete intended work or for performance on unintended work; and
3) A brief overview of the activities that occurred during the current reporting period and any problems (technical or financial) that occurred during the current reporting period.

(C) A full description of:

1) The work performed during the reporting period including progress on epitope discovery, validation of epitope recognition by antibodies or T cells *in vitro* and/or *in vivo*, relevance of the epitope with respect to activation of protective immunity, diagnostic potential, and/or technology development and implementation (where applicable to the goals of the original Technical Proposal);
2) Epitopes, protocols, algorithms, or other data released to the Immune Epitope Database and Analysis Resource; including a description of any data and information that was withheld from release, with a justification for withholding the data/information or future plans for release;
3) The relation between the accomplishments and the goals and objectives of the contract;
4) A full disclosure of all research results obtained during the performance period and their relevance, explanations of any differences between planned and actual progress, and, if necessary, what corrective steps are planned or have been implemented; and
5) Future plans for the upcoming quarter.

(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 or any protocol or method developed specifically under this contract during the performance period.

(E) A full disclosure of Contractor's 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; full disclosure of patent applications or copyrights filed, as well as copies of patent or copyright applications.

Quarterly Progress Reports are not required for periods in which an Annual or Final Report is due.

II. **Annual Progress Reports**

The Contract shall submit three (3) copies (as specified above) of each Annual Progress Report documenting and summarizing the results of the contract work performed during the previous twelve (12) months. This report shall be due the 30th of the month following each yearly anniversary date of the contract. An Annual Report shall not be due when the Final Report is submitted. The report shall conform to the following format:

(A) Face page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, E-mail address, and submission date;

(B) An executive summary, to include an overview describing the extent to which production goals and the specific aims set forth in the Contractor's original Technical Proposal have been fulfilled; and

(C) A detailed description of the work performed during the performance period, the results obtained, and a discussion of the relevance of the results (as described under Quarterly Progress Reports); the relation between the Contractor's accomplishments and the work being conducted in the area by other groups; and the Contractor's impact on the scientific community, based on annual workshop discussions and scientific reports.

III. **Final Report**

The Contractor shall submit three (3) copies (as specified above) of the Final Report documenting and summarizing the results of the entire contract period of performance. This report shall be submitted on or before the completion date of the contract. The report shall conform to the following format:

(A) Face page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, E-mail address, and submission date;

(B) An introduction describing the purpose and scope of the contract effort including a summary of salient results. The Contractor shall submit a summary, not to exceed 200 words, of salient results achieved during performance of the contract;

(C) An executive summary, to include an overview describing the extent to which production goals and the specific aims set forth in the Contractor's original Technical Proposal have been fulfilled; and

(D) A detailed description of all of the work performed during the performance period, the results obtained (including, but not limited to, a compilation of all the epitope identified and the results of validation studies), and a discussion of the relevance of the results (as described under Quarterly Progress Reports); the relation between the Contractor's accomplishments and the work being conducted in the area by other groups; and the Contractor's impact on the scientific community, based on annual workshop discussions and scientific reports.

Deliverable Reports	No. of Copies	Addressee/Distribution	Due Dates
Quarterly Progress Reports	Original	Contracting Officer CMB,DEA, NIAID 6700-B Rockledge Drive, MSC 7612 Bethesda, MD 20892-7612	The 15th of the month following the end of each quarterly performance period
	2	Project Officer BIB, DAIT,NIAID 6700-B Rockledge Drive, MSC 7640 Bethesda, MD 20892-7640	Same as above
Annual Reports	Original	Contracting Officer, as above	The 30th of the month following the yearly anniversary date of the contract.
	2	Project Officer, as above	Same as above
Final Report	Original	Contracting Officer, as above	To be determined
	2	Project Officer, as above	To be determined

IV. **Other Deliverables**

The Contractor shall deliver to the Government, at the request of the Project Officer, the following item, during the life of this contract:

(A) The Contractor shall submit detailed information to the Immune Epitope Database and Analysis Resource (as well as the Project Officer of the present contract), describing each newly identified epitope along with the results of studies validating epitope antigenicity and/or diagnostic potential *in vitro* and *in vivo*, binding studies, and other relevant data within six months following the completion of verification/validation studies. Submissions shall include detailed descriptions of all newly developed high-throughput screening methods and other epitope

identification software tools (such as predictive algorithms, mathematic models, and artificial neural network programs) developed under the contract. All submitted information will be made freely available to the public through the Immune Epitope Database and Analysis Resource website, unless otherwise determined by the Project Officer (e.g., proprietary information, security issues).

