

# SOLICITATION

## SECTION A - SOLICITATION/CONTRACT FORM

1. Purchase Authority: Public Law 92-218 as amended			
<b>2. Request for Proposal (RFP) Number:</b>  BAA-NIH-NIAID-DAIT-08-11	<b>3. Issue Date:</b>  October 4, 2007	<b>4. Just in Time:</b> <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes See Part IV Section L	<b>5. Set Aside:</b> <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes See Part IV Section L
6. Title : Adjuvant Development Program			
<b>7. ISSUED BY:</b> Office of Acquisitions, DEA National Institute for Allergy and Infectious Diseases National Institutes of Health, DHHS 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612  _____ _____		<b>8. SUBMIT OFFERS TO:</b> See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.	
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 eastern local time on January 4, 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: Doris C. McClain PHONE: 301-451-3692 e-MAIL: mcclainj@niaid.nih.gov COLLECT CALLS WILL NOT BE ACCEPTED.			
6700 B Rockledge Drive Room 3214/MSC 7612 Bethesda, MD 20892-7612		Wanda M. Neal Contracting Officer Office of Acquisitions, DEA, NIH, NIAID, DHHS  _____	

**RFP TABLE OF CONTENTS**

- PART I - THE SCHEDULE** ..... 5
  - SECTION A - SOLICITATION/CONTRACT FORM**..... 1
  - SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS**..... 5
  - SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT**..... 6
  - SECTION D - PACKAGING, MARKING AND SHIPPING**..... 8
  - SECTION E - INSPECTION AND ACCEPTANCE**..... 9
  - SECTION F - DELIVERIES OR PERFORMANCE**..... 10
  - SECTION G - CONTRACT ADMINISTRATION DATA**..... 11
  - SECTION H - SPECIAL CONTRACT REQUIREMENTS**..... 14
- PART II - CONTRACT CLAUSES**..... 23
- PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS**..... 32
  - SECTION J - LIST OF ATTACHMENTS**..... 32
    - SOLICITATION ATTACHMENTS..... 32
    - TECHNICAL PROPOSAL ATTACHMENTS..... 32
    - BUSINESS PROPOSAL ATTACHMENTS..... 33
    - INFORMATIONAL ATTACHMENTS..... 33
- PART IV - REPRESENTATIONS AND INSTRUCTIONS**..... 34
  - SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS**..... 34
  - SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS**..... 35
    - 1. GENERAL INFORMATION..... 35
      - a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION..... 35
      - b. NAICS CODE AND SIZE STANDARD..... 39
      - c. TYPE OF CONTRACT AND NUMBER OF AWARDS..... 39
      - d. ESTIMATE OF EFFORT..... 39
      - e. COMMITMENT OF PUBLIC FUNDS..... 39
      - f. COMMUNICATIONS PRIOR TO CONTRACT AWARD..... 40
      - g. RELEASE OF INFORMATION..... 40
      - h. COMPARATIVE IMPORTANCE OF PROPOSALS..... 40
      - i. PREPARATION COSTS..... 40
      - j. SERVICE OF PROTEST..... 40
      - k. LATE PROPOSALS AND REVISIONS..... 40
    - 2. INSTRUCTIONS TO OFFERORS..... 40
      - a. GENERAL INSTRUCTIONS..... 41
        - 1. Contract Type and General Clauses..... 41
        - 2. Authorized Official and Submission of Proposal..... 41
        - 3. Proposal Summary and Data Record (NIH-2043)..... 41
        - 4. Separation of Technical and Business Proposals..... 41
        - 5. Alternate Proposals..... 42
        - 6. Evaluation of Proposals..... 42
        - 7. Use of the Metric System of Measurement..... 42
        - 8. Standards for Privacy of Individually Identifiable Health Information..... 42
        - 9. Specific Copyright Provisions Applicable to Software Development and/or Enhancement(s)..... 42

