

# SOLICITATION

## SECTION A - SOLICITATION/CONTRACT FORM

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                     |                                                                                                                                                                                                                                                                      |                                                          |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------|
| 1. Purchase Authority: Public Law 92-218 as amended                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                     |                                                                                                                                                                                                                                                                      |                                                          |
| 2. Request for Proposal (RFP) Number:<br><br>BAA-NIAID-DAIT-NIHAI2008037                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | 3. Issue Date:<br><br>July 31, 2008 | 4. Just in Time:<br>[X] No<br>[ ] Yes See Part IV Section L                                                                                                                                                                                                          | 5. Set Aside:<br>[X] No<br>[ ] Yes See Part IV Section L |
| 6. Title : Innate Immune Receptors and Adjuvant Discovery                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                     |                                                                                                                                                                                                                                                                      |                                                          |
| 7. ISSUED BY:<br>Office of Acquisitions<br>National Institute of Allergy and Infectious Disease<br>National Institutes of Health<br>6700 B Rockledge Dr.<br>Room 3214, MSC 7612<br>Bethesda, MD 20892-7612<br><br>_____                                                                                                                                                                                                                                                                                                                                                                                               |                                     | 8. SUBMIT OFFERS TO:<br><br>See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.<br><br><b>[Note: This solicitation has a required total page limitation of not to exceed 150 pages for the technical proposal]</b> |                                                          |
| 9. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 3:00 pm local time on December 1, 2008. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.                                                                                                                                                                                  |                                     |                                                                                                                                                                                                                                                                      |                                                          |
| 10. THIS SOLICITATION REQUIRES DELIVERY OF PROPOSALS TO TWO DIFFERENT LOCATIONS. THE OFFICIAL POINT OF RECEIPT FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY IS THE ADDRESS PROVIDED FOR THE OFFICE OF ACQUISITIONS AS STATED IN ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH HHSAR CLAUSE 352.215-70, ENTITLED, "LATE PROPOSALS, AND REVISIONS" LOCATED IN SECTION L.1. OF THIS SOLICITATION. |                                     |                                                                                                                                                                                                                                                                      |                                                          |
| 11. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. <a href="http://www.ccr.gov">http://www.ccr.gov</a>                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                     |                                                                                                                                                                                                                                                                      |                                                          |
| 12. FOR INFORMATION CALL: Bryan Jones<br>PHONE: 301-451-3682<br>e-MAIL: jonesbry@niaid.nih.gov<br>COLLECT CALLS WILL NOT BE ACCEPTED.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                     |                                                                                                                                                                                                                                                                      |                                                          |
| 6700 B Rockledge Dr.<br>Room 3214, MSC 7612<br>Bethesda, MD 20892-7612                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                     | Wanda Neal<br>Contracting Officer and Team Lead, AIT-RCB<br>Office of Acquisitions, DEA<br>National Institute of Allergy and Infectious Diseases, NIH,<br>DHHS                                                                                                       |                                                          |

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## **PART I - THE SCHEDULE**

THE INFORMATION SET FORTH IN **SECTION A - SOLICITATION/CONTRACT FORM**, HEREIN CONTAINS IMPORTANT INFORMATION FOR ANY OFFEROR INTERESTED IN RESPONDING TO THIS SOLICITATION. ANY CONTRACT RESULTING FROM THIS SOLICITATION WILL INCLUDE IN ITS **SECTION A - SOLICITATION/CONTRACT FORM**, ACCOUNTING, APPROPRIATION AND GENERAL INFORMATION APPLICABLE TO THE CONTRACT AWARD.

THE CONTRACT SCHEDULE SET FORTH IN **SECTIONS B THROUGH H**, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS NOT AN EXACT REPRESENTATION OF THE CONTRACT DOCUMENT THAT WILL BE AWARDED AS A RESULT OF THIS SOLICITATION. THE CONTRACT COST OR PRICE AND OTHER CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror's proposal and requiring Contracting Officer Prior Approval) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

## **SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS**

### **ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES**

This Broad Agency Announcement (BAA) targets discovery of novel adjuvants that act via triggering of human innate immune receptors. The ultimate goal of this effort is to protect the human population from infectious diseases; therefore the research must focus on adjuvants that will be effective in the human innate immune system to help prevent or treat infectious disease. For the purpose of this BAA, adjuvants are defined as molecules that act via innate immune receptors to activate beneficial innate and/or adaptive (T and B cell-mediated) immune responses. The adjuvant products targeted in this program may encompass uses both as vaccine adjuvants, to elicit T and B cell responses when co-administered with an immunogen, as well as stand-alone immunomodulators to simulate short term protective responses against broad categories of infectious agents.

### **ARTICLE B.2. PRICES/COSTS**

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

### **ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS**

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

### **ARTICLE B.4. ADVANCE UNDERSTANDINGS**

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

## SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

### ARTICLE C.1. DESCRIPTION-SPECIFICATION-WORKSTATEMENT

- a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work proposed by the contractor and submitted in response to this Broad Agency Announcement.

### ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one (1) hardcopy of each report shall be submitted to the Contracting Officer, unless otherwise specified.

a. **Technical Progress Reports**

1. In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award.

[Note: Please see Attachment entitled "Reporting Requirements and Other Deliverables" at the end of this BAA]

Monthly

Quarterly

Semi-Annually

Annually

Annually (with a requirement for a Draft Annual Report)

Final - Upon final completion of the contract

Final - Upon final completion of the contract (with a requirement for a Draft Final Report)

2. **Summary of Salient Results**

The Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This report will be required on or before the expiration date of the contract.

3. **Annual Technical Progress Report for Clinical Research Study Populations**

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. The Contractor shall submit this information in the format indicated in the attachment entitled, "Inclusion Enrollment Report," which is set forth in SECTION J of this contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report.

The Contractor shall submit the report in accordance with the DELIVERIES Article in SECTION F of this contract.

In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October, 2001 applies. If this contract is for Phase III clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website:

[http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm)

Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol as approved by the IRB, and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

## **b. Other Reports/Deliverables**

### **1. Source Code and Object Code**

Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

### **2. Contract Review Meetings:**

a. Annual Program Meetings: Awardees will participate in two-day annual meetings held in the Bethesda, Maryland area, with the first meeting to be held within three months after contract award. All Contractor Principal Investigators (PIs) funded under this program, as well as selected other key contract investigators including subcontractor personnel, shall attend these meetings. The NIH Project Officer, Contracting Officer, and other designated NIH staff shall also attend. Meetings will be closed to the general public and shall involve oral and electronic presentations by the Contractors, including descriptions of planned work, updates on results of activities undertaken or completed in the prior contract year of performance (with the exception of the first meeting, which will update activities undertaken within the first three months of the contract's period of performance), descriptions of problems encountered or anticipated, approaches to resolve problems, and plans for the next year.

b. Site Visits: Within the first year after award, the Contractor shall plan, conduct, and be responsible for logistical arrangements for a one- to two-day site visit by NIH staff to the Contractor's site. The PI, Project Manager (PM), all key investigators, key subcontractor personnel, the Project Officer, and the Contracting Officer shall attend this meeting. Other NIH staff, as designated by the Project Officer, may also attend. The purpose of the site visit is to review plans and progress of the proposed work, and to coordinate activities and communication between the Contractor and the NIAID. The PI shall provide a copy of all slide presentations to the Project Officer. In addition to the initial site visit, the Project Officer and Contracting Officer may request additional site visits at the Contractor or subcontractor sites as needed.

c. Monthly Teleconferences: The Contractor shall plan and conduct a teleconference meeting with the Project Officer each month during the first year after award, and thereafter at the discretion of the Project Officer, to discuss technical progress and financial issues. One week prior to the teleconference, the Contractor shall submit an agenda to the Project Officer. Within one week after the teleconference, the Contractor shall provide a summary of the teleconference to the Project Officer.

Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

### 3. System Security Plan

Within 30 calendar days of the effective date of the contract, the contractor shall submit to the Project Officer a Draft System Security Plan (SSP) that identifies and details the management, operation, and technical controls of the computer-based data management system(s) to be used within the contract. Appropriate methods to ensure protection of personally identifiable information must be included in the SSP. Detailed guidance information regarding SSP development may be found at the following link: [http://irm.cit.nih.gov/nihsecurity/NIH\\_System\\_C&A.htm](http://irm.cit.nih.gov/nihsecurity/NIH_System_C&A.htm).

Project Officer comments on the Draft SSP will be provided within 30 calendar days after receipt. The Final SSP, revised as necessary to accommodate Project Officer comments, must be in place within 90 calendar days from the effective date of the contract. An updated SSP shall be provided to the Project Officer and Contracting Officer with the Annual Technical Progress Report following a major change in contractor infrastructure or computer-based systems.

### 4. Human Subjects IRB Annual Report (Form OMB No. 0990-0263, formerly Optional Form 310).

## ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040-A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer  
National Institutes of Health  
National Institute for Allergy and Infectious Disease  
DEA, Office of Acquisition  
6700B Rockledge Blvd  
Room 3214

Bethesda, Maryland 20892- 7612

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web ( <http://www.iedison.gov>), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.



## **SECTION D - PACKAGING, MARKING AND SHIPPING**

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

## SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, the Project Officer identified in Article G.1 is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:  
National Institutes of Health  
National Institute for Allergy and Infectious Diseases  
Division of Allergy, Immunology and Transplantation  
6610 Rockledge Drive  
Bethesda, MD 20892

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

- d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause **52.246-8, Inspection of Research and Development - Cost-Reimbursement** (May 2001).

*FAR Clause 52.246-9, Inspection of Research and Development (Short Form) (April 1984).*

## **SECTION F - DELIVERIES OR PERFORMANCE**

### **ARTICLE F.1. PERIOD OF PERFORMANCE**

The period of performance of this contract shall be from August 13, 2009 through August 12, 2014.

### **ARTICLE F.2. DELIVERIES**

- a. Satisfactory performance of this contract shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the Items specified in the Delivery Schedule which are described in SECTION C of this contract.

### **ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)**

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.acquisition.gov/comp/far/index.html>

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

**52.242-15, Stop Work Order** (August 1989) with **Alternate I** (April 1984).

## SECTION G - CONTRACT ADMINISTRATION DATA

### ARTICLE G.1. PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

[To be specified prior to award]

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

### ARTICLE G.2. KEY PERSONNEL, HHSAR 352.270-5 (January 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

(End of Clause)

The following individual(s) is/are considered to be essential to the work being performed hereunder:

| Name                           | Title |
|--------------------------------|-------|
| To be specified prior to award |       |

### ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

- a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted as follows:

- a. One original to the following designated billing office:

National Institutes of Health

Office of Financial Management  
Commercial Accounts  
2115 East Jefferson Street, Room 4B-432, MSC 8500  
Bethesda, MD 20892-8500

- b. One copy to the following approving official:

Contracting Officer  
Office of Acquisitions  
National Institute for Allergy and Infectious Disease  
National Institutes of Health Room 3214  
6700B Rockledge Dr. MSC 7612  
BETHESDA, MD 20892- 7612

E-Mail:

The Contractor shall submit an electronic copy of the payment request to the approving official in lieu of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in a format compatible with the computer systems at NIH [e.g., MS Word, MS Excel, or Adobe Portable Document Format (PDF)]. ***[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]***

2. In addition to the requirements specified in FAR Subpart 32.9 for a proper invoice, the Contractor shall include the following information on all payment requests:
- a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Institute for Allergy and Infectious Disease .
  - b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NIAID Invoices .
  - c. Vendor Identification Number. This is the 7 digit number that appears after the Contractor's name in Block 7 of Standard Form 26. *[Note: This only applies to new contracts awarded on/ after June 4, 2007, and any existing contract modified to include the number.]*
  - d. DUNS number or DUNS+4 that identifies the Contractor's name and address exactly as stated on the face page of the contract.
  - e. Identification of whether payment is to be made using a two-way or three-way match. This contract requires a Two-Way match.
  - f. Unique Invoice Number

- b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) - 496-6452.

#### **ARTICLE G.4. LETTER OF CREDIT PAYMENT INFORMATION**

- a. Advance payments will be provided under Letter of Credit Number Specified post award in accordance with FAR 32.406 Letters of Credit, Part 6, Chapter 2000 of the Treasury Financial Manual, and Department of Treasury Circular 1075 (31 CFR Part 205, [http://www.access.gpo.gov/nara/cfr/waisidx\\_00/31cfr205\\_00.html](http://www.access.gpo.gov/nara/cfr/waisidx_00/31cfr205_00.html) ).

The Contractor shall withdraw cash only when needed for disbursements and report cash disbursements and balances in accordance with the CONTRACT FINANCIAL REPORT ARTICLE in SECTION G of this contract. The Contractor shall impose the same standards of timing and amount upon any subcontractors, including the

furnishing of reports of cash disbursements and balances. Failure to adhere to these provisions may cause the Government to withhold further withdrawals under Letter of Credit.

- b. Inquiries regarding advance payments shall be directed to the following office:

Division of Payment Management  
11400 Rockville Pike  
Rockwall Building #1, Suite 700  
Rockville, MD 20852  
( <http://www.dpm.psc.gov/> under Contacts)

- c. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) - 496-6452.

## **ARTICLE G.5. INDIRECT COST RATES**

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services  
Office of Acquisition Management and Policy  
National Institutes of Health  
6100 Building, Room 6B05  
6100 EXECUTIVE BLVD MSC-7540  
BETHESDA MD 20892-7540

These rates are hereby incorporated without further action of the Contracting Officer.

## **ARTICLE G.6. GOVERNMENT PROPERTY**

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication, entitled, "Contractor's Guide for Control of Government Property," which can be found at:

<http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm>.

## **ARTICLE G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE**

- a. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) shall be submitted as deemed appropriate by OA, NIAID.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

- b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

<http://oamp.od.nih.gov/OD/CPS/cps.asp>

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

## **SECTION H - SPECIAL CONTRACT REQUIREMENTS**

### **ARTICLE H.1. HUMAN SUBJECTS**

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

### **ARTICLE H.2. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS**

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Contractor should access the [NIH Guide for Grants and Contracts Announcement](#) dated June 5, 2000 at the following website:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

The information below is a summary of the NIH Policy Announcement:

The Contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

### **ARTICLE H.3. DATA AND SAFETY MONITORING IN CLINICAL TRIALS**

The Contractor is directed to the full text of the NIH Policy regarding Data and Safety Monitoring and Reporting of Adverse Events, which may be found at the following web sites:

<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>

<http://grants.nih.gov/grants/guide/notice-files/not99-107.html>

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>

The Contractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract.

Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan.

The Data and Safety Monitoring Plan shall be established and approved prior to beginning the conduct of the clinical trial.

### **ARTICLE H.4. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)**

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform



Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

## **ARTICLE H.5. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH**

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

## **ARTICLE H.6. NEEDLE EXCHANGE**

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

## **ARTICLE H.7. PRESS RELEASES**

Pursuant to the current HHS annual appropriations act, the Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

## **ARTICLE H.8. LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES**

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to support activities that promote the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established under section 202 of the Controlled Substances Act (21 U.S.C. 812), except for normal and recognized executive-congressional communications. This limitation shall not apply when the Government determines that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

## **ARTICLE H.9. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING SCIENTIFIC INFORMATION**

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to disseminate scientific information that is deliberately false or misleading.