The Contractor shall deliver to the Government or a successor Contractor, at the request of the Project Officer, the following items, by the completion date of this contract:

(B) All technology protocols for high-throughput screening methods and other epitope identification tools/methods developed or utilized under this contract, including licenses obtained for use of commercially available technologies and tools;

(C) All hardcopy and software files relevant to the research conducted during the course of this contract, including l licenses obtained for use of commercially available software;

(D) Copies of all software packages generated during the course of this contract, including but not limited to, all predictive algorithms and models (e.g., mathematical models, artificial neural networks) for epitope identification and/or prediction of host immune responses to pathogens and/or their epitopes developed during the contract period, including licenses acquired for inclusion of commercially or privately-developed algorithms and models; and

(E) Government-owned equipment and property supplied or procured under this 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 GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

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

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

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

52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Dec 2002	Allowable Cost and Payment
52.216-11	Mar 1984	Cost Contract - No Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Jan 2002	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (NOTE: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-7	Feb 1988	Withholding of Funds
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	May 2002	Buy American Act - Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data – General
52-232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Feb 2002	Prompt Payment

52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	July 2002	Disputes
52.233-3	Aug 1996	Protest After Award
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B., Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays

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

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

[END OF GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – Rev. 12/2002]

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following clause(s) will be made part of the resultant contract:

ALTERNATE IV (OCTOBER 1997) of FAR Clause 52.215-21, REQUIREMENT FOR COST OR PRICING DATA OR INFORMATION OTHER THAN COST OR PRICING DATA – MODIFICATIONS (OCTOBER 1997) is added.

ALTERNATE II (OCTOBER 2001) of FAR Clause 52.219-9, SMALL BUSINESS SUBCONTRACTING PLAN (JANUARY 2002) is added.

FAR Clause 52.232-20, LIMITATION OF COST, is deleted in its entirety and FAR Clause 52.232-22, LIMITATION OF FUNDS (APRIL 1984) is substituted therefore. [Note: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]

Alternative I (FEBRUARY 2002), of FAR Clause 52.232-25, Prompt Payment (FEBRUARY 2002) is deleted.

FAR Clause 52.249-14, EXCUSABLE DELAYS (APRIL 1984) is substituted therefore.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

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

FAR 52.224-1, Privacy Act Notification (APRIL 1984)
FAR 52.224-2, Privacy Act (APRIL 1984)
Alternate IV (JUNE 1987), FAR 52.227-14, Rights in Data – General (JUNE 1987)
FAR 52.229-8, Taxes-Foreign Cost-Reimbursement Contracts (MARCH 1990)
FAR 52.230-2, Cost Accounting Standards (APRIL 1998)
FAR 52.230-5, Cost Accounting Standards – Educational Institution (APRIL 1998)
FAR 52.232-18, Availability of Funds (APRIL 1984)
FAR 52.237-3, Continuity of Services (JANUARY 1991)
FAR 52.243-2, Changes –Cost Reimbursement (AUGUST 1987, Alternate V (APRIL 1984)
FAR 52.245-1, Property Records (APRIL 1984)
FAR 52.246-23, Limitation of Liability (FEBRUARY 1997)
FAR 52.247-63, Preference for U.S. Flag Air Carriers (JANUARY 1997)

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION/PUBLIC HEALTH SERVICE ACQUISITION REGULATION (HHSAR)/(PHSAR) (48 CHAPTER 3) CLAUSES:

HHSAR 352.223-70, Safety and Health (JANUARY 2001)
HHSAR 352.224-70, Confidentiality of Information (APRIL 1984)

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

NIH (RC)-7, Procurement of Certain Equipment (APRIL 1984) (OMB Bulletin 81-16).

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

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

FEDERAL ACQUISITION REGULATION (FAR)(48 CFR CHAPTER 1) CLAUSES:

FAR Clause 52.244-6, SUBCONTRACTS FOR COMMERCIAL ITEMS (MAY 2002)

(a) Definitions. As used in this clause--

Commercial item, has the meaning contained in the clause at 52.202-1, Definitions.

Subcontract, includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

(b) To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or nondevelopmental items as components of items to be supplied under this contract.