- 10. Privacy Act - Treatment of Proposal Information..... 42
- 11. Selection of Offerors..... 43
- 12. Institutional Responsibility Regarding Conflicting Interests of Investigators..... 44
- 13. ROTC Access and Federal Military Recruiting on Campus..... 45
- 14. Prohibition on Contractor Involvement with Terrorist Activities..... 46
- 15. Solicitation Provisions Incorporated by Reference..... 46
- b. TECHNICAL PROPOSAL INSTRUCTIONS..... 46
  - 1. Technical Discussions..... 46
  - 2. Technical Evaluation..... 48
  - 3. Additional Technical Proposal Information..... 48
  - 4. Other Considerations..... 49
  - 5. Human Subjects..... 49
  - 6. Instructions to Offerors Regarding Protection of Human Subjects..... 50
  - 7. Required Education in the Protection of Human Research Participants..... 52
  - 8. Inclusion of Women and Minorities in Research Involving Human Subjects..... 52
  - 9. Inclusion of Children in Research Involving Human Subjects..... 54
  - 10. Research Involving Prisoners as Subjects..... 56
  - 11. Research Involving Human Fetal Tissue..... 56
  - 12. Research Involving Recombinant DNA Molecules (including Human Gene Transfer Research).... 56
  - 13. Human Embryonic Germ Cell (HEGC) Research..... 57
  - 14. Human Embryonic Stem Cell (HESC) Research..... 58
  - 15. Data and Safety Monitoring in Clinical Trials..... 58
  - 16. Care of Live Vertebrate Animals..... 59
  - 17. Possession, Use and Transfer of Select Biological Agents or Toxins..... 60
  - 18. Obtaining and Disseminating Biomedical Research Resources..... 61
  - 19. Information Security..... 63
- c. BUSINESS PROPOSAL INSTRUCTIONS..... 65
  - 1. Basic Cost/Price Information..... 66
  - 2. Proposal Cover Sheet..... 66
  - 3. Information Other than Cost or Pricing Data..... 66
  - 4. Salary Rate Limitation in Fiscal Year 2007..... 67
  - 5. Small Business Subcontracting Plan..... 68
  - 6. HUBZone Small Business Concerns..... 70
  - 7. Extent of Small Disadvantaged Business Participation..... 70
  - 8. Qualifications of the Offeror..... 71
  - 9. Other Administrative Data..... 72
  - 10. Subcontractors..... 74
  - 11. Proposer's Annual Financial Report..... 74
  - 12. Representations and Certifications - SECTION K..... 74
  - 13. Travel Costs/Travel Policy..... 74
  - 14. Certification of Visas for Non-U.S. Citizens..... 75
- SECTION M - TECHNICAL EVALUATION FACTORS..... 76**
  - 1. GENERAL..... 76

- 2. HUMAN SUBJECT EVALUATION..... 76
- 3. EVALUATION OF DATA SHARING PLAN..... 79
- 4. TECHNICAL EVALUATION CRITERIA..... 79
- 5. PAST PERFORMANCE FACTOR..... 79
- 6. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION..... 80

## **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**

The overall objective of the contracts awarded under this BAA is to further develop promising vaccine adjuvant candidates known to function by signaling through receptors of the innate immune system.

#### **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. Broad Agency Announcement

- 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 submitted in response to this Broad Agency Announcement (BAA) NIH-NIAID-DAIT-08-11. The Offerors' Statement of Work may be revised during negotiations leading to award of a contract.
- b. The applicable Privacy Act System of Records Number will be specified and shall be used in any design, development, or operation work to be performed under the resultant contract. Disposition of records shall be in accordance with SECTION C of the contract, and by direction of the Project Officer(s).

### ARTICLE C.2. REPORTING REQUIREMENTS

#### 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. The Contractor shall prepare and submit the reports in accordance with the Deliveries Articles in Section F.

**{Note: Please see Attachment 6 entitled "Reporting Requirements and Other Deliverables at the end of the 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.