## **ARTICLE H.10. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS**

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to employ workers described in section 274A(h)(3) of the Immigration and Nationality Act, which reads as follows:

"(3) Definition of unauthorized alien. - As used in this section, the term 'unauthorized alien' means, with respect to the employment of an alien at a particular time, that the alien is not at that time either (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

## **ARTICLE H.11. SALARY RATE LIMITATION LEGISLATION PROVISIONS**

- a. Pursuant to the current HHS annual appropriations act, the Contractor shall not use NIH Fiscal Year funds to pay the direct salary of an individual through this contract at a rate in excess of Executive Level I. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as "indirect costs" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor. The annual salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.
- b. Payment of direct salaries is limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred. See the following Web site for Executive Schedule rates of pay: <http://www.opm.gov/oca/>. *(For current year rates, click on Salaries and Wages / Executive Schedule / Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages / cursor to bottom of page and select year / Executive Schedule / Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)*

## **ARTICLE H.12. PRIVACY ACT, HHSAR 352.270-11 (January 2006)**

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as HHS employees. These provisions also apply to all subcontracts awarded under this contract which require the design, development or operation of the designated system(s) of records (5 U.S.C. 552a(m)(1)).

The contract work statement: (a) Identifies the system(s) of records and the design, development, or operation work to be performed by the Contractor; and (b) specifies the disposition to be made of such records upon completion of contract performance.

(End of clause)

45 CFR Part 5b contains additional information which includes the rules of conduct and other Privacy Act requirements and can be found at: [http://www.access.gpo.gov/nara/cfr/waisidx\\_06/45cfr5b\\_06.html](http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr5b_06.html).

The Privacy Act System of Records applicable to this project is Number TBD. This document is incorporated into this contract as an Attachment in SECTION J of this contract. This document is also available at: <http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm>.

## **ARTICLE H.13. ANIMAL WELFARE**

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at:

<http://grants1.nih.gov/grants/olaw/references/phspol.htm>.

## **ARTICLE H.14. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES**

All Contractor personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL:

<http://www1.od.nih.gov/oma/manualchapters/intramural/3044-2/>

## **ARTICLE H.15. OMB CLEARANCE**

In accordance with HHSAR 352.270-7, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Project Officer and the Contracting Officer has issued written approval to proceed.

## **ARTICLE H.16. SUBCONTRACTING PROVISIONS**

### **a. Small Business Subcontracting Plan**

1. The Small Business Subcontracting Plan, dated [To be specified upon award] is attached hereto and made a part of this contract.
2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

### **b. Subcontracting Reports**

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS)" at <http://www.esrs.gov>.

#### **1. Individual Subcontract Reports (ISR)**

Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:

April 30th

October 30th

#### **2. Summary Subcontract Report (SSR)**

Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes.

## ARTICLE H.17. INFORMATION SECURITY

The Statement of Work (SOW) requires the Contractor to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies, the Contractor and any subcontractor performing under this contract shall comply with the following requirements:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); <http://csrc.nist.gov/drivers/documents/FISMA-final.pdf>

### a. Information Type

Administrative, Management and Support Information

Scientific and Technical Research and Innovation

Mission Based Information

### b. Security Categories and Levels

Confidentiality Level:  Low  Moderate  High

Integrity Level:  Low  Moderate  High

Availability Level:  Low  Moderate  High

**Overall Level:**  **Low**  **Moderate**  **High**

### c. Position Sensitivity Designations

- The following position sensitivity designations and associated clearance and investigation requirements apply under this contract.

**Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI).** Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI)

**Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI).** Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

**Level 1: Non Sensitive (Requires Suitability Determination with an NACI).** Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).

- The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 calendar days of the effective date

of the contract. Any revisions to the roster as a result of staffing changes shall be submitted within 15 calendar days of the change. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for Contractor use at: <http://ais.nci.nih.gov/forms/Suitability-roster.xls>.

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

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

3. Contractor/Subcontractor employees shall comply with the HHS criteria for the assigned position sensitivity designations prior to performing any work under this contract. The following exceptions apply:

Levels 5 and 1: Contractor/Subcontractor employees may begin work under the contract after the Contractor has submitted the name, position and responsibility of the employee to the Project Officer, as described in paragraph c. (2) above.

Level 6: In special circumstances the Project Officer may request a waiver of the pre-appointment investigation. If the waiver is granted, the Project Officer will provide written authorization for the Contractor/Subcontractor employee to work under the contract.

#### d. Information Security Training

The Contractor shall ensure that each Contractor/Subcontractor employee has completed the NIH Computer Security Awareness Training course at: <http://irtsectraining.nih.gov/> prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract.

The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working under this contract that has completed the NIH required training. Any additional security training completed by Contractor/Subcontractor staff shall be included on this listing. [The listing of completed training shall be included in the first technical progress report. (See Article C.2. Reporting Requirements.) Any revisions to this listing as a result of staffing changes shall be submitted with next required technical progress report.]

Contractor/Subcontractor staff shall complete the following additional training prior to performing any work under this contract:

#### e. Rules of Behavior

The Contractor/Subcontractor employees shall comply with the NIH Information Technology General Rules of Behavior at: <http://irm.cit.nih.gov/security/nihitrob.html>.

#### f. Personnel Security Responsibilities

##### **Contractor Notification of New and Departing Employees Requiring Background Investigations**

1. The Contractor shall notify the Contracting Officer, the Project Officer, and the Security Investigation Reviewer **within five working days** before a new employee assumes a position that requires a suitability determination or when an employee with a security clearance stops working under the contract. The Government will initiate a background investigation on new employees requiring security clearances and will stop pending background investigations for employees that no longer work under the contract.
2. New employees: Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the Government will determine the appropriate security level.

## 3. Departing employees:

- Provide the name, position title, and security clearance level held by or pending for the individual.
- Perform and document the actions identified in the "Employee Separation Checklist", attached in Section J, ATTACHMENTS of this contract, when a Contractor/Subcontractor employee terminates work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request.

g. Commitment to Protect Non-Public Departmental Information Systems and Data

## 1. Contractor Agreement

The Contractor and its subcontractors performing under this SOW shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
- 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
- Public Law 96-511 (Paperwork Reduction Act)

## 2. Contractor-Employee Non-Disclosure Agreements

Each Contractor/Subcontractor employee who may have access to non-public Department information under this contract shall complete the Commitment to Protect Non-Public Information - Contractor Agreement. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer prior to performing any work under the contract.

h. NIST SP 800-53 Self-Assessment

The contractor shall annually update and re-submit its Self-Assessment required by NIST SP 800-53, *Recommended Security Controls for Federal Information Systems*. ( <http://csrc.nist.gov/publications> - under Special Publications).

Subcontracts: The Contractor's annual update to its Self-Assessment Questionnaire shall include similar information for any subcontractor that performs under the SOW to (1) develop a Federal information system(s) at the Contractor's/Subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the Contractor's/Subcontractor's facility.

The annual update shall be submitted to the Project Officer, with a copy to the Contracting Officer [For option contracts: no later than the completion date of the period of performance/ for all other contracts: indicate due date as determined by the Project Officer/Contracting Officer].

i. Information System Security Plan

The Contractor's draft ISSP submitted with its proposal shall be finalized in coordination with the Project Officer no later than 90 calendar days after contract award.

Following approval of its draft ISSP, the Contractor shall update and resubmit its ISSP to the Project Officer every three years or when a major modification has been made to its internal system. The Contractor shall use the current ISSP template in Appendix A of NIST SP 800-18, *Guide to Developing Security Plans for Federal Information Systems*. ( <http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf> ). The details contained in the Contractor's ISSP shall be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels of this Article.

Subcontracts: The Contractor shall include similar information for any subcontractor performing under the SOW with the Contractor whenever the submission of an ISSP is required.

j. Common Security Configurations

The contractor shall ensure that any information technology acquired under this contract incorporates the applicable common security configuration established by the National Institute of Standards and Technology (NIST) at <http://checklists.nist.gov>.

## **ARTICLE H.18. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY (January 2008)**

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, and/or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 provisions is available at <http://www.section508.gov/>. The complete text of Section 508 Final provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm>.

The Section 508 standards applicable to this contract/order are identified in the Statement of Work. The contractor must provide a written Section 508 conformance certification due at the end of each order/contract exceeding \$100,000 when the order/contract duration is one year or less. If it is determined by the Government that EIT products and services provided by the Contractor do not conform to the described accessibility in the Product Assessment Template, remediation of the products and/or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor at its own expense.

In the event of a modification(s) to the contract/order, which adds new EIT products and services or revised the type of, or specifications for, products and services the Contractor is to provide, including EIT deliverables such as electronic documents and reports, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products and services support Section 508 accessibility requirements. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at <http://508.hhs.gov>.

[(End of HHSAR 352.270-19(b))]

Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding increment funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Annual Report to the Contracting Officer and Contracting Officer's Technical Representative (also known as Project Officer or Contracting Officer's Representative). Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available at: <http://508.hhs.gov/> under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding incremental funding, as applicable.

### **Schedule for Contractor Submission of Section 508 Annual Report:**

[(End of HHSAR 352.270-19(c))]

## **ARTICLE H.19. ACCESS TO NATIONAL INSTITUTES OF HEALTH (NIH) ELECTRONIC MAIL**

All Contractor staff that have access to and use of NIH electronic mail (e-mail) must identify themselves as contractors on all outgoing e-mail messages, including those that are sent in reply or are forwarded to another user. To best comply with this requirement, the Contractor staff shall set up an e-mail signature ("AutoSignature") or an electronic

business card ("V-card") on each Contractor employee's computer system and/or Personal Digital Assistant (PDA) that will automatically display "Contractor" in the signature area of all e-mails sent.

## **ARTICLE H.20. CONFIDENTIALITY OF INFORMATION**

The following information is covered by **HHSAR 352.224-70, Confidentiality of Information** (January 2006):

## **ARTICLE H.21. PUBLICATION AND PUBLICITY**

In addition to the requirements set forth in HHSAR Clause **352.270-6, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institute for Allergy and Infectious Disease, National Institutes of Health, Department of Health and Human Services, under Contract No. [to be specified upon contract award]"

## **ARTICLE H.22. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE**

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The e-mail address is [Htips@os.dhhs.gov](mailto:Htips@os.dhhs.gov) and the mailing address is:

Office of Inspector General  
Department of Health and Human Services  
TIPS HOTLINE  
P.O. Box 23489  
Washington, D.C. 20026

## **ARTICLE H.23. YEAR 2000 COMPLIANCE**

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause(s):

### **1. Service Involving the Use of Information Technology YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY**

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

(End of Clause)

### **2. Noncommercial Supply Items Warranty YEAR 2000 WARRANTY--NONCOMMERCIAL SUPPLY ITEMS**

The Contractor warrants that each noncommercial item of hardware, software, and firmware delivered or developed under this contract and listed below shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations, when used in accordance with



the item documentation provided by the Contractor, provided that all listed or unlisted items (e.g., hardware, software and firmware) used in combination with such listed item properly exchange date data with it. If the contract requires that specific listed items must perform as a system in accordance with the foregoing warranty, then that warranty shall apply to those listed items as a system. The duration of this warranty and the remedies available to the Government for breach of this warranty shall be as defined in, and subject to, the terms and limitations of any general warranty provisions of this contract provided that notwithstanding any provision to the contrary in such warranty provision(s), or in the absence of any such warranty provision(s), the remedies available to the Government under this warranty shall include repair or replacement of any listed item whose noncompliance is discovered and made known to the Contractor in writing within ninety (90) days after acceptance. Nothing in this warranty shall be construed to limit any rights or remedies the Government may otherwise have under this contract with respect to defects other than Year 2000 performance.

|                                                         |
|---------------------------------------------------------|
| <b>YEAR 2000 COMPLIANT ITEMS</b>                        |
| applicable information to be included at contract award |
|                                                         |
|                                                         |

(End of Clause)

**3. Commercial Supply Products Warranty  
YEAR 2000 WARRANTY--COMMERCIAL SUPPLY ITEMS**

The Contractor warrants that each hardware, software and firmware product delivered under this contract and listed below shall be able to accurately process date data (including, but not limited to, calculating, comparing, and sequencing) from, into, and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations, when used in accordance with the product documentation provided by the Contractor, provided that all listed or unlisted products (e.g., hardware, software, firmware) used in combination with such listed product properly exchange date data with it. If the contract requires that specific listed products must perform as a system in accordance with the foregoing warranty, then that warranty shall apply to those listed products as a system. The duration of this warranty and the remedies available to the Government for breach of this warranty shall be as defined in, and subject to, the terms and limitations of the Contractor's standard commercial warranty or warranties contained in this contract, provided that notwithstanding any provision to the contrary in such commercial warranty or warranties, the remedies available to the Government under this warranty shall include repair or replacement of any listed product whose non-compliance is discovered and made known to the Contractor in writing within ninety (90) days after acceptance. Nothing in this warranty shall be construed to limit any rights or remedies the Government may otherwise have under this contract with respect to defects other than Year 2000 performance.

|                                                          |
|----------------------------------------------------------|
| <b>YEAR 2000 COMPLIANT ITEMS</b>                         |
| applicable information to be included at contract award. |
|                                                          |
|                                                          |

(End of Clause)

**ARTICLE H.24. SHARING RESEARCH DATA**

If the data sharing plan submitted by the Contractor is acceptable/The Contractor's data sharing plan, dated to be specified upon award is hereby incorporated by reference. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to serve health. this contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at <http://www.hhs.gov/ocr/>). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

## **ARTICLE H.25. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)**

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at: <http://www.usfa.fema.gov/hotel/index.htm>.

## **ARTICLE H.26. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES**

The 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 this contract.

## **ARTICLE H.27. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH**

Beginning April 7, 2008, NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: <http://www.pubmedcentral.nih.gov>.

Additional information is available at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html>.

## **ARTICLE H.28. CONSTITUTION DAY**

Each educational institution that receives Federal funds for a fiscal year shall hold an educational program on the United States Constitution on September 17 of such year for the students serviced by the educational institution in accordance with Public Law 108-447.

## **PART II - CONTRACT CLAUSES**

### **SECTION I - CONTRACT CLAUSES**

THE FOLLOWING ARTICLE I.1. GENERAL CLAUSE LISTING(S) WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

The complete listing of these clauses may be accessed at:

<http://rcb.cancer.gov/rcb-internet/appl/general-clauses/clausesDGS.jsp>

### **General Clauses for a Cost-Reimbursement Research and Development Contract**

## 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 substitution(s) will be made part of the resultant contract:

- a. FAR Clause **52.204-7, Central Contractor Registration** (October 2003) is deleted in its entirety.

FAR Clause **52.232-33, Payment By Electronic Funds Transfer--Central Contractor Registration** (October 2003) is deleted in its entirety and FAR Clause **52.232-34, Payment by Electronic Funds Transfer--Other Than Central Contractor Registration** (May 1999) is substituted therefor.

- b. FAR Clause **52.204-10, Reporting Subcontract Awards (Over \$500,000,000)** (September 2007) is deleted in its entirety.

- c. **Alternate II** (April 1998) of FAR Clause **52.215-2, Audit and Records--Negotiation** (June 1999) is added.

- d. FAR Clauses **52.215-15, Pension Adjustments And Asset Reversions** (October 2004); **52.215-18, Reversion Or Adjustment Of Plans For Post Retirement Benefits (PRB) Other Than Pensions** (July 2005); and, **52.215-19, Notification Of Ownership Changes** (October 1997), are deleted in their entirety.

- e. **Alternate IV** (October 1997) of FAR Clause **52.215-21, Requirements For Cost Or Pricing Data Or Information Other Than Cost Or Pricing Data--Modifications** (October 1997) is added.

- f. FAR Clauses **52.219-9, Small Business Subcontracting Plan** (November 2007), and **52.219-16, Liquidated Damages--Subcontracting Plan** (January 1999) are deleted in their entirety.

- g. **Alternate I** (April 1984), of FAR Clause **52.227-1, Authorization and Consent** (December 2007) is deleted in its entirety.

FAR Clause **52.227-11, Patent Rights--Ownership by the Contractor** (December 2007) is deleted in its entirety.