(c) (1) The Contractor shall insert the following clauses in subcontracts for commercial items:

(i) 52.219-8, Utilization of Small Business Concerns (OCT 2000) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $500,000 ($1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
(ii) 52.222-26, Equal Opportunity (APR 2002) (E.O. 11246).
(iii) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (DEC 2001) (38 U.S.C. 4212(a)).
(iv) 52.222-36, Affirmative Action for Workers with Disabilities (JUN 1998) (29 U.S.C. 793).
(v) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (JUN 2000) (46 U.S.C. Appx 1241) (flowdown not required for subcontracts awarded beginning May 1, 1996).

(2) While not required, the Contractor may flow down to subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(d) The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

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

PACKAGING AND DELIVERY OF PROPOSALS (Attached to this listing)

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

PROPOSAL INTENT RESPONSE SHEET
[SUBMIT ON/BEFORE: December 15, 2003] (Attached to this listing)

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

RFP FORMS AND ATTACHMENTS:

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

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

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

- **Technical Proposal Cover Sheet**
- **NIH-1688, Project Objectives**
- **Technical Proposal Cost Information**
- **Summary of Related Activities**
- **Government Notice for Handling Proposals**

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

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

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH-2706: Financial Report of Individual Project Contract**
- **Instructions for Completing Form NIH-2706**
- **NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)**
- **Safety and Health, HHSAR Clause 352.223-70**
- **Disclosure of Lobbying Activities, OMB Form LLL**
- **Privacy Act System of Records**
- **Report of Government Owned, Contractor Held Property**

PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

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

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

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

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

A. EXTERNAL PACKAGE MARKING:

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

"RFP NO. NIH-NIAID-DAIT-04-39: TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. NUMBER OF COPIES:

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

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

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

C. PAPER COPIES and CD-Rom or Zip Disk to:

If Hand Delivery or Express Service	**If using U.S. Postal Service**
Yvette Brown Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Yvette Brown Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, Maryland 20892-7612

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

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

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

PAGE LIMITS -- THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED **ONE HUNDRED FIFTY (150)** PAGES. PAGES THAT ARE 2-SIDED WILL COUNT AS 2 PAGES. [THIS PAGE LIMIT INCLUDES: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc.]. ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.

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

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

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

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

Formatting Requirements:

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- 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-04-39
RFP Title: Large Scale Antibody and T Cell Epitope Discovery Program

Please review the attached Request for Proposal. Furnish the information requested below and return this page by **December 15, 2003**. 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:
CMB, NIAID, NIH
Room 2230
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Yvette Brown
RFP-NIH-NIAID-DMID-04-39
FAX# (301) 402-0972
Email : ybrown@niaid.nih.gov

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

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

1. **REPRESENTATIONS AND CERTIFICATIONS**

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

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

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

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE 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. GENERAL INFORMATION

a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Clause 52.215-1 (May 2001)]

(a) *Definitions*. As used in this provision--

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"*In writing*", "writing", or "*written*" any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time*," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations.* If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

(i) The solicitation number;
(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals*. (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or
(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.
(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.
(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]

(e) *Restriction on disclosure and use of data*. (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

> "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as

indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) The Government may disclose the following information in postaward debriefings to other offerors:

(i) The overall evaluated cost or price and technical rating of the successful offeror;
(ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iii) A summary of the rationale for award; and
(iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of Provision)

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

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

b. NAICS CODE AND SIZE STANDARD

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

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

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

c. NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS

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

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

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

d. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that MULTIPLE AWARDS will be made from this solicitation and that the award(s) will be made on/about September 4, 2004.

It is anticipated that the award(s) from this solicitation will be a multiple-year COST REIMBURSEMENT type COMPLETION contract with a PERIOD OF PERFORMANCE OF five (5) years, and that incremental funding will be used [see Section L.2 Business Proposal Instructions].

e. ESTIMATE OF EFFORT

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the total five (5) year effort to be approximately 35,360 labor hours. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

f. COMMITMENT OF PUBLIC FUNDS

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

g. COMMUNICATIONS PRIOR TO CONTRACT AWARD

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

h. RELEASE OF INFORMATION

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

i. 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.

j. PREPARATION COSTS

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

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

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

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

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

(End of Provision)

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

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

m. LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70

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

(End of Provision)

n. AVAILABILITY OF THE "FEDERAL ADP AND TELECOMMUNICATIONS STANDARDS INDEX."