### **ARTICLE C.3. INVENTION REPORTING REQUIREMENT**

All reports and documentation required by FAR Clause 52.227-13 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(a)(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 Article F DELIVERIES outlined in Attachment 6. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to appropriate personnel as outlined in Article F.

Contracting Officer  
National Institute for Allergy and Infectious Diseases  
DEA, Office of Acquisition  
6700-B Rockledge Drive  
Bethesda, Maryland 20892-7612, Room 3214

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 Institutes of 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**

- a. The period of performance of this contract shall be from September 18, 2008 through September 17, 2013.

### **ARTICLE F.2. 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 items in accordance with the stated delivery schedule in Attachment 6 entitled "Reporting Requirements and Other Deliverables at the end of the BAA.

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).

### **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. An electronic copy to the Contracting Officer, transmitted as an attachment via e-mail to the NIAID OA central invoice e-mail address listed below. The subject line of the e-mail must include the following information: Name of Contractor, Contract Number, and Invoice Number. Only one invoice should be submitted per e-mail. The invoice should be in Adobe PDF format, though a MS Word or MS Excel compatible format will also be considered acceptable. 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." {E-mail: [NIAIDOAInvoices@niaid.nih.gov](mailto:NIAIDOAInvoices@niaid.nih.gov)}

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 of Allergy and Infectious Diseases.
- b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NIAIDOA 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: Each payment request shall be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or purchase orders held by an organization (or business unit identified by a separate DUNS or DUNS+4 number). The NIH does not prescribe a particular numbering format. The only parameters for the invoice number are that it must be limited to 30 characters. There are no restrictions on the use of special characters, such as colons, dashes, forward slashes, or parentheses. Payment requests with duplicate invoice numbers will be considered improper and will be returned to the Contractor.

- b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) - 499-6088.

#### **ARTICLE G.4. 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.5. 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.6. 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 evaluations will be prepared as deemed appropriate by the Office of Acquisitions, 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 may 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. 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.4. RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (Including Human Gene Transfer Research)**

All research involving Recombinant DNA Molecules shall be conducted in accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules ( <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>) and the May 28, 2002 Notice, Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules ( <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html>) (and any subsequent revisions to the Guide Notice) which stipulates biosafety and containment measures for recombinant DNA research and delineates critical, ethical principles and key safety reporting requirements for human gene transfer research (See Appendix M of the Guidelines). These guidelines apply to both basic and clinical research studies.

The Recombinant DNA Advisory Committee (RAC) is charged with the safety of manipulation of genetic material through the use of recombinant DNA techniques. Prior to beginning any clinical trials involving the transfer of recombinant DNA to humans, the trial must be registered with the RAC. If this contract involves new protocols that contain unique and/or novel issues, the RAC must discuss them in a public forum and then the Institutional Biosafety Committee (IBC), the Institutional Review Board (IRB), and the project officer and contracting officer must approve the protocol prior to the start of the research.

Failure to comply with these requirements may result in suspension, limitation, or termination of the contract for any work related to Recombinant DNA Research or a requirement for contracting officer prior approval of any or all Recombinant DNA projects under this contract. This includes the requirements of the Standing Institutional Biosafety Committee (IBC) (See <http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm> ).

As specified in Appendix M-1-C-4 of the NIH Guidelines, any serious adverse event must be reported immediately to the IRB, the IBC, the Office for Human Research Protections (if applicable), and the NIH Office for Biotechnology Activities (OBA), followed by the filing of a written report with each office/group and copies to the project officer and contracting officer. ( [http://www4.od.nih.gov/oba/rac/guidelines\\_02/Appendix\\_M.htm#\\_Toc7255836](http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm#_Toc7255836)).

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

- a. Pursuant to Public Law(s) cited in paragraph b., below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used 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

b.

Public Law and Section No.	Fiscal Year	Period Covered
[applicable information to be included at award]		

**ARTICLE H.6. NEEDLE EXCHANGE**

- a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

b.