**Alternate IV** (December 2007), of FAR Clause **52.227-14, Rights In Data--General** (December 2007) is deleted in its entirety.

**Alternate II** (June 2007), of FAR Clause **52.245-1, Government Property** (June 2007) is deleted in its entirety.

- h. FAR Clause **52.227-1, Authorization and Consent** (December 2007), and

FAR Clause **52.227-2, Notice and Assistance Regarding Patent and Copyright Infringement** (December 2007) are deleted in their entirety.

- i. FAR Clause **52.229-3, Federal, State And Local Taxes** (April 2003), is deleted in its entirety, and FAR Clause **52.229-6, Taxes--Foreign Fixed-Price Contracts** (June 2003) is substituted therefor.

- j. FAR Clause **52.229-3, Federal, State And Local Taxes** (April 2003) is deleted in its entirety, and FAR Clause **52.229-7, Taxes--Fixed-Price Contracts With Foreign Governments** (January 1991) is substituted therefor.
  - k. FAR Clause **52.232-17, Interest** (June 1996) is deleted.
  - i. FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefor. **[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.]**
  - m. FAR Clause **52.232-33, Payment By Electronic Funds Transfer--Central Contractor Registration** (October 2003), is deleted in its entirety and FAR Clause **52.232-36, Payment By Third Party** (May 1999) is substituted therefor.
  - n. **Alternate I**, (December 1991), of FAR Clause **52.233-1, Disputes** (December 1998) is added.
  - o. **Alternate II**, (September 1996), of FAR Clause **52.249-2, Termination For Convenience Of The Government (Fixed-Price)** (September 1996) is added.
  - p. **Alternate II**, (September 1996), of FAR Clause **52.249-6, Termination (Cost-Reimbursement)** (September 1996) is added.
  - q. FAR Clause **52.216-11, Cost Contract--No Fee** (April 1984) is deleted in its entirety and FAR Clause **52.216-8 Fixed Fee** (March 1997) is substituted therefor.
- FAR Clause **52.232-17, Interest** (June 1996) is added.
- FAR Clause **52.249-5, Termination For Convenience Of the Government (Educational And Other Non-Profit Institutions)** (April 1984) is deleted in its entirety and FAR Clause **52.249-6, Termination (Cost-Reimbursement)** (May 1986) is substituted therefor.
- HHSAR Clause **352.249-14, Excusable Delays** (January 2006) is deleted in its entirety and FAR Clause **52.249-14, Excusable Delays** (April 1984) is substituted therefor.

## 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

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (December 2007).
2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (December 2007).

".....(3) Any required posters may be obtained as follows:

| Poster(s)                                                 | Obtain From"                                                                                                              |
|-----------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------|
| HHS Contractor Code of Ethics and Business Conduct Poster | <a href="http://www.oig.hhs.gov/hotline/OIG_Hotline_Poster.pdf">http://www.oig.hhs.gov/hotline/OIG_Hotline_Poster.pdf</a> |

3. FAR Clause **52.207-5, Option to Purchase Equipment** (February 1995).
4. FAR Clause **52.208-9, Contractor Use of Mandatory Sources of Supply** (July 2004).
5. FAR Clause **52.211-11, Liquidated Damages--Supplies, Services, or Research and Development** (September 2000).

"(a) If the Contractor fails to deliver the supplies or perform the services within the time specified in this contract, the Contractor shall, in place of actual damages, pay to the Government liquidated damages of \$\_\_\_\_\_ per calendar day of delay."

6. FAR Clause **52.216-15, Predetermined Indirect Cost Rates** (April 1998).
7. FAR Clause **52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting** (October 1999).
8. FAR Clause **52.219-26, Small Disadvantaged Business Participation Program--Incentive Subcontracting** (October 2000).

"(b) If the Contractor exceeds its total monetary target for subcontracting to small disadvantaged business concerns in the authorized NAICS Industry Subsectors, it will receive \_ percent of the dollars in excess of the monetary target, unless the Contracting Officer determines that the excess was not due to the Contractor's efforts...."

9. FAR Clause **52.224-1, Privacy Act Notification** (April 1984).

10. FAR Clause **52.224-2, Privacy Act** (April 1984).
11. FAR Clause **52.226-1, Utilization of Indian organizations and Indian-owned Economic Enterprises** (June 2000).
12. FAR Clause **52.227-13, Patent Rights--Ownership by the Government** (December 2007).
13. **Alternate I** (December 2007), FAR Clause **52.227-14, Rights in Data--General** (December 2007).
14. **Alternate II** (December 2007), FAR Clause **52.227-14, Rights in Data--General** (December 2007).

Additional purposes for which the limited rights data may be used are:

15. **Alternate III** (December 2007), FAR Clause **52.227-14, Rights in Data--General** (December 2007).

Additions to, or limitations on, the restricted rights set forth in the Restricted Rights Notice of subparagraph (g)(4) of the clause are expressly stated as follows:

16. **Alternate IV** (December 2007), FAR Clause **52.227-14, Rights in Data - General** (December 2007).
17. **Alternate V** (December 2007), FAR Clause **52.227-14, Rights in Data--General** (December 2007).

Specific data items that are not subject to paragraph (j) include:

18. FAR Clause **52.227-16, Additional Data Requirements** (June 1987).
19. FAR Clause **52.227-19, Commercial Computer Software License** (December 2007).
20. FAR Clause **52.229-8, Taxes-Foreign Cost-Reimbursement Contracts** (March 1990).
21. FAR Clause **52.229-9, Taxes-Cost-Reimbursement Contracts with Foreign Governments** (March 1990).
22. FAR Clause **52.230-2, Cost Accounting Standards** (April 1998).
23. FAR Clause **52.230-3, Disclosure and Consistency of Cost Accounting Practices** (April 1998).
24. FAR Clause **52.230-5, Cost Accounting Standards - Educational Institution** (April 1998).
25. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (March 2008).
26. FAR Clause **52.232-18, Availability of Funds** (April 1984).

27. FAR Clause **52.232-36, Payment by Third Party** (May 1999).
  28. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).
  29. FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984).
  30. FAR Clause **52.246-23, Limitation of Liability** (February 1997).
  31. FAR Clause **52.246-24, Limitation of Liability - High-Value Items** (February 1997).
  32. FAR Clause **52.247-63, Preference for U.S. Flag Air Carriers** (June 2003).
  33. FAR Clause **52.247-64, Preference for Privately Owned U.S. Flag Commercial Vessels** (February 2006).
  34. FAR Clause **52.247-68, Report of Shipment (REPSHIP)** (February 2006).
  35. FAR Clause **52.248-1, Value Engineering** (February 2000).
  36. FAR Clause **52.251-1, Government Supply Sources** (April 1984).
- b. *DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:*
1. *HHSAR Clause **352.224-70, Confidentiality of Information** (January 2006).*
  2. *HHSAR Clause **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).*
  3. *HHSAR Clause **352.270-8(b), Protection of Human Subjects** (January 2006).*
  4. *HHSAR Clause **352.270-9(b), Care of Live Vertebrate Animals** (January 2006).*
  5. *HHSAR Clause **352.333-7001, Choice of Law (Overseas)** (March 2005).*
  6. *THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.*
- c. *NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:*
- The following clauses are attached and made a part of this contract:*
1. ***NIH (RC)-7, Procurement of Certain Equipment** (April 1984).*



## 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:

a. FAR Clause **52.219-28, Post-Award Small Business Program Representation** (June 2007).

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

*Long-term contract* means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend Services, or other appropriate authority.

*Small business concern* means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause.

(b) If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall rerepresent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the exercise date specified in the contract for any option thereafter.

(c) The Contractor shall rerepresent its size status in accordance with the size standard in effect at the time of this rerepresentation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at <http://www.sba.gov/services/contractingopportunities/sizestandardsttopics/>.

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the rerepresentation required by paragraph (b) of this clause by validating or updating all its representations in the Online Representations and Certifications Application and its data in the Central Contractor Registration, as necessary, to ensure they reflect current status. The Contractor shall notify the contracting office by e-mail, or otherwise in writing, that the data have been validated or updated, and provide the date of the validation or update.

(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in ORCA, or does not have a representation in ORCA for the NAICS code applicable to this contract, the Contractor is required to complete the following rerepresentation and submit it to the contracting office, along with the contract number and the date on which the rerepresentation was completed:

The Contractor represents that it [ ] is, [ ] is not a small business concern under NAICS Code assigned to contract number.

[Contractor to sign and date and insert authorized signer's name and title].

(End of clause)

b. **FAR Clause 52.222-39, Notification Of Employee Rights Concerning Payment Of Union Dues Or Fees (December 2004)**

(a) *Definition. As used in this clause --*

*United States means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.*

*(b) Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).*

*Notice to Employees*

*Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.*

*If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.*

*For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:*

*National Labor Relations Board  
Division of Information  
1099 14th Street, N.W.  
Washington, DC 20570  
1-866-667-6572  
1-866-316-6572 (TTY)*

*To locate the nearest NLRB office, see NLRB's website at <http://www.nlr.gov>.*

(c) *The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR part 470, and orders of the Secretary of Labor.*

(d) *In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.*

(e) *The requirement to post the employee notice in paragraph (b) does not apply to--*

*(1) Contractors and subcontractors that employ fewer than 15 persons;*

*(2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;*

*(3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;*

*(4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that--*

*(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and*

*(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or*

*(5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.*

(f) *The Department of Labor publishes the official employee notice in two variations; one for contractors covered by the Railway Labor Act and a second for all other contractors. The Contractor shall--*

*(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 2021, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;*

*(2) Download a copy of the poster from the Office of Labor-Management Standards website at <http://www.olms.dol.gov>; or*

*(3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.*

(g) *The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c).*

*For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint*

*Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States.*

*(End of Clause)*

## PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

### SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

#### SOLICITATION ATTACHMENTS

| Attachment No. | Title                                      | Location        |
|----------------|--------------------------------------------|-----------------|
| Attachment 1:  | Packaging and Delivery of Proposal (R & D) | Attached to BAA |
| Attachment 2:  | Broad Agency Announcement Description      | Attached to BAA |
| Attachment 3:  | Proposal Intent Response Sheet             | Attached to BAA |

#### TECHNICAL PROPOSAL ATTACHMENTS

| Attachment No. | Title                                                                                                                                                | Location                                                                                                                          |
|----------------|------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|
| Attachment 4:  | Targeted/Planned Enrollment Table                                                                                                                    | <a href="http://rcb.cancer.gov/rcb-internet/forms/enroll-table.pdf">http://rcb.cancer.gov/rcb-internet/forms/enroll-table.pdf</a> |
| Attachment 5:  | BAA Background and Information                                                                                                                       | Attached to BAA                                                                                                                   |
| Attachment 6:  | Research and Technical Objectives                                                                                                                    | Attached to BAA                                                                                                                   |
| Attachment 7:  | Reporting and Deliverables                                                                                                                           | Attached to BAA                                                                                                                   |
| Attachment 8:  | Evaluation Factors for Award                                                                                                                         | Attached to BAA                                                                                                                   |
| Attachment 9:  | Additional Technical Proposal Instructions                                                                                                           | Attached to BAA                                                                                                                   |
| Attachment 10: | Advance Understandings                                                                                                                               | Attached to BAA                                                                                                                   |
| Attachment 11: | BAA Specific Materials                                                                                                                               | Attached to BAA                                                                                                                   |
| Attachment 12: | Technical Proposal Cost Summary                                                                                                                      | <a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>                             |
| Attachment 13: | Summary of Related Activities                                                                                                                        | <a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>                             |
| Attachment 14: | Government Notice for Handling Proposals                                                                                                             | <a href="http://www.niaid.nih.gov/contract/forms/form7.pdf">http://www.niaid.nih.gov/contract/forms/form7.pdf</a>                 |
| Attachment 15: | Protection of Human Subject Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (Formerly Optional Form 310) | <a href="http://rcb.cancer.gov/rcb-internet/forms/of310.pdf">http://rcb.cancer.gov/rcb-internet/forms/of310.pdf</a>               |
| Attachment 16: | Project Objectives, NIH 1688-1                                                                                                                       | <a href="http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf">http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf</a>       |

#### BUSINESS PROPOSAL ATTACHMENTS

| Attachment No. | Title                                                                | Location                                                                                                                            |
|----------------|----------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|
| Attachment 17: | Proposal Summary and Data Record, NIH-2043                           | <a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>                               |
| Attachment 18: | Additional Business Proposal Instructions                            | Attached to BAA                                                                                                                     |
| Attachment 19: | Small Business Subcontracting Plan                                   | <a href="http://www.hhs.gov/osdbu/read/SampleSubcontractingPlan.doc">http://www.hhs.gov/osdbu/read/SampleSubcontractingPlan.doc</a> |
| Attachment 20: | Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet | <a href="http://oamp.od.nih.gov/contracts/BUSCOST.HTM">http://oamp.od.nih.gov/contracts/BUSCOST.HTM</a>                             |

| <b>Attachment No.</b> | <b>Title</b>                                       | <b>Location</b>                                                                                                                                                                                                                  |
|-----------------------|----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Attachment 21:        | Offeror's Points of Contact                        | <a href="http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls">http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls</a>                                                                                                                |
| Attachment 22:        | Disclosure of Lobbying Activities, OMB Form SF-LLL | <a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a><br><a href="http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf">http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf</a> |

## **INFORMATIONAL ATTACHMENTS**

| <b>Attachment No.</b> | <b>Title</b>                                                                                           | <b>Location</b>                                                                                                                                       |
|-----------------------|--------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|
| Attachment 23:        | Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4 | <a href="http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf">http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf</a>                                       |
| Attachment 24:        | Privacy Act System of Records                                                                          | <a href="http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm">http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm</a>                 |
| Attachment 25:        | Safety and Health, HHSAR Clause 352.223-70                                                             | <a href="http://rcb.cancer.gov/rcb-internet/forms/safety&amp;health-1-06.pdf">http://rcb.cancer.gov/rcb-internet/forms/safety&amp;health-1-06.pdf</a> |
| Attachment 26:        | Procurement of Certain Equipment, NIH(RC)-7                                                            | <a href="http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf">http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf</a>                               |
| Attachment 27:        | Research Patient Care Costs, NIH(RC)-11                                                                | <a href="http://www.niaid.nih.gov/contract/forms/nih-rc-11.pdf">http://www.niaid.nih.gov/contract/forms/nih-rc-11.pdf</a>                             |
| Attachment 28:        | Inclusion Enrollment Report                                                                            | <a href="http://rcb.cancer.gov/rcb-internet/forms/inclusion-enrollment.pdf">http://rcb.cancer.gov/rcb-internet/forms/inclusion-enrollment.pdf</a>     |
| Attachment 29:        | Government Property Schedule                                                                           | To be determined during negotiations.                                                                                                                 |
| Attachment 30:        | Commitment to Protect Non-Public Information Contractor Agreement                                      | <a href="http://irm.cit.nih.gov/security/Nondisclosure.pdf">http://irm.cit.nih.gov/security/Nondisclosure.pdf</a>                                     |
| Attachment 31:        | Roster of Employees Requiring Suitability Investigations                                               | <a href="http://ais.nci.nih.gov/forms/Suitability-roster.xls">http://ais.nci.nih.gov/forms/Suitability-roster.xls</a>                                 |
| Attachment 32:        | Employee Separation Checklist                                                                          | <a href="http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf">http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf</a>           |

## **PART IV - REPRESENTATIONS AND INSTRUCTIONS**

### **SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS**

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

1. Go to the Online Representations and Certifications Application (ORCA) at: <https://orca.bpn.gov/> and complete the Representations and Certifications; and
2. Complete, and include as part of your BUSINESS PROPOSAL, SECTION K which can be accessed electronically from the INTERNET at the following address:  
<http://rcb.cancer.gov/rcb-internet/wkf/sectionk.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.

## SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

### 1. GENERAL INFORMATION

#### a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Provision 52.215-1 (January 2006)]

(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" means 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).*

*(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 statements, specifying the particular portions of the proposal which are to be restricted:*

*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 must 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 statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).*

*(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) *If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:*

  - (i) *The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.*
  - (ii) *The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.*
  - (iii) *The overall ranking of all offerors, when any ranking was developed by the agency during source selection;*
  - (iv) *A summary of the rationale for award.*

*(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.*

*(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.*

*(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 541712.
2. The small business size standard is 500.

**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. TYPE OF CONTRACT AND NUMBER OF AWARDS**

It is anticipated that multiple awards will be made from this solicitation and that the award(s) will be made on/about August 13, 2009.

It is anticipated that the award(s) from this solicitation will be a multiple-year Cost-Reimbursement type Completion contract with a Term of 5Years/Period of Performance of 9/30/2009-9/29/2014, and that incremental funding will be used (See Section L.2.c. Business Proposal Instructions).

**d. COMMITMENT OF PUBLIC FUNDS**

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

**e. COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

**f. RELEASE OF INFORMATION**

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

**g. PREPARATION COSTS**

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

**h. SERVICE OF PROTEST (SEPTEMBER 2006) - 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 Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer  
Office of Acquisitions  
National Institute for Allergy and Infectious Disease  
NIH Room 3214  
6700 B Rockledge Drive 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)

**i. LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70 (January 2006)**

*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 appears to offer the best value 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)*

**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, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

### **II. TECHNICAL PROPOSAL**

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

### **III. BUSINESS PROPOSAL**

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

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

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

## **4. Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See SECTION J, Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY.) 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. Standards for Privacy of Individually Identifiable Health Information

The Department of Health and Human Services (DHHS) issued final modifications to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities" must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply).

Decisions about the applicability and implementation of the Privacy Rule reside with the Contractor and his/her institution. The OCR Web site (<http://www.hhs.gov/ocr/>) provides information of the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements and contracts can be found at: <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

#### 10. 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 Government Accountability 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.

## 11. 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 order of merit ranking. 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 order of merit ranking 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 order of merit ranking.

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



While it is NIAID's policy to conduct discussions with all offerors in the order of merit ranking, NIAID reserves the right, in special circumstances, to limit the number of proposals included in the order of merit ranking 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 order of merit ranking 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 source 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.
- f. The NIAID 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 NIAID requirements. Synopses of awards exceeding \$25,000 will be published in FedBizOpps.

## 12. 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.

### 13. **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.

#### 14. Past Performance Information

- a. Offerors shall submit the following information as part of their Business proposal.

A list of the last 3 contracts completed during the past Five years and [ALL CONTRACTS/ THE LAST 3 CONTRACTS AWARDED] currently being performed that are similar in nature to the Research and Technical objectives. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as any subcontract equal to or greater than \$550,000.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. North American Industry Classification System (NAICS) Code

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

- b. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

#### 15. Electronic and Information Technology Accessibility, HHSAR 352.270-19(a) (January 2008)

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794D), as amended by the Workforce Investment Act of 1998, and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Provisions (36 CFR part 1194), require that, unless an exception applies, all EIT products and services developed, acquired, maintained, or used by any Federal department or agency permit:

1. Federal employees with disabilities to have access to and use information and data that is comparable to the access and use of information and data by Federal employees who are not individuals with disabilities; and
2. Members of the public with disabilities seeking information or services from a Federal agency to have access to and use of information and data that is comparable to the access and use of information and data by members of the public who are not individuals with disabilities.

Accordingly, any vendor submitting a proposal/quotations/bid in response to this solicitation must demonstrate compliance with the established EIT accessibility provisions. Information about Section 508 provisions is available at <http://www.section508.gov/>. The complete text of Section 508 Final Provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm>.

The Section 508 standards applicable to this solicitation are identified in the Statement of Work/ Specification/Performance Work Statement. In order to facilitate the Government's evaluation to determine whether EIT products and services proposed meet applicable Section 508 accessibility standards, offerors must prepare an HHS Section 508 Product Assessment Template, in accordance with its completion instructions, and provide a binding statement of conformance. The purpose of the template is to assist HHS acquisition and program officials in determining that EIT products and services proposed support applicable Section 508 accessibility standards. The template allows vendors or developers to self-evaluate their products or services and document in detail how they do or do not conform to a specific Section 508 standard. Instructions for preparing the HHS Section 508 Product Assessment Template may be found at <http://508.hhs.gov>.

Respondents to this solicitation must also provide any additional detailed information necessary for determining applicable Section 508 standards conformance, as well as for documenting EIT products and/or services that are incidental to the project, which would constitute an exception to Section 508 requirements. If a vendor claims its products and/or services, including EIT deliverables such as electronic documents and reports, meet applicable Section 508 standards in its completed HHS Section 508 Product Assessment Template, and it is later determined by the Government - i.e., after award of a contract/order, that products and/or services delivered do not conform to the described accessibility in the Product Assessment Template, remediation of the products and/or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor at its expenses.

(End of provision)

**16. Prohibition on Contractor Involvement with Terrorist Activities**

The 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 this contract.

**17. 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.acquisition.gov/far/index.html>.*

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a. *Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).*
- b. *Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).*

- c. *Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).*
- d. *Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).*
- e. *Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).*
- f. *Preaward On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).*
- g. *SAFETY Act--Equitable Adjustment, FAR Clause 52.250-5, (November 2007).*

## 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. [ **See also, Attachment 9 entitled "Additional Technical Proposal Instructions**]

### 1. Technical Discussions

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

#### 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** :"

#### b. Research and Technical Objectives and Statement of Work

##### 1. Objectives

Offerors shall submit proposals for coordinated research programs leading to adjuvant development that encompass all four of the research areas described below. The adjuvant products sought may be developed as vaccine adjuvants or as stand-alone immunomodulators to prevent or treat infectious disease. Proposed research shall encompass the discovery, characterization, refinement, and testing of novel candidate adjuvants using appropriate high throughput screening and analysis of human innate immune system receptors and/or their ligands.

## 2. Approach

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

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.

### c. 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. Single 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. 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.

## 3. Technical Evaluation

Proposals will be technically evaluated in accordance with SECTION M - Evaluation Factors for Award of this solicitation.

**IMPORTANT NOTE TO OFFERORS:** The following [12] paragraphs [(4) through (15)] shall be addressed, as applicable, in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

#### 4. Human Subjects

The following notice is applicable when contract performance is expected to involve risk to human subjects: **Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects, HHSAR 352.270-8(a) (January 2006)**

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

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

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

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

(e) In accordance with 45 CFR Part 46, prospective Contractors being considered for award shall be required to file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. HHS regulations for the protection of human subjects (45 CFR Part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information can be accessed at the OHRP Web site: <http://www.hhs.gov/ohrp/>.

(f) It is recommended that OHRP be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects."

(End of provision)

#### 5. Instructions to Offerors Regarding Protection of Human Subjects

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



## a. Risks to the subjects

- Human Subjects Involvement and Characteristics:
  - Describe the proposed involvement of human subjects in response to the solicitation.
  - Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
  - Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.
- Sources of Materials:
  - Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.
- Potential Risks:
  - Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.
  - Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

## b. Adequacy of Protection Against Risks

- Recruitment and Informed Consent:
  - Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the Contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the Contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.
- Protection Against Risk:
  - Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
  - Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.
  - In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

## c. Potential Benefits of the Proposed Research to the Subjects and Others

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

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

d. Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

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

**Collaborating Site(s)**

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

## 6. Required Education in the Protection of Human Research Participants

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

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

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at <http://ohsr.od.nih.gov/cbt/>. You may download the information at this site at no cost and modify it, if desired. The University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at [http://www.centerwatch.com/order/pubs\\_profs\\_protect.html](http://www.centerwatch.com/order/pubs_profs_protect.html).

In addition, the NCI sponsors an online training course at:

<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>

If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the

contracting officer with the title of the education program and a one sentence description of the program that the replacement has completed.

## 7. Inclusion of Women and Minorities in Research Involving Human Subjects

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

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

[http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm)

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research," at:

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

### Information Required for ALL Clinical Research Proposals

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

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

The proposal must include the following information:

- A description of the subject selection criteria
- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group

- The proposed sample composition using the "Targeted/Planned Enrollment Table"(see Section J, Attachments)

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

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

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

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

[http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm), Definitions - Significant Difference).

\*The definition of an " **NIH-Defined Phase III clinical trial**" can also be found at this website.)

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

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

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

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

**OR**

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

**OR**

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

**Use the form entitled, "Targeted/Planned Enrollment Table," when preparing your response to the solicitation requirements for inclusion of women and minorities. (See Section J-List of Documents, Exhibits and Other Attachments of the RFP)**

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

**Use the form entitled, "Inclusion Enrollment Report," for reporting in the resultant contract.**

## 8. Inclusion of Children in Research Involving Human Subjects

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

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

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

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

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

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. The "Human Subjects" section of your technical proposal should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. This solicitation contains a review criterion addressing the adequacy of: (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

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

### **Justifications for Exclusion of Children**

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

- The objective of the solicitation is not relevant to children.
  - There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.

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

#### **Definition of a Child**

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

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

### **9. Research Involving Prisoners as Subjects**

- a. HHS Regulations at 45 CFR Part 46, Subpart C provide additional protections pertaining to biomedical and behavioral research involving prisoners or those individuals who, during the period of the contract become prisoners, as subjects. These regulations also set forth the duties of the Institutional Review Board (IRB) where prisoners are involved in the research. HHS funded research involving prisoners as subjects may not proceed until the Office for Human Research Protections (OHRP) issues approval, in writing, as required by 45 CFR 46.306(a)(2). In addition, OHRP Guidance on the Involvement of Prisoners in Research may be found at: <http://www.hhs.gov/ohrp/humansubjects/guidance/prisoner.pdf>.
- b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

On June 20, 2003 the Secretary of HHS waived the applicability of certain provisions of Subpart C of 45 CFR Part 46, (Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects) to specific types of epidemiological research involving prisoners as subjects.

The applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain epidemiological research conducted or funded by DHHS is waived when:

1. The sole purposes are:
  - a. to describe the prevalence or incidence of a disease by identifying all cases, or
  - b. to study potential risk factor associations for a disease, and
2. The Institution responsible for the conduct of the research certifies to the OHRP that the Institutional Review Board (IRB) approved the research and fulfilled its duties under 45 CFR 46.305(a)(2 7) and determined and documented that:
  - a. the research presents no more than minimal risk, and
  - b. no more than inconvenience to the prisoner subjects, and
  - c. prisoners are not a particular focus of the research.

For more information about this Waiver see [http://www.hhs.gov/ohrp/special/prisoners/Prisoner waiver 6-20-03.pdf](http://www.hhs.gov/ohrp/special/prisoners/Prisoner%20waiver%206-20-03.pdf)

#### 10. **Research Involving Human Fetal Tissue**

Human Fetal Tissue means tissue or cells obtained from a dead human fetus, including human embryonic stem cells, human pluripotent stem cells and human embryonic germ cells.

The governing federal statute is the Public Health Service Act, 42 U.S.C. 289g 1 and 289g 2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and <http://grants1.nih.gov/grants/guide/notice-files/not93-235.html> and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

By signing the face page of the proposal, the offeror (authorized institutional official) certifies that researchers using human fetal tissue are in compliance with 42 USC 289g 2. This statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. "Valuable consideration" is a concept similar to profit, and does not include reasonable payment for costs associated with the collection processing, preservation, storage, quality control or transportation of these tissues.

Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local law.

#### 11. **Human Embryonic Stem Cell (HESC) Research**

On August 9, 2001, the President announced the criteria that must be met for Federal funds to be used for research on existing human embryonic stem cell lines. These criteria were subsequently published by the NIH at: <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html>. The following eligibility criteria must be met:

1. The derivation process (which commences with the removal of the inner cell mass from the blastocyst) must have already been initiated prior to August 9, 2001;
2. Prior to August 9, 2001, the embryo from which the stem cell line was derived no longer had the possibility of development as a human being;
3. The stem cells must have been derived from an embryo that was created for reproductive purposes;

4. The embryo was no longer needed for these purposes;
5. Informed consent must have been obtained for the donation of the embryo;
6. No financial inducements were provided for the donation of the embryo.

To facilitate research using human embryonic stem cells, the NIH has established a Human Embryonic Stem Cell Registry ("the NIH Registry") that lists the human embryonic stem cells that meet the eligibility criteria. This registry is available at: <http://stemcells.nih.gov/registry/>.

Research involving the derivation of new stem cells from human embryos or the use of human embryonic stem cells that are not listed on the NIH Human Embryonic Stem Cell Registry may not be conducted with Federal funding.

If a particular human embryonic stem cell line has not been required by the Statement of Work, an offeror proposing research involving human embryonic stem cells must cite a human embryonic stem cell line that is listed in the NIH Registry in its proposal.

## 12. Data and Safety Monitoring in Clinical Trials

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

<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>

<http://grants.nih.gov/grants/guide/notice-files/not99-107.html>

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>

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

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

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

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

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

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



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

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

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

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

### 13. 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 Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, HHSAR 352.270-9(a) (January 2006)**

The PHS Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before award may be made to an applicant organization, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No award involving the use of animals shall be made unless OLAW approves the Animal Welfare Assurance. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information contact OLAW, at NIH, Bethesda, Maryland 20892 (301-496-7163).

(End of Provision)

The following specific address for OLAW is provided for ease of contact:

Office of Laboratory Animal Welfare  
 National Institutes of Health  
 RKL 1 - Suite 360, MSC 7982  
 6705 Rockledge Drive  
 Bethesda, MD 20892-7982 (For Hand-delivered/express mail use Zip code 20817)

FAX copies 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. The following information must be included in the offerors technical proposal:

- identification of the species and approximate number of animals to be used;
- rationale for involving animals, and for the appropriateness of the species and numbers used;
- a complete description of the proposed use of the animals;
- a description of procedures designed to assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals; and
- a description of any euthanasia method to be used.

c. 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, if required by the SOW contained in this solicitation.

#### 14. **Obtaining and Disseminating Biomedical Research Resources**

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

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a condition 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>

##### a. **Sharing Research Data**

[Note: This policy applies to **all** NIH contracts, regardless of dollar value, that are expected to generate research data.]

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan in its

technical proposal for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>

[If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. Coordinating Center proposals should describe methods to coordinate the dissemination planning and implementation. The Coordinating Center must include a budget and justification for any additional costs of this collaborative effort.]

#### b. **Sharing of Model Organisms for Biomedical Research**

The NIH Research Tools Policy ( [http://www.ott.nih.gov/policy/research\\_tool.html](http://www.ott.nih.gov/policy/research_tool.html)) also referred to as NIH Principles and Guidelines for Sharing of Biomedical Resources: Final Notice, December 1999, supports the concept of timely sharing and distribution of research resources. In accordance with NIH Guide Notice NOT-OD-04-042 at: ( <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html> ), dated May 7, 2004, and the September 10, 2004 extension of this policy NOT-OD-04-066 at: ( <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-066.html> ), the NIH provides further sharing guidance with particular attention on model organisms for biomedical research. Such organisms include, but are not limited to: mammalian models such as the mouse and rat, and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

Offerors must include in their technical proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, OR provide appropriate reasons why such sharing is restricted or not possible. A reasonable time frame for periodic disposition of material and associated data must be specified in the proposal. In addition, the plan must address if, or how, offerors will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. At a minimum, the plan should address the following:

- Will material transfers be made with no more restrictive terms than in a Simple Letter Agreement (SLA) at: ( [http://ott.od.nih.gov/forms\\_model\\_agreements/forms\\_model\\_agreements.html#MTACTA](http://ott.od.nih.gov/forms_model_agreements/forms_model_agreements.html#MTACTA) ) for the transfer of materials or the Uniform Biological Material Transfer Agreement (UBMTA) ( <http://www.autm.net/aboutTT/> , then search "Implementing Letter")
- How will inappropriate "reach-through" requirements (as discussed in the NIH Research Tools Policy) on materials transferred be discussed?
- How will technologies remain widely available and accessible to the research community, for example, if any intellectual property rights arise for which a patent application may be filed?