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

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

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

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

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

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

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

I. COVER PAGE

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

a. Project Objectives, NIH-1688-1

The Offeror shall insert a completed NIH Form 1688-1, Project Objective, as provided in Section J, Attachments, behind the Title Page of each copy of the proposal, along with the "Government Notice for Handling Proposals." The NIH Form 1688-1 is to be completed as follows:

- For an Institution of Higher Education: The form MUST be completed in its entirety.
- For OTHER than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank.

The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled, **"INSTRUCTIONS:"**

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

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

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

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

(5) **Alternate Proposals**

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

(6) **Evaluation of Proposals**

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

(7) **Potential Award Without Discussions**

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

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

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

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

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

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

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

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

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

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

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare assurance which commits the organization

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(12) **Selection of Offerors**

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

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

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

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

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

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

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

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

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

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

(13) **Small Business Subcontracting Plan**

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

a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS OR NON-U.S. CONCERNS.

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

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

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

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

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

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

- 23% Small Business
- 5% Small Disadvantaged Business
- 3% Women-Owned Small Business
- 5% HUBZone Small Business
- 3% Veteran-Owned Small Business
- 3% Service-Disabled Veteran-Owned Small Business

(14) **HUBZone Small Business Concerns**

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

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

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

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

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

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

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

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

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

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

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

(16) **Reimbursement of Costs for Independent Research and Development Projects** (Commercial Organizations Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

(17) **Salary Rate Limitation in Fiscal Year 2003**

NOTE: This award is intended to be made in Fiscal Year 2004. The current Fiscal Year 2003 Salary Rate Limitations should be adhered to in the preparation of your proposal. All costs associated with any resultant award will be required to be in compliance with the current Fiscal Year 2003 limitations and will be subject to change based on Fiscal Year 2004 Salary Rate Limitations.

Offerors are advised that pursuant to P.L. 108-7, no NIH Fiscal Year 2003 (October 1, 2002 - September 30, 2003) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patent care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I. The salary rate limitation set by P.L. 108-7 applies only to Fiscal Year 2003 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 108-7 states in pertinent part:

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

LINK TO EXECUTIVE SCHEDULE SALARIES: <http://www.opm.gov/oca/PAYRATES/index.htm>
(click on "Executive Schedule" for the current Fiscal Year's salary rate or scroll down to the "General Schedule Salary Tables from Previous Years" to locate the Executive Level salary rates from previous years).

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- Submission of Offerors 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)
- Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997)
- Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997)
- Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

(19) **Prohibition on Contractor Involvement with Terrorist Activities**

The Offeror/Contractor acknowledges that U. S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under any resultant contract(s).

(20) **Office of Health and Safety – Laboratory Registration / Select Agent Transfer Program**

The awardee is responsible for ensuring that all work under this grant, cooperative agreement, or contract complies with all Federal requirements related to select agents including CDC's that can be found at http://www.cdc.gov/od/ohs/lrsat.htm and NIH's OBA that can be found at http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html .

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

EACH INSTITUTION MUST:

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

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

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

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

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

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

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

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

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

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

4) the Institution will otherwise comply with the regulations.

INSTITUTIONAL MANAGEMENT OF CONFLICTING INTERESTS

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

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

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

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

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

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

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

(23) **Possession, Use and Transfer of Select Biological Agents or Toxins**

Work involving select biological agents or toxins shall not be conducted under this contract until the contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents.

For possession, use and transfer of biological agents or toxins that have been determined to have the potential to pose a severe threat to: 1) public health and safety; 2) both human and animal health, animal health, or animal products; and/or 3) plant health or plant products, registration information must be submitted to the Centers for Disease Control and Prevention, Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA) as applicable.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at <<http://www.cdc.gov/od/sap/>>

The following notice is applicable when contract performance is expected to involve possession, use and/or transfer of select biological agents or toxins:

Notice to Offerors of Requirements of: 42 CFR Part 73, Select Agents and Toxins (relating to public health and safety); Agricultural Bioterrorism Protection Act of 2002, which consists of 7 CFR Part 331, Possession, Use, and Transfer of Biological Agents and Toxins (relating to plant health or plant products); and 9 CFR Part 121, Possession, Use, and

Transfer of Biological Agents and Toxins (relating to human and animal health, animal health or animal products) - December 13, 2002