Public Law and Section No.	Fiscal Year	Period Covered

[applicable information to be included at award]		

**ARTICLE H.7. PRESS RELEASES**

- a. Pursuant to Public Law(s) cited in paragraph b., below, 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.

- b.
 

Public Law and Section No.	Fiscal Year	Period Covered
[applicable information to be included at award]		

**ARTICLE H.8. ANTI -LOBBYING**

- a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall only be used for normal and recognized executive-legislative relationships. Contract funds shall not be used, for publicity or propaganda purposes; or for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.
- b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

- c.
 

Public Law and Section No.	Fiscal Year	Period Covered
[applicable information to be included at award]		

**ARTICLE H.9. 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 09-25-0200. 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.10. 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.11. 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.12. SUBCONTRACTING PROVISIONS**

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

1. The Small Business Subcontracting Plan, dated \_\_\_\_\_ 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.13. SALARY RATE LIMITATION LEGISLATION PROVISIONS**

a. Pursuant to the P.L.(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown or the applicable Executive Level for the fiscal year covered. 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.

Public Law and Section No.*	Fiscal Year*	Dollar Amount of Salary Limitation*

c. Payment of direct salaries is limited to the Executive Level rate which was in effect on the date(s) the expense was incurred.

[\*Applicable information to be included at award]

**ARTICLE H.14. INFORMATION SECURITY**

If 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/policies/FISMA-final.pdf>

a. Information Type  
 Administrative, Management and Support Information  
 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  
 1. 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).

2. 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. 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.

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 he 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 BAA 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 800-26 Self-Assessment Questionnaire

The contractor shall annually update and re-submit its Self-Assessment Questionnaire required by NIST Draft SP 800-26, Revision 1, Guide for Information Security Program Assessments and System Reporting Form (<http://csrc.nist.gov/publications/drafts/Draft-sp800-26Rev1.pdf> - See Appendix B for format).

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.

## **ARTICLE H.15. ENERGY STAR REQUIREMENTS**

Executive Order 13123, "Greening the Government Through Efficient Energy Management" and FAR 23.203 require that when Federal Agencies acquire energy using products, they select, where life-cycle cost-effective, and available, ENERGY STAR® or other energy efficient products.

Unless the Contracting Officer determines otherwise, all energy-using products acquired under this contract must be either an ENERGY STAR® or other energy efficient product designated by the Department of Energy's Federal Energy Management Program (FEMP).

For more information about ENERGY STAR® see <http://www.energystar.gov/>

For more information about FEMP see <http://www.eere.energy.gov/>

## **ARTICLE H.16. 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 of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. \_\_\_\_\_"

## **ARTICLE H.17. 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** 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.18. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES**

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, 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]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at : <http://ott.od.nih.gov/NewPages/64FR72090.pdf> is intended to help contractors 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.

Note: For the purposes of this Article, the terms, "research tools", "research materials", and "research resources" are used interchangeably and have the same meaning.

## ARTICLE H.19. SHARING RESEARCH DATA

IF the data sharing plan submitted by the contractor is acceptable, the contractor's data sharing plan, dated \_\_\_\_\_ 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.20. POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

The contractor shall not conduct work involving select agents or toxins under this contract until it and any associated subcontractor(s) comply with the following:

For prime or subcontract awards to **domestic institutions** that possess, use, and/or transfer Select Agents under this contract, the institution must comply with the provisions of 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 ( [http://www.aphis.usda.gov/programs/ag\\_selectagent/FinalRule3-18-05.pdf](http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) ) as required, before using NIH funds for research involving Select Agents. No NIH funds can be used for research involving Select Agents if the final registration certificate is denied.