Offerors may request funds in their cost proposal to defray reasonable costs associated with sharing materials or data or transfer of model organisms and associated data to appropriate repositories.

15. **Information Security** is applicable to this solicitation and the following information is provided to assist in proposal preparation.

**IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Technical Proposal entitled, "INFORMATION SECURITY."**

The Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor (including subcontractor), or other source. The National Institute of Standards and Technology (NIST) has issued a number of publications that provide guidance in the establishment of minimum security controls for management, operational and technical safeguards needed to protect the confidentiality, integrity and availability of a Federal information system and its information.

The Statement of Work (SOW) requires the successful offeror to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies the following requirements apply to this solicitation:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); <http://csrc.nist.gov/drivers/documents/FISMA-final.pdf>

a. Information Type

Administrative, Management and Support Information:

Scientific and Technical Research and Innovation

Mission Based Information:

b. Security Categories and Levels

Confidentiality Level:       Low  Moderate  High  
 Integrity Level:             Low  Moderate  High  
 Availability Level:         Low  Moderate  High  
**Overall Level:               Low  Moderate  High**

c. Position Sensitivity Designations

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

**Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI).** Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI).

**Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI).** Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI)

**[X] Level 1: Non Sensitive (Requires Suitability Determination with an NACI).**

Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).

Upon award, the Contractor will be required to submit a roster of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a federal information system(s). The Government will determine and notify the Contractor of the appropriate level of suitability investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for Contractor use at:

<http://ais.nci.nih.gov/forms/Suitability-roster.xls>

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: <http://ais.nci.nih.gov>.

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

d. Information Security Training

HHS policy requires Contractors/Subcontractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each Contractor/Subcontractor employee has completed the NIH Computer Security Awareness Training course at: <http://irtsectraining.nih.gov/> prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract. The successful offeror shall maintain a listing of all individuals who have completed this training and shall submit this listing to the Project Officer.

Additional security training requirements commensurate with the position may be required as defined in NIST Special Publication 800-16, Information Technology Security Training Requirements ( <http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf>). This document provides information about information security training that may be useful to potential offerors.

e. Offeror's Official Responsible for Information Security

The offeror shall include in the "Information Security" part of its Technical Proposal the name and title of its official who will be responsible for all information security requirements should the offeror be selected for an award.

f. NIST SP 800 53 Self Assessment

The offeror must include in the "Information Security" part of its Technical Proposal, a completed Self-Assessment required by NIST Draft SP 800-53, Recommended Security Controls for Federal Information Systems. ( <http://csrc.nist.gov/publications> - under Special Publications).

Subcontracts: The offeror must include similar information for any proposed subcontractor that will perform under the SOW to (1) develop a Federal information system(s) at the offeror's/subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the offeror's/subcontractor's facility.

## g. Draft Information System Security Plan

The offeror must include a draft Information System Security Plan (ISSP) using the current template in Appendix A of NIST SP 800 18, Guide to Developing Security Plans for Federal Information Systems ( <http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf>). The details contained in the offeror's draft ISSP must be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels.

Subcontracts: The offeror must include similar information for any proposed subcontractor that will perform under the SOW with the offeror whenever the submission of an ISSP is required.

Note to Offeror: The resultant contract will require the draft ISSP to be finalized in coordination with the Project Officer no later than 90 calendar days after contract award. Also, a contractor is required to update and resubmit its ISSP to NIH every three years following award or when a major modification has been made to its internal system.

## h. Common Security Configurations

The contractor shall ensure that any information technology acquired under this contract incorporates the applicable common security configuration established by the National Institute of Standards and Technology (NIST) at <http://checklists.nist.gov>.

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. **Proposal Cover Sheet**

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

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

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

### 3. Information Other than Cost or Pricing Data

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

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

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

#### 1. Direct Labor

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

#### 2. Materials

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

#### 3. Subcontracted Items

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

#### 4. Raw Materials

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

#### 5. Purchased Parts

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

#### 6. Fringe Benefits

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

#### 7. **Indirect Costs**

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

#### 8. **Special Equipment**

If direct charge, list any equipment in accordance with Item (13) Other Administrative Data, subparagraph (2) Government Property of this Section L.2.c of this solicitation.

#### 9. **Travel**

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

#### 10. **Other Costs**

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

### 4. **Salary Rate Limitation in Fiscal Year 2008**

Offerors are advised that pursuant to P.L.110-161, no NIH Fiscal Year 2008 (October 1, 2007 - September 30, 2008) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I\* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I\*. The salary rate limitation set by P.L. 110-161 applies only to Fiscal Year 2008 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 limitation also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 110-161 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 other extramural mechanism at a rate in excess of Executive Level I\*."

**LINK TO EXECUTIVE SCHEDULE SALARIES:** <http://www.opm.gov/oca/08tables/pdf/ex.pdf>

**\*Note to Offerors:** The current Fiscal Year Executive Level I Salary Rate should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year Executive Level I Salary rates.



## 5. Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of \$550,000 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 - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

- a. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
- b. The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
- c. The offeror understands that:
  1. No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
  2. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
  3. If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.
  4. Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.
  5. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.
  6. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.
- d. Each plan must contain the following:
  1. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
  2. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

3. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.
4. A description of the method used to develop the subcontracting goals.
5. A description of the method used to identify potential sources for solicitation purposes.
6. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
7. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
8. A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
9. Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of \$550,000 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 (Individual Subcontract Reports (ISRs) and Summary Subcontract Reports (SSRs) 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 in 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:

\_ % for Small Business; \_ % for Small Disadvantaged Business; \_ % for Women-Owned Small Business; \_ % for HUBZone Small Business; and \_ % for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

#### **6. 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>.

#### **7. 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 \$550,000 (\$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.

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 for NAICS codes\* is: <http://www.arnet.gov/References/sdbadjustments.htm>.

\* *Note: Public Law 103-355 which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.*

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

|                                                          | <b>SDB Percentage of Total Contract Value</b> | <b>SDB Dollars</b> |
|----------------------------------------------------------|-----------------------------------------------|--------------------|
| 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.

## 8. Other Administrative Data

### a. Property

1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the Contracting Officer. If the offeror requests that Government property be provided, other than that specified under "Government Furnished Property," below, the proposal must include a comprehensive justification addressing the following items:

- a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.
- b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

### 2. Government Property

The offeror shall identify Government property in its possession which it proposes to use in the performance of the prospective contract as follows:

- a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);
- b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;
- c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and
- d. The voluntary consensus standard or industry leading practices and standards to be used in the management of Government property, or existing property management plans, methods, practices, or procedures for accounting for property.

**NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from the Contractor possessing Government property, and for evaluation purposes only, adjust the offers using a rental equivalent evaluation factor, as appropriate.**

- 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.*

*(End of Provision)*

#### **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 provision is applicable:

##### **Incremental Funding, HHSAR 352.232-75 (January 2006)**

(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 as specified in FAR 52.232-22. 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. The Government intends to allot additional funds up to and including the full estimated cost of the contract for the remaining years of performance by contract modifications. However, the Government is not obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor is the Contractor obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract, as specified in FAR 52.232-22, shall supersede the Limitation of Cost clause found in the Section I, Contract Clauses.

(End of provision)

## 9. 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.

## 10. 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/FDPclausecover.htm>

#### 11. Proposer's Annual Financial Report

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

#### 12. Representations and Certifications - SECTION K

One copy of SECTION K (which includes FAR Clause 52.204-8 Annual Representations and Certifications) shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of SECTION K shall be submitted from any proposed subcontractor. SECTION K can be found at: <http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf>

#### 13. 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 31.205-46.

##### b. Travel Policy

***This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1. of this RFP.***

All offerors included within the competitive range will be required to submit one copy of their written travel policy. A written travel policy for any proposed subcontractors shall also be submitted at that time. If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

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.

#### 14. Certification of Visas 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 outlying areas, then the offeror must indicate in the proposal that these individuals have the required visas.

## SECTION M - EVALUATION FACTORS FOR AWARD

### 1. GENERAL

Proposals will be evaluated against the following three evaluation factors in the order of importance: technical, cost, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, cost/price, and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The estimated cost of an offer must be reasonable for the tasks to be performed and will be subject to a cost realism analysis by the Government.

The merit of each technical proposal will be evaluated by a peer review group. The Government reserves the right to convene multiple peer review groups to evaluate proposals. Offerors must demonstrate in their proposals that they have the necessary expertise and capabilities for conducting the proposed research. The evaluation will be based on the demonstrated capabilities of the offerors in relation to the needs of the project as set forth in the BAA. Each proposal must document the feasibility of successful implementation of its approach to the Research and Technical Objectives of the BAA. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria.

Following the peer review, the Government will establish an Order of Merit Ranking of all proposals. Negotiations are conducted with offerors selected from the Order of Merit Ranking to address identified weaknesses, questions, and areas for clarification, as well as to refine the proposed Statement of Work. The final selection for award(s) is based upon the evaluation factors, in addition to importance to the agency programs (programmatic balance) and fund availability.

### 2. Pre Award Site Visit or Site Audit

Offerors selected for negotiations from the Order of Merit Ranking may be subject to auditing of their facilities and Quality Assurance/Quality Control (QA/QC) capabilities. The decision to audit specific facilities will be made by the Project Officer. If audits are performed during the negotiations, the results of the audits will be considered in final selection for award of a contract. Offerors, including proposed subcontractors, will be requested to make all non-proprietary records, including previous regulatory inspection records, and staff available in response to a pre-award site visit or audit by the NIAID or its designee. Due to timeline requirements, pre-award site visits may be made with short notice. Offerors are expected to guarantee the availability of key staff or other staff determined by the Government as essential for purposes of this site visit.

### 3. HUMAN SUBJECT EVALUATION

This research project involves human subjects. NIH Policy requires:

#### a. Protection of Human Subjects from Research Risks

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

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

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



against risk to human subjects) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the order of merit ranking, or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the protection of human subjects from research risks is still found to be unacceptable, then your proposal may not be considered further for award.

**b. Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide [http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm) , Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

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

**OR**

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

**OR**

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

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

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

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.

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

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

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

If the Government includes your proposal in the order of merit ranking, or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion/exclusion of women and minorities is still found to be unacceptable, then your proposal may not be considered further for award.

#### c. **Children**

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them.

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a

sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' evaluation of the offeror's response, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance with NIH policy guidelines) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the order of merit ranking, or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion of children is still found to be unacceptable, then your proposal may not be considered further for award.

#### **d. Data and Safety Monitoring**

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

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

If the Government includes your proposal in the order of merit ranking or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for data and safety monitoring is still found to be unacceptable, then your proposal may not be considered further for award.

#### **4. EVALUATION OF DATA SHARING PLAN**

The offeror's plan for the sharing of final research data, or, if data sharing is not possible, the offeror's documentation of its inability to share research data, shall be assessed for appropriateness and adequacy.

#### **5. TECHNICAL EVALUATION CRITERIA**

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

OFFERORS AND REVIEWERS ARE ADVISED TO REFER TO THE ATTACHMENT ENTITLED "ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS" OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATION RELATED TO THE PREPARATION OF TECHNICAL PROPOSALS.

#### CRITERIA WEIGHT

All subcriteria to be evaluated under each criterion should be considered to be of equal weight.

#### CRITERION 1: TECHNICAL PLAN/APPROACH - **60**

The relevance and feasibility of the proposed research for the development of vaccine adjuvants and/or stand-alone immune modulator products for use in vaccination or other proposed strategies of defense against infectious disease in the human population. Overall focus of the proposed research on adjuvant discovery, design, and development for a specific goal; for example, targeting a specific route of delivery, eliciting a specific type of immune response, and protecting against particular classes of infection. Effective use of milestones and timelines that define and delimit research objectives and tangible outcomes.

Effectiveness and feasibility of the rationale, strategies, milestones, criteria, and methodology to comply with each of the requirements specified in the Offeror's Statement of Work to conduct:

- A. Research Area 1: high throughput analytical approaches to identify and characterize novel human innate immune receptors and/or their ligands as targets for adjuvant discovery;
- B. Research Area 2: analysis and evaluation of mechanisms of action of novel adjuvant candidates acting through innate immune receptors/ligands;
- C. Research Area 3: lead compound optimization based on mechanism of action; and
- D. Research Area 4: preclinical testing of adjuvant candidates using animal model systems and in vitro studies with human cells/tissues.

#### CRITERION 2: SCIENTIFIC AND TECHNICAL PERSONNEL - **20**

- A. Principal Investigator (PI): Appropriateness and adequacy of the education, training, experience, expertise, qualifications, and effort of the proposed PI with respect to: planning and directing the proposed studies; knowledge of and productivity in the fields of innate immunity, adjuvant development, and/or high throughput screening with biological readout.
- B. Other Scientific and Technical Personnel: Appropriateness and adequacy of the education, training, experience, expertise, qualifications, and effort of all other proposed scientific and technical personnel, including proposed subcontractors, with respect to: knowledge of and productivity in the field of innate immunity, adjuvant development, and/or high throughput screening with biological readout.

#### CRITERION 3: FACILITIES, EQUIPMENT, AND OTHER RESOURCES - **10**

Documented availability of equipment, adequate throughput capacity, and computing and analytical services needed to undertake the proposed research. If subcontractors are proposed, documentation that they possess the required equipment and capabilities to carry out the work of the subcontract. Documentation of sufficient and appropriate space and physical resources, including biocontainment capabilities, where necessary, to support the proposed research.

#### CRITERION 4: PROJECT MANAGEMENT - **10**

As required and/or appropriate for the Offeror's proposed Statement of Work:

- A. Adequacy of the overall Project Management in terms of staffing, organization, responsibilities, leadership, and lines of authority.
- B. Suitability of systems proposed for tracking project activities and monitoring progress, timelines, milestones, and budgets.
- C. Suitability of the plan for how the PI and PM will communicate with the Project Officer and the Contracting Officer, as well as establish lines of communication between all performance sites and activities.
- D. Ability to manage, coordinate, and oversee the tasks performed by subcontractors and/or consultants, as appropriate.

**TOTAL POSSIBLE POINTS: 100**

## 6. PAST PERFORMANCE FACTOR

An evaluation of offeror's past performance information will be conducted subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal would not be selected for award based on the results of the evaluation of factors other than past performance.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

## 7. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

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

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

Offers will be evaluated on the following sub-factors:

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

**ATTACHMENT 1: PACKAGING AND DELIVERY OF THE PROPOSAL**

**INNATE IMMUNE RECEPTORS AND ADJUVANT DISCOVERY  
AI2008037**

**PAPER SUBMISSION:** The paper copy is the official copy for recording timely receipt of proposals.

**SUBMISSION OF PROPOSALS BY FACSIMILE OR E-MAIL IS NOT ACCEPTABLE.**

**A. EXTERNAL PACKAGE MARKING:**

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

**"BAA-NIAID-DAIT-NIHAI20080037 Innate Immune Receptors and Adjuvant Discovery"**

**"TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"**

**B. PAPER COPIES and CD-Rom to:**

| <b>If Hand Delivery or Express Service</b>                                                                                                                        | <b>If using U.S. Postal Service</b>                                                                                                                                    |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Bryan E. Jones, J.D.<br>Contract Specialist<br>Office of Acquisitions, DEA, NIAID, NIH<br>6700-B Rockledge Drive, Room 3214, MSC 7612<br>Bethesda, Maryland 20817 | Bryan E. Jones, J.D.<br>Contract Specialist<br>Office of Acquisitions, DEA, NIAID, NIH<br>6700-B Rockledge Drive, Room 3214, MSC 7612<br>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).