These regulations implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and the USA Patriot Act. They are designed to improve the United States Government's ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies. Unless exempted, entities must receive a certificate of registration or be authorized to work with the applicable select agents as follows:

(24) **Anti-lobbying**

a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall not be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.

b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c. Public Law and Section No.	Fiscal Year	Period Covered
for a. above: 108-7, Div. G, Title V - General Provisions, Section 503a	2003	10/01/2002 - 09/30/2003
for b. above 108-7, Div. G, Title V - General Provisions, Section 503b	2003	10/01/2002 - 09/30/2003

b. TECHNICAL PROPOSAL INSTRUCTIONS

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

(1) **Technical Discussions**

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

a) Statement of Work

(1) Objectives

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

(2) Approach

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

(3) Methods

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

(4) Schedule

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

b) Personnel

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

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

(1) Principal Investigator/Project Director

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

(2) Other Investigators

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

(3) Additional Personnel

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

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

(4) Resumes

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

(2) **Technical Evaluation**

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

(3) **Additional Technical Proposal Information**

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

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

(4) **Other Considerations**

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

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

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

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

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

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

c. BUSINESS PROPOSAL INSTRUCTIONS

(1) **Basic Cost/Price Information**

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

(2) **Cost and Pricing Data**

1. General Instructions

   Proposal Cover Sheet

   A. You must provide the following information on the first page of your pricing proposal:

      1. Solicitation, contract, and/or modification number;
      2. Name and address of offeror;
      3. Name and telephone number of point of contact;
      4. Name of contract administration office (if available);
      5. Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
      6. Proposed cost; profit or fee; and total;
      7. Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
      8. Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
      9. The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
      10. Date of submission; and
      11. Name, title and signature of authorized representative.

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

2. Cost Elements

   Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

   A. **Materials and services**. Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A.(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.

(1) *Adequate Price Competition*. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).

(2) *All Other*. Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

B. **Direct Labor**. Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.

C. **Indirect Costs**. Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

D. **Other Costs**. List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

E. **Royalties**. If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

1) Name and address of licensor.
2) Date of license agreement.
3) Patent numbers.
4) Patent application serial numbers, or other basis on which the royalty is payable.
5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
6) Percentage or dollar rate of royalty per unit.
7) Unit price of contract item.
8) Number of units.
9) Total dollar amount of royalties.
10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).

F. **Facilities Capital Cost of Money**. When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

(3) **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours (SECTION J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

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

(4) **Information Other than Cost or Pricing Data**

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

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

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

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

(a) Exceptions from cost or pricing data

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

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

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

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

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

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

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices,

or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

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

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

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

(End of provision)

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

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

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

As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

Federal Acquisition Regulation Clauses incorporated by Reference

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

By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

(6) **Qualifications of the Offeror**

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

a) General Experience

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

b) Organizational Experience Related to the RFP

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

c) Performance History

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

d) Pertinent Contracts

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

e) Pertinent Grants

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

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

(7) **Other Administrative Data**

a) Property

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

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

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

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

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

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

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

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's

financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) Financial Capacity

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

d) Incremental Funding

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

HHSAR 352.232-75, Incremental Funding (January 2001)

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

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

(End of provision)

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

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(8) **Subcontractors**

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

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

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

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

d) Information on their cognizant field audit offices.

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

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

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

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

(9) **Proposer's Annual Financial Report**

All offerors included in the competitive range will be required to submit a copy of the organization's most recent annual financial report.

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

(10) **Representations and Certifications**

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

(11) **Travel Costs/Travel Policy**

a) Travel Costs-Commercial

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis, the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-45.

b) Travel Policy

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

(12) **Certification of Visa's for Non-U.S. Citizens**

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its territories, then the offeror must indicate in the proposal that these individuals have the required visas.

(13) **Guidance Regarding Federal Government Collaborations**

In keeping with FAR 3.6 and recent legal decisions involving conflict of interest issues, it is the policy of the NIAID that any proposal either submitted by a Federal Agency or submitted by an offeror that includes the collaboration of a Federal Agency or Federal employee must include a letter describing the role and effort being provided by that government agency and/or employee and stating that: (1) no actual or potential conflict of interest exists with the proposed effort; and (2) the collaborator's supervisor is aware of and approves of the effort. This letter must be signed by both the agency's ethics official and the head of the agency (or his/her designate). The NIAID reserves the right to reject a proposal that includes effort by Federal government employees in order to avoid any actual or apparent conflict of interest.