For prime or subcontract awards to **foreign institutions** that possess, use, and/or transfer Select Agents under this contract, before using NIH funds for any work directly involving the Select Agents, the foreign institution must provide information satisfactory to the NIAID, NIH that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: ( [http://www.aphis.usda.gov/programs/ag\\_selectagent/FinalRule3-18-05.pdf](http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) )

are in place and will be administered on behalf of all Select Agent work sponsored by these funds. The process for making this determination includes inspection of the foreign laboratory facility by an NIAID representative. During this inspection, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents. An NIAID-chaired committee of U.S. federal employees (including representatives of NIH grants/contracts and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will ultimately assess the results of the laboratory facility inspection, and the regulations, policies, and procedures of the foreign institution for equivalence to the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 ( [http://www.aphis.usda.gov/programs/ag\\_selectagent/FinalRule3-18-05.pdf](http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) ). The committee will provide recommendations to the DEA Director, NIAID. The DEA Director will make the approval decision and notify the Contracting Officer. The Contracting Officer will inform the prime contractor of the approval status of the

foreign institution. No NIH funds can be used for research involving Select Agents at a foreign institution until NIAID grants this approval.

Listings of HHS select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at <http://www.cdc.gov/od/sap/> and <http://www.cdc.gov/od/sap/docs/salist.pdf>. Listings of USDA select agents and toxins as well as information about the registration process for domestic institutions are available on the APHIS/USDA website at: [http://www.aphis.usda.gov/programs/ag\\_selectagent/index.html](http://www.aphis.usda.gov/programs/ag_selectagent/index.html) and: [http://www.aphis.usda.gov/programs/ag\\_selectagent/ag\\_bioterr\\_forms.html](http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_forms.html)  
For foreign institutions, see the NIAID Select Agent Award information: ([http://www.niaid.nih.gov/ncn/clinical/default\\_biodefense.htm](http://www.niaid.nih.gov/ncn/clinical/default_biodefense.htm)).

## **ARTICLE H.21. 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.22. 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.23. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH**

The Policy requests that beginning May 2, 2005, NIH-funded investigators 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-05-022.html>.

## **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/clauses.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. *Alternate I (October 1997) of FAR Clause 52.215-14, Integrity of Unit Prices (October 1997) is added.*
- c. *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.*
- d. *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.*
- e. *Alternate II (October 2001) of FAR Clause 52.219-9, Small Business Subcontracting Plan (September 2006) is added.*
- f. *FAR Clause 52.229-3, Federal, State And Local Taxes (April 2003) is deleted in its entirety, and FAR Clause 52.229-4, Federal, State And Local Taxes (State And Local Adjustments) (April 2003) is substituted therefor.*
- g. *FAR Clause 52.232-17, Interest (June 1996) is deleted.*
- h. *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.]*
- i. *Alternate II, (September 1996), of FAR Clause 52.249-2, Termination For Convenience Of The Government (Fixed-Price) (September 1996) is added.*

## 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 **52.216-15, Predetermined Indirect Cost Rates** (April 1998).
2. FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (July 2005).
 

"(c) Waiver of evaluation preference.....  
 Offeror elects to waive the evaluation preference."
3. FAR Clause **52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting** (October 1999).
4. FAR Clause **52.223-3, Hazardous Material Identification and Material Safety Data** (January 1997), with **Alternate I** (July 1995).
5. FAR Clause **52.224-1, Privacy Act Notification** (April 1984).
6. FAR Clause **52.224-2, Privacy Act** (April 1984).
7. FAR Clause **52.226-1, Utilization of Indian organizations and Indian-owned Economic Enterprises** (June 2000).
8. FAR Clause **52.227-14, Rights in Data - General** (June 1987).
9. **Alternate II** (June 1987), FAR Clause **52.227-14, Rights in Data--General** (June 1987).
10. **Alternate III** (June 1987), FAR Clause **52.227-14, Rights in Data--General** (June 1987).
11. **Alternate V** (June 1987), FAR Clause **52.227-14, Rights in Data--General** (June 1987).
12. FAR Clause **52.227-16, Additional Data Requirements** (June 1987).
13. FAR Clause **52.229-8, Taxes-Foreign Cost-Reimbursement Contracts** (March 1990).
14. FAR Clause **52.229-9, Taxes-Cost-Reimbursement Contracts with Foreign Governments** (March 1990).
15. FAR Clause **52.230-2, Cost Accounting Standards** (April 1998).