**C. NUMBER OF COPIES:**

**TOTAL PAGE COUNT DOES NOT INCLUDE:** Title and Back Page; NIH-2043; Table of Contents; Section Dividers that do not contain information other than title of Section.

**PAGES THAT ARE 2-SIDED WILL COUNT AS 2 PAGES.**

**FORMATTING AND LAYOUT:**

Use your usual word processing and spreadsheet programs to prepare and format the technical and business proposals.

**Documents submitted using Adobe .pdf shall be submitted using a .pdf searchable format.**

- Type size must be 10 to 12 points.
- Type spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
- Print margins must be at least one inch on each edge of the paper.
- Print setup should be single-sided on standard letter size paper (8.5 x 11" in the U.S., A4 in Europe).

- Proposals shall NOT include links to Internet Web site addresses (URLs) or otherwise direct readers to alternate sources of information.

**CREATING AND NAMING ELECTRONIC FILES:**

1. A separate CD should be submitted for the Technical Proposal and Business Proposal information.  
*Offerors who submit both Technical and Business Proposals on the same CD will be required to resubmit them on separate CDs.*

2. It is preferred that the Technical Proposal be submitted as one electronic file document.

**Note:** if multiple files are submitted for either proposal, please include the name of the section in the file name.

*EXAMPLE: XYX Company-07-16-Technical-Approach-3-6-06*

3. CDs should be named using the following format:

**Technical Proposal:** *Company name-RFP number-technical-date*

**Business Proposal:** *Company name-RFP number-business-date*

**THE NUMBER OF COPIES AND APPLICABLE PAGE LIMITATIONS REQUIRED OF EACH PART OF YOUR PROPOSAL ARE AS SPECIFIED BELOW.**

**PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE PROVIDED TO THE REVIEWERS TO BE READ OR EVALUATED.**

**OFFERORS MUST CERTIFY THAT THE INFORMATION IN THE PAPER AND ELECTRONIC COPIES IS EXACTLY THE SAME.**

| Document                                                                                  | Number of Copies                                                                                                                                                                                                                                                                                | Page Limits                                                                  |
|-------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| <b>Technical Proposal and all Appendices</b>                                              | <p><b><u>PAPER</u></b><br/>           One (1) unbound SIGNED ORIGINAL.<br/>           Four (4) unbound COPIES</p> <p><b><u>ELECTRONIC FILES ON CD</u></b><br/>           Fifteen (15) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices)</p>      | <b>Not to Exceed 150 pages (inclusive of all Attachments and Appendices)</b> |
| <b>Business Proposal</b>                                                                  | <p><b><u>PAPER</u></b><br/>           One (1) unbound SIGNED ORIGINAL.<br/>           Four (4) unbound COPIES</p> <p><b><u>ELECTRONIC FILES ON CD</u></b><br/>           Fifteen (15) Compact Disks containing an electronic copy of the Business Proposal</p>                                  | N/A                                                                          |
| <b>Breakdown of Proposed Estimated Cost using Electronic Cost Proposal EXCEL Workbook</b> | <p>This Attachment to the Business Proposal should be submitted as a separate EXCEL file on the Business Proposal Compact Disk.<br/> <b>See Section J, Attachment entitled <u>Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet</u> to access the Excel Workbook.</b></p> | N/A                                                                          |

## **ATTACHMENT 2: BROAD AGENCY ANNOUNCEMENT DESCRIPTION**

### **INNATE IMMUNE RECEPTORS AND ADJUVANT DISCOVERY AI2008037**

#### **BROAD AGENCY ANNOUNCEMENT INFORMATION**

You are invited to submit a proposal in accordance with the requirements of this BROAD AGENCY ANNOUNCEMENT (BAA). The BAA is authorized by Federal Acquisition Regulation (FAR) 6.102 and further described in FAR 35.016 as well as the NIH Policy Manual, Manual Chapter 6035, Broad Agency Announcements. A BAA is a general announcement of an agency's research interest and constitutes a solicitation. The intent of a BAA is to encourage the submission of creative and innovative approaches to specific research areas identified by the Government.

A proposal submitted in response to this BAA must present a detailed technical and cost proposal designed to meet the Research and Technical Objectives described. The proposed Statement of Work, including the specific work requirements and performance specifications, is developed and defined by the offeror, not the Government.

Proposals are NOT evaluated against a common Statement of Work issued by the Government. Instead, Research and Technical Objectives are provided in the BAA that describe the research areas in which the Government is interested. Proposals received as a result of the BAA are evaluated in accordance with Evaluation Factors for Award specified in Section M of the BAA.

The NIAID will assess whether the work proposed should be redirected, removed, and/or whether schedule or budget adjustments should be made. As a result, during discussions with offerors, the NIAID reserves the right to modify or delete proposed milestones, decision points, research plans, process, schedule, budget or product.

The NIAID estimates that the average annual total cost (direct and indirect costs combined) is approximately \$2 million per award. However, it is anticipated that the total cost for the award(s) may vary depending upon the scope of the project and the technical objectives of the award(s). The length of time for which funding is requested should be consistent with the nature and complexity of the proposed research. In no event shall the period of performance proposed by an offeror exceed five years.



**ATTACHMENT 3: PROPOSAL INTENT RESPONSE SHEET**

**INNATE IMMUNE RECEPTORS AND ADJUVANT DISCOVERY  
AI2008037**

**RFP No.:** BAA-NIAID-DAIT-NIHAI2008037

**RFP Title:** Innate Immune Receptors and Adjuvant Discovery

Please review the attached Request for Proposal. Furnish the information requested below and return this page by **September 8<sup>th</sup>, 2008**. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

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:

OA, DEA, NIAID, NIH  
6700-B Rockledge Drive, Room 3214, MSC 7612  
Bethesda, MD 20892-7612

Attn: Bryan E. Jones, J.D.  
BAA-NIAID-DAIT-NIHAI200837  
FAX# (301) 451-3682  
Email: jonesbry@niaid.nih.gov

## **ATTACHMENT 5: BACKGROUND and INTRODUCTION**

### **INNATE IMMUNE RECEPTORS AND ADJUVANT DISCOVERY AI2008037**

The Division of Allergy, Immunology, and Transplantation (DAIT), at the National Institute of Allergy and Infectious Diseases (NIAID), promotes and supports a broad range of research projects on basic mechanisms of immune function, including studies of innate immunity and the immunological basis of vaccines and adjuvants. This Broad Agency Announcement (BAA) solicits proposals for a renewed research program that includes the discovery, characterization, and preclinical testing of new adjuvant candidates based upon triggering of the human innate immune system. For the purpose of this BAA, adjuvants are defined as molecules that act *via* innate immune receptors to activate beneficial innate and/or adaptive (T and B cell-mediated) immune responses. The adjuvant products targeted in this program may be developed as components of antigen specific vaccines against infectious disease, or may serve as stand-alone agents that transiently prevent or treat infectious disease.

The initiation of effective immune responses requires triggering of the innate immune system, which is comprised of cells located throughout the body that express receptors to detect and respond to infectious agents. The innate immune system includes antigen presenting cells such as dendritic cells and macrophages, and other cell types, that can be directly triggered by microbes for immediate defensive responses, and that also initiate stimulatory signals that control both the strength and particular type of adaptive immune response, as well as long term immune memory. Innate immune system activation is an essential part of immune responses, and vaccines that lack the ability to activate the innate immune system require co-administration with adjuvants to induce lasting protection. Some types of vaccine adjuvants may function by providing a depot for increased antigen localization or by absorbing antigens to microparticles to enhance uptake by antigen presenting cells. However, this solicitation involves only adjuvants defined as molecules that act *via* innate immune receptors to activate beneficial innate and/or adaptive (T and B cell-mediated) immune responses.

Among the best characterized innate immune receptors are members of the Toll-like Receptor (TLR) family of proteins that participate in recognition of structures such as bacterial cell wall components, including lipoproteins and lipopolysaccharides; bacterial DNA sequences that contain unmethylated CpG motifs; and virus double stranded RNA. In addition to TLR, innate immune receptors include complement receptors; scavenger receptors such as CD36; C-type lectin-like receptors such as mannose-binding proteins, dectin-1, and DC-SIGN; and intracellular receptors such as the RIG-like helicases RIG-1 and MDA5, and NOD-like receptors such as NOD1/2, IPAF, and NALP3. Diverse innate receptors exist to enable appropriate immediate responses to a broad range of pathogens and also to influence the particular type of antigen specific T or B cell responses induced by a particular type of pathogen. For example, some TLR ligands may trigger Th1 type proinflammatory responses, whereas parasite carbohydrates tend to trigger Th2 responses. In addition, combinations of innate receptors can act together to modulate the response.

Currently, only one adjuvant is licensed in the U.S. for general human use, aluminum hydroxide/aluminum phosphate, and it has failed to provide optimal immunostimulatory activity for a number of vaccine candidates. Therefore, new adjuvants are needed to induce robust immunity and to direct the most effective type of response, e.g., antibody production or cytotoxic T cell induction. No single adjuvant will be sufficient for all vaccine applications and it is expected that important new adjuvant candidates will emerge from adjuvant discovery research. Furthermore, in addition to their use for specific vaccine applications, adjuvants targeting innate immune receptors might be useful as stand-alone immunotherapeutic agents for the short term prevention or treatment of infectious disease.

Until relatively recently, identifying and characterizing innate immune receptors and their ligands was a difficult task. However, the emergence of genetic screens and novel genomic and proteomic technologies facilitates the efficient identification of gene products involved in innate immune activation. Thus, high throughput screening of libraries of natural and synthetic compounds should enable the isolation, development, and optimization of novel adjuvant candidates.

This solicitation is a renewal of requests for proposals (RFPs) NIH-NIAID-DAIT-BAA-03-41 and NIH-NIAID-DAIT-BAA-04-38, each entitled "Innate Immune Receptors and Adjuvant Discovery." Five awards were issued in fiscal year 2004 as a result of these two previous solicitations:

HHSN266200400008C Corixa Corporation, Hamilton MT  
HHSN266200400009C Montana State University, Bozeman MT  
HHSN266200400010C Caliper Life Sciences Corporation, Hanover MD  
These awards are due to expire in December 2008.

HHSN266200400043C VaxInnate Corporation, New Haven CT  
HHSN266200400044C Coley Pharmaceutical Group, Inc., Wellesley MA  
These awards are due to expire in June 2009.

Funding under the prior RFPs is NOT required for the current solicitation; ALL qualified offerors are invited to apply.

All incumbent contractors currently funded under this program have discovered candidate molecules with adjuvant activity and are in the process of optimizing lead compounds and testing for safety and effectiveness using *in vitro* and *in vivo* model systems. The goal of this solicitation is to continue support for the discovery and initial characterization of novel adjuvant candidates at the earliest stage of discovery using high throughput screening approaches. Thus, research solicited under this acquisition will continue a pipeline of new adjuvant leads that exploit the natural capacity of the innate immune system to initiate and sustain effective T and B cell responses and induce long term immune memory, and/or may act alone to transiently prevent or mitigate infectious disease. To aid in designing safe and effective new adjuvants, this program will support the application and improvement of analytical tools for the discovery of new adjuvant candidates, the in-depth functional analysis of adjuvant-triggered responses on the cellular and molecular levels, *in vitro* testing with human cells or tissue, and *in vivo* testing in animals to assess efficacy and feasibility for further development that is beyond the scope of this program.

## ATTACHMENT 6: RESEARCH AND TECHNICAL OBJECTIVES

### INNATE IMMUNE RECEPTORS AND ADJUVANT DISCOVERY AI2008037

#### RESEARCH and TECHNICAL OBJECTIVES

This BAA targets discovery of novel adjuvants that act *via* triggering of human innate immune receptors. The ultimate goal of this effort is to protect the human population from infectious diseases; therefore the research must focus on adjuvants that will be effective in the human innate immune system to help prevent or treat infectious disease. For the purpose of this BAA, adjuvants are defined as molecules that act *via* innate immune receptors to activate beneficial innate and/or adaptive (T and B cell-mediated) immune responses. The adjuvant products targeted in this program may encompass uses both as vaccine adjuvants, to elicit T and B cell responses when co-administered with an immunogen, as well as stand-alone immunomodulators to stimulate short-term protective responses against broad categories of infectious agents.

The scope of adjuvant discovery research to be supported includes the following:

- (1) high throughput analytical approaches to identify and characterize human innate immune receptors and/or their ligands as targets for adjuvant discovery;
- (2) analysis and evaluation of the mechanisms of action of novel adjuvant candidates acting through innate immune receptors/ligands;
- (3) lead compound optimization based on mechanism of action; and
- (4) preclinical testing of adjuvant candidates using animal model systems and *in vitro* studies with human cells/tissues.

This solicitation will NOT support the following:

- human clinical trials;
- *in vivo* pathogen challenge studies in humans;
- HIV/AIDS research;
- optimization of specific vaccine antigens;
- studies limited to immune effector molecules, such as antibodies or antimicrobial peptides, rather than the innate immune induction process;
- proposals based strictly on non-human receptors or carried out only with non-human cells; and
- studies limited to further preclinical or clinical testing of previously identified adjuvant candidates, which includes:
  - o compounds already discovered to have adjuvant activity;
  - o adjuvant candidates that are already at the stage of lead optimization or are approaching preclinical or clinical testing; and
  - o adjuvant candidates presently or previously in clinical testing for adjuvant activity.

Offerors shall submit proposals for coordinated research programs leading to adjuvant development that encompass all four of the research areas described below. The adjuvant products sought may be developed as vaccine adjuvants or as stand-alone immunomodulators to prevent or treat infectious disease.

Proposed research shall encompass the discovery, characterization, refinement, and testing of novel candidate adjuvants using appropriate high throughput screening and analysis of human innate immune system receptors and/or their ligands.

All proposed research shall:

- (1) begin at the discovery stage and progress to preclinical testing of adjuvant candidates. Discovery includes: (a) starting with the earliest identification of novel human innate immune receptors and/or ligands of human innate immune receptors; and (b) evaluating a set of compounds - with the potential to stimulate human innate immune responses - in terms of receptor usage, signal transduction pathways, and the cell types and soluble mediators involved;
- (2) be based on appropriate technology to achieve high throughput analysis of human innate immune system recognition and characterization of responses;
- (3) target and elicit immunostimulatory responses in the human innate immune system, as assessed using human cells or tissues *in vitro*; and
- (4) focus on adjuvant discovery, design, and development for a specific goal in infectious disease vaccine or immunomodulator research; for example, mucosal function, cytotoxic T cell responses, neutralizing antibody production, or protection against specific infections.

**Animal studies:** Animal model studies that support research on human molecules, human immune signaling pathways, and human immune responses are encouraged. Animal research may include, for example:

- use of animal models for gene discovery, provided that a link to human gene counterparts is made;
- application of genetic homologies to guide the discovery and characterization of human molecules and pathways;
- transgenic expression of human receptors or other molecules in animal models;
- use of non-human primates if well justified; and
- use of animals for preclinical *in vivo* safety and efficacy studies.

**Milestones and timelines:** Milestones and timelines must be provided for each stage of research based on Research Areas 1 through 4 listed below. Milestones must reflect key criteria of success in each proposed Research Area and tangible outcomes of each stage of research. Stages of research may be undertaken simultaneously or sequentially as required for optimal performance of the work.