SECTION M - EVALUATION FACTORS FOR AWARD

GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost/price, when combined, are significantly more important than cost or price. The trade-off process described in FAR 15.101-1 may be employed. This process permits tradeoffs among cost/price and non-cost factors and allows the Government to consider award to other than the lowest priced or highest technically rated offeror. In any event, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

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

TECHNICAL EVALUATION CRITERIA — TOTAL 100 POINTS

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

CRITERIA — **WEIGHT**

1. TECHNICAL APPROACH: — 50 POINTS

(a) Strength and merit of the documented ability of the Offeror to design, develop, and implement programs for large-scale epitope discovery in areas relevant to those described in the RFP, including the plans for performing the tasks listed in sections II-IV, namely: the feasibility and suitability of plans for submission of data to the Immune Epitope Database and Analysis Resource, documented commitment to participate in the required annual workshop, and appropriateness of plans to assist with establishing a Scientific Advisory Committee (SAC).

(b) For those proposals responding to Research Areas A and/or B: Appropriateness and adequacy of the methods, technologies, and other procedures proposed for large-scale epitope discovery and validation, including the Offeror's rationale for using these methods to identify likely candidates that induce or maintain protective immunity or may be valuable as a diagnostic tool. Appropriateness and adequacy of plans to validate immune cell reactivity *in vitro* and/or *in vivo*, where applicable.

(c) For those proposals that include development of novel or improved high-throughput screening methods: Appropriateness and adequacy of the high-throughput screening methods, technologies, and other procedures that the Offeror proposes to develop for epitope discovery, including the appropriateness and adequacy of the proposed approach for validating the screening methods *in vitro* or *in vivo*.

(d) For those proposals that include development of novel or improved algorithms and mathematical models: Appropriateness and adequacy of the predictive algorithms, mathematical models, and artificial neural network programs that the Offeror proposes to develop for epitope discovery and the prediction of host responses, including the appropriateness and adequacy of the proposed approach for validating the predictive algorithms *in vitro* or *in vivo*.

(e) Adequacy and appropriateness of the documented plans for the protection of vertebrate animals and/or human subjects from research risks, where applicable. Appropriateness and adequacy of plans for the protection of personnel from Biohazards, including plans for complying with all applicable local, state and federal regulations for the receipt and use of Category A-C agents, as applicable.

2. PERSONNEL: 35 POINTS

a) Principal Investigator: Strength and adequacy of the Principal Investigator's documented training, expertise, leadership, and availability with respect to technical and administrative competence to successfully manage a project of comparable size and complexity. It is expected that the Principal Investigator shall have extensive knowledge of immunology related to epitopes, as needed to plan and direct the project. (**20 points)**

b) Scientific and Technical Staff: For staff at the contract site, and for subcontractors and consultants, the strength and adequacy of the documented training, experience, and availability of the proposed professional, technical and support staff and their documented capabilities to perform their roles with respect to the proposed studies, including expertise gained from participating in projects of a similar nature. The logistical adequacy of the staffing plan for the project shall include the time commitments and project-related roles of the professional and technical staff. The above information shall be provided for staff working at the contract site as well as for subcontractors and consultants. (**15 points)**

3. FACILITIES, RESOURCES AND EQUIPMENT: 15 POINTS

Strength and appropriateness of the documented availability and adequacy of facilities, equipment, and resources necessary to conduct all phases of the proposed project. This documentation includes the detailed facilities plan, including access to pathogens (source), available equipment, appropriate containment facilities (e.g., CDC regulations) for research involving potential agents of bioterrorism or health threats, and proper security measure to ensure pathogen containment; information regarding ownership/lease of the proposed facilities and equipment, including their demonstrated availability for the duration of the proposed contract; and a plan for obtaining, adding, or deleting personnel, facilities, and/or equipment, as necessary, based on progress expected to be made during the course of the contract.

TOTAL: 100 POINTS

4. EVALUATION OF TARGETS FOR EXTENT OF SMALL DISADVANTAGED BUSINESS (SDB) 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 SDB participation targets will be evaluated before determination of the competitive range. The evaluation will be based on information provided by the Offeror in their technical proposal. 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 as the prime contractor.

Offers will be evaluated on the following sub-factors:

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