16. FAR Clause **52.230-3, Disclosure and Consistency of Cost Accounting Practices** (April 1998).
  17. FAR Clause **52.230-5, Cost Accounting Standards - Educational Institution** (April 1998).
  18. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (April 2005).
  19. FAR Clause **52.232-36, Payment by Third Party** (May 1999).
  20. FAR Clause **52.237-3, Continuity of Services** (January 1991).
  21. FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).
  22. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).
  23. FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984).
  24. FAR Clause **52.244-2, Subcontracts** (June 2007).
  25. FAR Clause **52.246-23, Limitation of Liability** (February 1997).
  26. FAR Clause **52.246-24, Limitation of Liability - High-Value Items** (February 1997).
  27. FAR Clause **52.247-63, Preference for U.S. Flag Air Carriers** (June 2003).
  28. FAR Clause **52.247-64, Preference for Privately Owned U.S. Flag Commercial Vessels** (February 2006).
  29. FAR Clause **52.247-68, Report of Shipment (REPSHIP)** (February 2006).
  30. 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 **352.223-70, Safety and Health** (January 2006).
  2. HHSAR Clause **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).
  3. HHSAR Clause **352.270-7, Paperwork Reduction Act** (January 2006).
  4. HHSAR Clause **352.270-8(b), Protection of Human Subjects** (January 2006).

5. *HHSAR Clause **352.270-9(b), Care of Live Vertebrate Animals** (January 2006).*

6. *HHSAR Clause **352.333-7001, Choice of Law (Overseas)** (March 2005).*

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).*

2. ***NIH(RC)-11, Research Patient Care Costs** (4/1/84).*

## 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 52.222-39, 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)*

b. FAR Clause **52.247-67, Submission of Transportation Documents for Audit** (February 2006).

(a) The Contractor shall submit to the address identified below, for prepayment audit, transportation documents on which the United States will assume freight charges that were paid--

- (1) By Contractor under a cost-reimbursement contract; and
- (2) By a first-tier subcontractor under a cost-reimbursement subcontract thereunder.

(b) Cost-reimbursement Contractors shall only submit for audit those bills of lading with freight shipment charges exceeding \$100. Bills under \$100 shall be retained on-site by the Contractor and made available for on-site audits. This exception only applies to freight shipment bills and is not intended to apply to bills and invoices for any other transportation services.

(c) Contractors shall submit the above referenced transportation documents to--

---

---

---

*[To be filled in by the Contracting Officer]*

## 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	See Attachment at the end of BAA.
Attachment 2:	Proposal Intent Response Sheet	See Attachment at the end of BAA.
Attachment 3:	Broad Agency Announcement Description	See Attachment at the end of BAA.
Attachment 4:	Background and Introduction	See Attachment at the end of BAA.
Attachment 5:	Research and Technical Objectives	See Attachment at the end of BAA.
Attachment 6:	Reporting Requirements and other Deliverables	See Attachment at the end of BAA.
Attachment 7:	Technical Evaluation Factors	See Attachment at the end of BAA.
Attachment 8:	Additional Technical Proposal Instructions	See Attachment at the end of BAA.
Attachment 9:	Additional Business Proposal Instructions and Uniform Cost Assumptions	See Attachment at the end of BAA.
Attachment 10:	Information Technology Systems Security - Prospective Offeror Non-Disclosure Agreement	See Attachment at the end of BAA.

#### TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 11:	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 12:	Annual Technical Progress Report Format for Each Study	<a href="http://rcb.cancer.gov/rcb-internet/forms/atpr.pdf">http://rcb.cancer.gov/rcb-internet/forms/atpr.pdf</a>
Attachment 13:	Technical Proposal Cost Summary	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>
Attachment 14:	Summary of Related Activities	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>
Attachment 15:	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 16:	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 17:	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**

<b>Attachment No.</b>	<b>Title</b>	<b>Location</b>
Attachment 18:	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 19:	Small Business Subcontracting Plan	<a href="http://rcb.cancer.gov/rcb-internet/forms/SBA_Plan_Nov_2005.pdf">rcb.cancer.gov/rcb-internet/forms/SBA_Plan_Nov_2005.pdf</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> <a href="http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls">http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls</a>
Attachment 21:	Offeror's Points of Contact	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>
Attachment 22:	Disclosure of Lobbying Activities, OMB Form SF-LLL	<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:	Safety and Health, HHSAR Clause 352.223-70	<a href="http://rcb.cancer.gov/rcb-internet.nci.nih.gov/forms/safety&amp;health-1-06.pdf">http://rcb.cancer.gov/rcb-internet.nci.nih.gov/forms/safety&amp;health-1-06.pdf</a>
Attachment 25:	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 26:	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 27:	Government Property Schedule	To be determined during negotiations.
Attachment 28:	Disclosure of Lobbying Activities, OMB Form SF-LLL	<a href="http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf">http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf</a>
Attachment 29:	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 30:	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 31:	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 order of merit ranking, 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. 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).*

(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.*

*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.*

*(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 order of merit ranking range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the order of merit ranking 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 order of merit ranking. If the Contracting Officer determines that the number of proposals that would otherwise be in the order of merit ranking exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the order of merit ranking 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 3-5 awards will be made from this solicitation and that the award(s) will be made on/about September 18, 2008.

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 September 18, 2008-September 17, 2013, and that incremental funding will be used (See Section L.2.c. Business Proposal Instructions).

**d. ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 6.2 FTE's per year. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

**e. 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.

**f. 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.

**g. 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.

**h. COMPARATIVE IMPORTANCE OF PROPOSALS**

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

**i. PREPARATION COSTS**

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

**j. 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

U.S. Department of Health and Human Services

National Institutes of Health

National Institute of Allergy and Infectious Diseases, Office of Acquisitions Room 3214

6700B 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)

**k. 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. 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.

## 8. 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>.

## 9. Specific Copyright Provisions Applicable to Software Development and/or Enhancement(s)

Under the provisions of the Rights in Data General clause (52.227-14), contractors must seek permission to establish a copyright for software and associated data generated under a contract. As a general rule, permission is normally granted provided, a paid-up, world-wide, irrevocable, nonexclusive license to the government is provided. This is to advise offerors that for this project, the government intends to assert additional copyright permissions under this contract. [The scope of the Government's interest in the copyright will be determined during negotiations. - **OR**- The government will require: *State specific requirements* ].

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

## 11. Selection of Offerors

- a. The acceptability of the 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. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.
- 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. 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.

**15. 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).*

**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 8, Additional Technical Proposal Instructions at the end of this BAA}.

**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. 1. Research and Technical Objectives and Statement of Work

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it. Offerors are required to provide a statement of work in accordance with attachment 5 entitled "Research and Technical Objectives".

2. Approach

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

3. Methods

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

4. Schedule

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

5. Proposals may be submitted for more than one candidate vaccine adjuvant; however, separate Technical and Business Proposals are required for each candidate vaccine adjuvant.

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. Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in SECTION M - Evaluation Factors for Award of this solicitation.

**3. Additional Technical Proposal Information**

- a. Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.
- b. The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only. **{Note: Please refer to Attachment 8-when preparing your proposal}.**

#### 4. Other Considerations

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

- a. Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
- b. Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
- c. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- d. Other factors you feel are important and support your proposed research.
- e. Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

**IMPORTANT NOTE TO OFFERORS: The following 12 paragraphs (5) through (16) shall be addressed, as applicable, in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."**

#### 5. 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. The contracting officer will direct the offeror/contractor to the OHRP IRB Registration and Assurance Filing website, found at <http://www.hhs.gov/ohrp/> or to the physical address if the offeror/contractor cannot access the Internet. 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)*

## **6. 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.

## 7. 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](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html) 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.