Contracts awarded in response to this BAA will support research programs that include each of the following Research Areas 1 through 4:

**Research Area 1. High throughput analytical approaches to identify and characterize human innate immune receptors and/or their ligands as targets for adjuvant discovery.** This area includes the use of existing techniques or development of improved technologies to identify NEW human innate immune receptors and/or novel ligands for human innate immune receptors. Ligands may include both direct and indirect triggers of the receptors. Examples of research approaches may include, but are not limited to:

- gene expression and gene sequence profiles, including microarray chip technology, expression libraries, and RNA-based knockdown approaches;

- protein expression analysis, including mass spectrometry, analytical chromatography, and analytical electrophoresis; and
- mutational analysis, including chemical mutagenesis and gene knockout technology.

**Research Area 2. Analysis and evaluation of mechanisms of action of novel adjuvant candidates acting through innate immune receptors/ligands.**

The overall goal of this area is to understand the direct or indirect effects of receptor-mediated activation to focus on desired responses for lead development. Research in this area may include, but is not limited to:

- application of methods to map signaling pathways, establish the molecular basis of phenotypic changes in responding cells, and characterize effector molecule production and links to adaptive immunity;
- identification of an optimal route of adjuvant delivery;
- analysis of responses in cells at the site of adjuvant delivery, for example, at the mucosa, skin, and other tissues; and
- identification and characterization of relevant molecular and cellular regulatory pathways and their functions in overall response outcomes.

**Research Area 3. Lead compound optimization based on mechanism of action.**

This area includes the establishment and application of criteria for structure-activity relationship (SAR) studies of innate immune receptor-ligand interactions; lead optimization; *in vitro* and *in vivo* immune response analysis; improvements in the potency, specificity, and regulation of immune responses; toxicity reduction; and formulation. Examples of research approaches include, but are not limited to:

- synthesis and library screening of compounds for SAR;
- structural and mutational analysis to guide optimization;
- targeting adjuvants to specific cell populations or cellular compartments; and
- rational chemical modification for optimization.

**Research Area 4. Preclinical testing of adjuvant candidates using animal model systems and *in vitro* studies with human cells/tissues.**

This area includes the application or development of appropriate *in vitro* assays using human cells or tissues, and animal models for *in vivo* immunogenicity and safety testing. Research may include, but is not limited to:

- validation of *in vitro* assays to establish relevance to human responses;
- generation of transgenic animals expressing human receptors or other molecules;
- development of methods to monitor results *in vivo*; and
- evaluation of adjuvant candidates in vaccination or pathogen challenge models in appropriate animal models.

**ATTACHMENT 7: REPORTING REQUIREMENTS AND OTHER  
DELIVERABLES**

**INNATE IMMUNE RECEPTORS AND ADJUVANT DISCOVERY  
AI2008037**

**ARTICLE C.2. REPORTING REQUIREMENTS**

All reports required herein shall be submitted in electronic format. In addition, one (1) hardcopy of each report shall be submitted to the Contracting Officer, unless otherwise specified.

a. Technical Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the DELIVERIES ARTICLE in SECTION F.

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

Format of Cover page: All reports shall include a cover page prepared in accordance with the following format:

- Contract Number and Project Title
- Period of Performance Being Reported
- Contractor's Name and Address
- Author(s)
- Date of Submission
- Delivery Address

(1) Monthly Progress Report

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

(2) Quarterly Progress Report

This report is required only for the first year after award. This report shall include a [ summation of the monthly progress reports  a description of the activities during the reporting period] and the activities planned for the ensuing reporting period. Relevant raw data and processed data will be provided within the report. The first reporting period consists of the first full three months of performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full calendar months.

(3) Semi-Annual Progress Report

This report shall include a [ summation of the monthly progress reports  a description of the activities during the reporting period] and the activities planned for the ensuing reporting period. Relevant raw data and processed data will be provided within the report. This report will start at the beginning of year 2 of the contract and continue for the remainder of the contract. The reporting period shall consist of six full calendar months.

(4) Annual Progress Report

This report includes a summation of the results of the entire contract work for the period covered. Relevant raw data and processed data will be provided within the report. An Annual Progress Report will not be required for the period when the Final Report is due. A [ Monthly  Quarterly  Semi-Annual] Report shall not be submitted when an Annual Report is due.

(5) Annual Technical Progress Report for Clinical Research Study Populations

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. The Contractor shall submit this information in the format indicated in the attachment entitled, "Inclusion Enrollment Report," which is set forth in Section J of the contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the Final Report.

The Contractor shall submit the report in accordance with the DELIVERIES Article in SECTION F of this contract.

In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October 2001, applies. If this contract is for Phase 3 clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website:  
[http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm)

(6) Final Report

This report is to include a summation of the work performed and the results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. All relevant raw data and processed data will be provided within the report. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. An annual report will not be required for the period when the Final Report is due.

- The Contractor shall provide the Contracting Officer with 2 copies of the Final Report in **draft** form [ in accordance with the DELIVERIES Article in SECTION F of this contract  60 calendar days prior to the completion date of this contract.] The Project Officer will review the draft report and provide the Contractor with



comments within 30 calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary and the final version delivered as specified in the above paragraph.

(7) Summary of Salient Results

The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

b. Other Reports and Deliverables

(1) System Security Plan:

Within 30 calendar days of the effective date of the contract, the contractor shall submit to the Project Officer a Draft System Security Plan (SSP) that identifies and details the management, operation, and technical controls of the computer-based data management system(s) to be used within the contract. Appropriate methods to ensure protection of personally identifiable information must be included in the SSP. Detailed guidance information regarding SSP development may be found at the following link: [http://irm.cit.nih.gov/nihsecurity/NIH\\_System\\_C&A.htm](http://irm.cit.nih.gov/nihsecurity/NIH_System_C&A.htm).

Project Officer comments on the Draft SSP shall be provided within 30 calendar days after receipt. The Final SSP, revised as necessary to accommodate Project Officer comments, must be in place within 90 calendar days from the effective date of the contract. An updated SSP will be provided to the Project Officer and Contracting Officer with the Annual Technical Progress Report following a major change in contractor infrastructure or computer-based systems.

(2) Contract Review Meetings:

- a. Annual Program Meetings: Awardees will participate in two-day annual meetings held in the Bethesda, Maryland area, with the first meeting to be held within three months after contract award. All Contractor Principal Investigators (PIs) funded under this program, as well as selected other key contract investigators including subcontractor personnel, shall attend these meetings. The Project Officer, Contracting Officer, and other designated NIH staff shall also attend. Meetings will be closed to the general public and shall involve oral and electronic presentations by the Contractors, including descriptions of planned work, updates on results of activities undertaken or completed in the prior contract year of performance (with the exception of the first meeting, which will update activities undertaken within the first three months of the contract's period of performance), descriptions of problems encountered or anticipated, approaches to resolve problems, and plans for the next year.
- b. Site Visits: Within the first year after award, the Contractor shall plan, conduct, and be responsible for logistical arrangements for a one- to two-day site visit by NIH staff to the Contractor's site. The PI, Project Manager (PM), all key investigators, key subcontractor personnel, the Project Officer, and the Contracting Officer shall attend this meeting.

Other NIH staff, as designated by the Project Officer, may also attend. The purpose of the site visit is to review plans and progress of the proposed work, and to coordinate activities and communication between the Contractor and the NIAID. The PI shall provide a copy of all slide presentations to the Project Officer. In addition to the initial site visit, the Project Officer and Contracting Officer may request additional site visits at the Contractor or subcontractor sites as needed.

- c. Monthly Teleconferences: The Contractor shall plan and conduct a teleconference meeting with the Project Officer each month during the first year after award, and thereafter at the discretion of the Project Officer, to discuss technical progress and financial issues. One week prior to the teleconference, the Contractor shall submit an agenda to the Project Officer. Within one week after the teleconference, the Contractor shall provide a summary of the teleconference to the Project Officer.

In addition to the above reports, the following are considered other reports and deliverables under this contract and are identified in the Statement of Work. A listing is included in the DELIVERIES Article in SECTION F.

- Human Subjects IRB Annual Report** (Form OMB No. 0990-0263- formerly Optional Form 310)
- Invention Report Requirement**
- Source Code and Object Code**

Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

#### **SECTION D – PACKAGING, MARKING, AND SHIPPING**

- Cannot be determined at this time
- Temperature controlled environment is required
- Shipments will be time sensitive/time critical
- International shipping will apply
- Shipping insurance is required
- Hazardous Materials shipping is applicable
- Other (list as necessary) \_\_\_\_\_
- N/A to this solicitation

#### **ARTICLE F - DELIVERIES**

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the STATEMENT OF WORK Article in SECTION C of this contract and upon delivery and acceptance by the Contracting

Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract. will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below [and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract]:

**a. Technical Progress Reports**

| Item | Reports                                                                                                                                     | Recipients                                                          | Delivery Schedule                                                                                                                                                                                                                                                         |
|------|---------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.   | Quarterly Progress Report                                                                                                                   | 1 hard copy to PO<br>1 hard copy to CO<br>1 elec. copy to PO and CO | The first report is due on/before _____. Thereafter, each report is due on/before the 30 <sup>th</sup> of each month following each reporting period for the first year of award.                                                                                         |
| 2.   | Semi-Annual Progress Report                                                                                                                 | 1 hard copy to PO<br>1 original to CO<br>1 elec. copy to PO and CO  | The first report is due on/before _____. Thereafter, each report is due on/before the 30 <sup>th</sup> of the month following each 6-month period starting in the second year of award.                                                                                   |
| 3.   | Annual Progress Report                                                                                                                      | 1 hard copy to PO<br>1 original to CO<br>1 elec. copy to PO and CO  | The first report is due on/before _____. Thereafter, each report is due on/before the 30 <sup>th</sup> of the month following each anniversary date of the contract. Semi-Annual and Quarterly Progress reports will not be submitted the month the Annual Report is due. |
| 4.   | Final Invention Statement                                                                                                                   | 1 copy to CO                                                        | Due on/before completion date of the contract.                                                                                                                                                                                                                            |
| 5.   | All reports and documentation including the invention disclosure report, the confirmatory license, and the government support certification | 1 copy to OPERA                                                     | As required by FAR Clause 52.227-11.                                                                                                                                                                                                                                      |
| 6.   | Draft Final and Final Report and Summary of Salient Results                                                                                 | 1 hard copy to PO<br>1 original to CO<br>1 elec. copy to PO and CO  | Draft Final Report is due ___ calendar days prior to the completion date of contract.<br><br>Final Report is due on/before the completion date of the contract. Annual Report will not be submitted the month the Final Report is due.                                    |

**b. Other Reports and Deliverables (Delivery Schedule)**

| <b>Item</b> | <b>Deliverables</b>                                                                           | <b>Recipient</b>                                                   | <b>Delivery Schedule</b>                                                                                                                                   |
|-------------|-----------------------------------------------------------------------------------------------|--------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1.          | Draft and Final System Security Plan (SSP)                                                    | 1 hard copy to PO<br>1 original to CO<br>1 elec. copy to PO and CO | Draft SSP is due within 30 calendar days of the effective date of the contract. The final SSP is due within 90 days of the effective date of the contract. |
| 2a.         | Annual Program Meeting presentations: slides and other materials supporting the presentations | Project Officer                                                    | One week prior to the Annual Program Meeting                                                                                                               |
| 2b.         | Site Visit Presentations: slides and other materials supporting the presentations             | Project Officer                                                    | One week prior to the Site Visit                                                                                                                           |
| 2c.         | Monthly Teleconference Agendas                                                                | Project Officer                                                    | One week prior to the Teleconference                                                                                                                       |
| 2c.         | Monthly Teleconference Summaries                                                              | Project Officer                                                    | One week after the Teleconference                                                                                                                          |

## ATTACHMENT 8: SECTION M - EVALUATION FACTORS FOR AWARD

### INNATE IMMUNE RECEPTORS AND ADJUVANT DISCOVERY AI2008037

#### 1. GENERAL

Proposals will be evaluated against the following three evaluation factors in the order of importance: technical, cost, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, cost/price, and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The estimated cost of an offer must be reasonable for the tasks to be performed and will be subject to a cost realism analysis by the Government.

The merit of each technical proposal will be evaluated by a peer review group. The Government reserves the right to convene multiple peer review groups to evaluate proposals. Offerors must demonstrate in their proposals that they have the necessary expertise and capabilities for conducting the proposed research. The evaluation will be based on the demonstrated capabilities of the offerors in relation to the needs of the project as set forth in the BAA. Each proposal must document the feasibility of successful implementation of its approach to the Research and Technical Objectives of the BAA. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria.

Following the peer review, the Government will establish an Order of Merit Ranking of all proposals. Negotiations are conducted with offerors selected from the Order of Merit Ranking to address identified weaknesses, questions, and areas for clarification, as well as to refine the proposed Statement of Work. The final selection for award(s) is based upon the evaluation factors, in addition to importance to the agency programs (programmatic balance) and fund availability.

#### 2. PRE-AWARD SITE VISIT OR SITE AUDIT

Offerors selected for negotiations from the Order of Merit Ranking may be subject to auditing of their facilities and Quality Assurance/Quality Control (QA/QC) capabilities. The decision to audit specific facilities will be made by the Project Officer. If audits are performed during the negotiations, the results of the audits will be considered in final selection for award of a contract. Offerors, including proposed subcontractors, will be requested to make all non-proprietary records, including previous regulatory inspection records, and staff available in response to a pre-award site visit or audit by the NIAID or its designee. **Due to timeline requirements, pre-award site visits may be made with short notice. Offerors are expected to guarantee the availability of key staff or other staff determined by the Government as essential for purposes of this site visit.**

#### 3. TECHNICAL EVALUATION CRITERIA:

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

OFFERORS AND REVIEWERS ARE ADVISED TO REFER TO THE ATTACHMENT ENTITLED "ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS" OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATION RELATED TO THE PREPARATION OF TECHNICAL PROPOSALS.

## **CRITERIA**

## **WEIGHT**

All subcriteria to be evaluated under each criterion should be considered to be of equal weight.

### **CRITERION 1: TECHNICAL PLAN/APPROACH**

**60**

The relevance and feasibility of the proposed research for the development of vaccine adjuvants and/or stand-alone immune modulator products for use in vaccination or other proposed strategies of defense against infectious disease in the human population. Overall focus of the proposed research on adjuvant discovery, design, and development for a specific goal; for example, targeting a specific route of delivery, eliciting a specific type of immune response, and protecting against particular classes of infection. Effective use of milestones and timelines that define and delimit research objectives and tangible outcomes.

Effectiveness and feasibility of the rationale, strategies, milestones, criteria, and methodology to comply with each of the requirements specified in the Offeror's Statement of Work to conduct:

- A. Research Area 1: high throughput analytical approaches to identify and characterize novel human innate immune receptors and/or their ligands as targets for adjuvant discovery;
- B. Research Area 2: analysis and evaluation of mechanisms of action of novel adjuvant candidates acting through innate immune receptors/ligands;
- C. Research Area 3: lead compound optimization based on mechanism of action; and
- D. Research Area 4: preclinical testing of adjuvant candidates using animal model systems and *in vitro* studies with human cells/tissues.

### **CRITERION 2: SCIENTIFIC AND TECHNICAL PERSONNEL**

**20**

- A. Principal Investigator (PI): Appropriateness and adequacy of the education, training, experience, expertise, qualifications, and effort of the proposed PI with respect to: planning and directing the proposed studies; knowledge of and productivity in the fields of innate immunity, adjuvant development, and/or high throughput screening with biological readout.
- B. Other Scientific and Technical Personnel: Appropriateness and adequacy of the education, training, experience, expertise, qualifications, and effort of all other proposed scientific and technical personnel, including proposed subcontractors, with respect to: knowledge of and productivity in the field of

innate immunity, adjuvant development, and/or high throughput screening with biological readout.

**CRITERION 3: FACILITIES, EQUIPMENT, AND OTHER RESOURCES**  
**10**

Documented availability of equipment, adequate throughput capacity, and computing and analytical services needed to undertake the proposed research. If subcontractors are proposed, documentation that they possess the required equipment and capabilities to carry out the work of the subcontract. Documentation of sufficient and appropriate space and physical resources, including biocontainment capabilities, where necessary, to support the proposed research.

**CRITERION 4: PROJECT MANAGEMENT**  
**10**

As required and/or appropriate for the Offeror's proposed Statement of Work:

- A. Adequacy of the overall Project Management in terms of staffing, organization, responsibilities, leadership, and lines of authority.
- B. Appropriateness and adequacy of the education, training, experience, qualifications, and effort of the Project Manager (PM) with respect to the management of complex research activities.
- C. Suitability of systems proposed for tracking project activities and monitoring progress, timelines, milestones, and budgets.
- D. Suitability of the plan for how the PI and PM will communicate with the Project Officer and the Contracting Officer, as well as establish lines of communication between all performance sites and activities.
- E. Ability to manage, coordinate, and oversee the tasks performed by subcontractors and/or consultants, as appropriate.

**TOTAL POSSIBLE POINTS:**

**100**

**Other Factors:**

- HUMAN SUBJECT EVALUATION  
Protection of Human Subjects from Research Risks, Data and Safety Monitoring, Women and Minorities, Children
- EVALUATION OF DATA SHARING PLAN
- EVALUATION OF PLAN FOR SHARING MODEL ORGANISMS FOR BIOMEDICAL RESEARCH
- EVALUATION OF FOREIGN CURRENCY OFFERS, FAR 52.225-17, (FEBRUARY 2000)  
Use when foreign currency offers are anticipated and allowed. This factor describes the currency conversion procedures.
- PAST PERFORMANCE FACTOR
- EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION
- SUBCONTRACTING PROGRAM EVALUATION CRITERIA  
Use when additional evaluation of the offeror's subcontracting program is warranted and desired.





**ATTACHMENT 9: ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS,  
FORMAT FOR TECHNICAL PROPOSAL, and TABLE OF CONTENTS**

**INNATE IMMUNE RECEPTORS AND ADJUVANT DISCOVERY  
AI2008037**

**It is strongly recommended that offerors use the following template as the Table of Contents for the Technical Proposal. All information presented in the Technical Proposal should be presented in the order specified below.**

These additional Technical Proposal instructions reflect the requirements of the BAA and provide specific instructions and formatting for the Technical Proposal. While Section L.2.b. of the BAA provides a generic set of Technical Proposal instructions applicable to all NIH R&D solicitations, these instructions are tailored to the specific requirements of the BAA. The information requested in these instructions should be used to format and prepare the Technical Proposal, and should be used as a Table of Contents for your Technical Proposal. Offerors should follow the instructions in Section L of the solicitation, and include the information requested here.

Offerors are advised to give careful consideration to the Broad Agency Announcement Description, Background and Introduction, Research and Technical Objectives, all reference materials, and attachments, the Technical Evaluation Criteria in Section M, and the BAA as a whole in the development of their Technical Proposals.

Offerors proposing subcontracts to perform portions of the Statement of Work should clearly identify the specific tasks for which they plan to utilize subcontractors, as well as the method and level of integration/coordination between the prime Contractor and all proposed subcontractors, and the expected advantages of such an approach.

**Offerors are reminded that the total page limitation for the entire Technical Proposal is 150 pages including all appendices and attachments. Any pages in excess of this limit will be expunged from the proposal and will not be considered in the technical review.**

**TECHNICAL PROPOSAL – TABLE OF CONTENTS**

**SECTION 1:**

**This Section will precede the Technical Proposal requirements identified in Section L.2. of the BAA.**

- 1) PROPOSAL TITLE PAGE. Include BAA title and number, name of organization, DUNS number, proposal part, and identify if the proposal is an original or a copy.
- 2) PROJECT OBJECTIVES, NIH FORM 1688
- 3) GOVERNMENT NOTICE FOR HANDLING PROPOSALS
- 4) PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)
- 5) TABLE OF CONTENTS

## **SECTION 2: TECHNICAL PROPOSAL OVERVIEW (3 page maximum)**

Provide a brief description of the proposed project, including:

- 1) A 1-2 sentence summary describing the adjuvant discovery approach the offeror is proposing to advance.
- 2) A description of the activities to be performed by the offeror and those that shall be provided by any proposed subcontractor, including the identification of the proposed subcontractors and a list of key personnel of the offeror and the proposed subcontractors with degrees and titles.
- 3) A brief description of the facilities and other resources to be made available by the offeror and any proposed subcontractors.
- 4) A summary of the proposed milestones and a timeline in the form of a Gantt chart.

## **SECTION 3: OFFEROR'S PROPOSED STATEMENT OF WORK (10 page maximum)**

In contracts awarded under this BAA, the Statement of Work shall be the Statement of Work proposed by the offeror and negotiated and accepted by the NIAID. This section of the offeror's Technical Proposal should outline the activities to be performed by the Contractor during performance of the contract using an outline format. The offeror's proposed Statement of Work should begin as follows: "Independently, and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below. Specifically, the Contractor shall: " The opening paragraph should be followed by a full Statement of Work describing each activity that the Contractor shall perform after the award of the contract. The Statement of Work shall include all activities required to effectively implement the discovery and characterization of novel human innate immune receptors/ligands as adjuvant candidates. The Statement of Work should also include a description of all items to be delivered to the Government during performance of the contract, such as progress reports, financial reports, end products, and other deliverables and a timetable for their delivery.

The Statement of Work is distinguished from the Technical Plan in that it describes what the Contractor shall provide, while the Technical Plan describes the specific detailed plan for the implementation of the discovery and characterization of novel innate immune receptors/ligands as adjuvant candidates.

Each activity described in the Statement of Work will begin with the words "The Contractor shall..." Where appropriate, divide the Statement of Work into separate Activities and Sub-activities. Examples of Activities and Sub-activities include:

- High Throughput Screening: The Contractor shall provide the equipment, facilities, and other resources required for high throughput screens of compounds to identify adjuvant activity in the human innate immune system. This includes the design and conduct of:

- screening studies.
  - studies to identify a gene of interest.
  - proteomic and immunological analyses to determine the potential adjuvant activity.
- Human *In Vitro* Studies: The Contractor shall perform:
    - proteomic and immunological analyses to determine whether the innate immune receptor/ligand identified in the screen functions similarly in primary human immune cells.
    - studies to determine the cell types affected by the adjuvant candidate.

#### **SECTION 4: TECHNICAL PLAN/APPROACH**

This solicitation provides an opportunity to identify compounds that regulate innate immune receptors and pathways. Under this program, investigators will discover new adjuvant candidates, and will provide a description of one or more well-developed assays automated for high throughput screening, as well as a systematic plan, including secondary and counter-screening assays, for evaluating active compounds identified in the primary high throughput screen. The proposal will also include a strategy for further testing to provide a final refinement in composition and function of the active compound(s) leading to optimum adjuvant candidate(s).

Describe the detailed scientific rationale, technical approaches, proposed methodologies, proposed plans and procedures, milestones, and timelines for achieving the Research and Technical Objectives of Research Areas 1 through 4 described in this solicitation, presented in the following order; for each of the Research Areas, describe potential problems and proposed solutions:

Research Area 1. High throughput analytical approaches to identify and characterize human innate immune receptors and/or their ligands as targets for adjuvant discovery. This area includes the use of existing techniques or development of improved technologies to identify NEW human innate immune receptors and/or novel ligands for human innate immune receptors. Ligands may include both direct and indirect triggers of the receptors.

Research Area 2. Analysis and evaluation of mechanisms of action of novel adjuvant candidates acting through innate immune receptors/ligands. The overall goal of this area is to understand the direct or indirect effects of receptor-mediated activation to focus on desired responses for lead development.

Research Area 3. Lead compound optimization based on mechanism of action. This area includes the establishment and application of criteria for structure-activity relationship (SAR) studies of innate immune receptor-ligand interactions; lead optimization; *in vitro* and *in vivo* immune response analysis; improvements in the potency, specificity, and regulation of immune responses; toxicity reduction; and formulation.

Research Area 4. Preclinical testing of adjuvant candidates using animal model systems and *in vitro* studies with human cells/tissues. This area includes the

application or development of appropriate *in vitro* assays using human cells or tissues, and animal models for *in vivo* immunogenicity and safety testing.

## **SECTION 5: SCIENTIFIC AND TECHNICAL PERSONNEL**

The Technical Proposal should include all information relevant to document individual training, education, experience, qualifications, and expertise necessary for the successful completion of all contract requirements. Clearly identify who is to be assigned as Key Personnel. Limit CVs to 2-3 pages and provide selected references for publications relevant to the scope of the BAA, and include experience with projects of similar scope, size, and complexity carried out by the offeror and any proposed subcontractors over the past 5 years.

- 1) **Principal Investigator (PI):** include experience and qualifications of the PI to plan, manage, and direct the activities to be carried out under this contract.
- 2) **Other Scientific and Technical Personnel:** include experience and qualifications of the other investigators or additional personnel to plan, manage, and direct the activities to be carried out under this contract.

## **SECTION 6: FACILITIES, EQUIPMENT, AND OTHER RESOURCES**

The Technical Proposal should document availability and adequacy of facilities, equipment, space, and other resources necessary to carry out the Statement of Work, including:

- 1) Location and features of facilities including a floor plan and a list of equipment and resources dedicated to the project for the prime contractor and any proposed subcontractors (lease or ownership information should be provided).
- 2) Identification and description of ALL support resources (including Information Technology systems) which will be required to effectively complete the SOW. Include descriptions of any biocontainment facilities needed as well as safety training for personnel, and animal facilities, including animal care and handling.

## **SECTION 7: PROJECT MANAGEMENT**

- 1) Provide a plan for project organization, staffing, and management including a detailed description of the responsibilities and level of effort for all proposed personnel who will be assigned to the contract, including proposed subcontractors and consultants, and provide an administrative and technical framework indicating clear lines of authority and responsibility for all proposed personnel. If consultants and/or subcontractors are proposed, include a plan to manage, coordinate, and oversee the work performed by consultants and/or subcontractor(s) efforts. Include a chart of the proposed organizational/management structure for the project.
- 2) Describe the education, training, experience, qualifications, and effort of the Project Manager (PM) with respect to the management of complex research activities.

- 3) Describe the project management systems that will be used to track activities and to keep multiple activities on time and budget. The plan must include a description of the quality control methods that will be used to ensure the effective and efficient initiation, implementation, management, and oversight of contract requirements.
- 4) Outline how the PI/PM will communicate with the Project Officer and Contracting Officer and how the PI/PM will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).

## **SECTION 8: OTHER CONSIDERATIONS**

Section L of the BAA provides minimum documentation requirements for the following items. The required information described in Section L should be assembled together, in the following clearly marked sections of the Technical Proposal. Refer to Section L of the BAA for specific requirements. Read each section below carefully. In some cases, offerors may be asked to provide documentation which is in addition to the minimum requirements identified in Section L.

### **1) Human Subjects**

Section L of the BAA specifies the minimum documentation requirements for Human Subjects use. All related documentation should be included in the proposal in a clearly marked section. The Technical Proposal should document all information necessary to evaluate Human Subject use.

### **2) Care of Live Vertebrate Animals**

Section L of the BAA specifies the minimum documentation requirements for Animal Welfare compliance. All related documentation should be included in the proposal in a clearly marked section. The Technical Proposal should document all information necessary to evaluate Animal Welfare issues.

### **3) Biological Agents or Toxins**

The Technical Proposal should include a plan for biohazard safety and security requirements, where applicable.

### **4) Obtaining and Disseminating Biomedical Research Resources**

Section L of the BAA specifies the minimum documentation requirements for this element. The Technical Proposal should document all information necessary to evaluate this issue.

### **5) Sharing Research Data (Plan)**

Section L of the BAA specifies the minimum documentation requirements for Data Sharing. All related documentation should be included in the proposal in this clearly marked section. The Technical Proposal should include a plan for Data Sharing as required by this BAA.

### **6) Sharing of Model Organisms for Biomedical Research (Plan)**

Section L of the BAA specifies the minimum documentation requirements for Model Organism sharing. All related documentation should be included in the proposal in this clearly marked section. The Technical Proposal should include a plan for sharing Model Organisms as required by this BAA.

**7) Information Technology (IT) Systems Security**

Section L of the BAA specifies the minimum documentation requirements for IT Systems security. All related documentation should be included in the Technical Proposal in this clearly marked section. The Technical Proposal should include a plan for IT Systems security as required by this BAA.

**ATTACHMENT 10: ADVANCE UNDERSTANDINGS**  
**INNATE IMMUNE RECEPTORS AND ADJUVANT DISCOVERY**  
**AI2008037**

- There are ***NO*** Advance Understandings applicable to this solicitation.
- The below Advance Understandings are applicable to this solicitation.

**ATTACHMENT 11: ADDITIONAL BAA-SPECIFIC MATERIALS**  
**INNATE IMMUNE RECEPTORS AND ADJUVANT DISCOVERY**  
**AI2008037**

- There are ***NO*** BAA-Specific Materials applicable to this solicitation.
- The below BAA-Specific Materials are applicable to this solicitation.



**ATTACHMENT 18: ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND  
UNIFORM COST ASSUMPTIONS**

**INNATE IMMUNE RECEPTORS AND ADJUVANT DISCOVERY  
AI2008037**

**In addition to the format requirements for the Business Proposal that are contained in Section L of the solicitation, the information presented in this section of the BAA is intended to provide uniform cost assumptions and business clarifications.**

Offerors are advised to give careful consideration to the Broad Agency Announcement Description, Background and Introduction, Research and Technical Objectives, all reference material provided as attachments, the technical evaluation criteria, and, the BAA as a whole, in the development of your proposal. The information requested in these instructions should be used as a guide for the development and formatting of your Business Proposal. Offerors should consider and include the information requested here, as well as **any other** information which will benefit the proposal.

**BUSINESS PROPOSAL – TABLE OF CONTENTS**

**SECTION 1 – PROPOSAL COVER SHEET** (use form NIH 2043 identified in Section J)

**SECTION 2 – COST OR PRICE SUPPORT**

Section L of the BAA specifies the minimum documentation requirements for cost data and all cost related support. All related documentation should be included in the proposal in a clearly marked section.

**SECTION 3 – UNIFORM COST ASSUMPTIONS**

**Travel**

Annual Program Meetings: Assume one meeting in Bethesda, Maryland in each of years 1-5 of the award to meet with other awardees under this program as well as NIH staff to present and discuss results. Assume that each meeting will require a two-night stay and shall be attended by the Principal Investigator plus additional relevant key personnel up to 6 total attendees.

Site Visits: Assume annual site visits of 1-2 days from the Project Officer and the Contracting Officer. Include costs associated with travel for any subcontractors or collaborators as well as the preparation of presentation materials.

General Scientific Meetings: Offerors shall propose a total of \$5,000 annually for the Principal Investigator and selected Contractor/subcontractor staff for travel to general scientific meetings for presentations of work conducted under this contract.

## **SECTION 4 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION**

### **1) Small Business Subcontracting Plan**

Section L of the BAA specifies the minimum documentation requirements for completing a subcontracting plan. This plan should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

### **2) Extent of Small Disadvantaged Business Participation**

Section L of the BAA specifies the minimum documentation requirements for small disadvantaged business utilization. This information should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

### **3) Past Performance Data, including references**

Section L of the BAA specifies the minimum documentation requirements for providing past performance information. This information should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.