## 8. 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.**

## 9. 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.

## 10. 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)

## 11. 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.

## 12. Research Involving Recombinant DNA Molecules (including Human Gene Transfer Research)

Recombinant DNA Molecules are either 1) molecules that are constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or 2) DNA molecules that result from the replication of those described in 1).

The NIH Guidelines for Research Involving Recombinant DNA Molecules at:

( <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html> and the May 28, 2002 Notice, Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules at:

( <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html> )

and any subsequent revisions to the Guide Notice) stipulates biosafety and containment measures for recombinant DNA research and delineates critical, ethical principles and key safety reporting requirements for human gene transfer research (See Appendix M of the NIH Guidelines). These guidelines apply to both basic and clinical research studies.

The Recombinant DNA Advisory Committee (RAC) is charged with the safety of manipulation of genetic material through the use of recombinant DNA techniques. Prior to beginning any clinical trials involving the transfer of recombinant DNA to humans, the trial must be registered with the RAC. If this contract involves new protocols that contain unique and/or novel issues, the RAC must discuss them in a public forum and then the Institutional Biosafety Committee (IBC), the Institutional Review Board (IRB), and the project officer and contracting officer must approve the protocol prior to the start of the research.

Failure to comply with these requirements may result in suspension, limitation, or termination of NIH funding for any work related to Recombinant DNA Research or a requirement for the contracting officer's prior approval of any or all Recombinant DNA projects under any contract awarded from this solicitation. This includes the requirements of the Standing Institutional Biosafety Committee (IBC) (See <http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm>).

As specified in Appendix M 1 C 4 of the NIH Guidelines, any serious adverse event must be reported immediately to the IRB, the IBC, the Office for Human Research Protections (if applicable), and the NIH Office for Biotechnology Activities (OBA), followed by the filing of a written report with each office/group and copies to the project officer and contracting officer, at:

( [http://www4.od.nih.gov/oba/rac/guidelines\\_02/Appendix\\_M.htm#\\_Toc7255836](http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm#_Toc7255836)).

### 13. Human Embryonic Germ Cell (HEGC) Research

#### 1. Guidelines.

Research use of human embryonic germ cells derived from fetal tissue with Federal funds requires review of compliance with the NIH Guidelines for Research Using Human Pluripotent Stem Cells ( <http://stemcells.nih.gov/policy/guidelines.asp> ) (only the information regarding human embryonic germ cells is relevant). Embryonic germ cells are pluripotent stem cells derived from human embryos. See NIH Guide for Grants and Contracts Notice NOT OD 02 049, requiring that offerors/contractors submit certain documents to the Human Pluripotent Stem Cell Review Group (HPSCRG), which will be reviewed in a public meeting. Research using human embryonic germ cells may not be performed prior to approval by the HPSCRG.

All offerors should read the "NIH Guidelines" ( <http://stemcells.nih.gov/policy/guidelines.asp> ) if they either: (1) propose to respond to the Statement of Work requirements by conducting research that uses human embryonic germ cells or, (2) are responding to a Statement of Work that requires the use of human embryonic germ cells.

Offerors may obtain copies of these Guidelines from the website above or from the contact person listed in this solicitation.

#### 2. Procedure for Review by Human Pluripotent Stem Cell Review Group (HPSCRG)

If, in response to the solicitation, the offeror proposes to use human embryonic germ cells, it must submit, as a separate attachment to its proposal, an original and two copies of the documentation and assurances that address the areas covered in the "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" at:

( <http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html> ). Prior to any award made under this solicitation, the documentation and assurances will be subject to review by the HPSCRG, which meets in a public meeting. No research involving the use of human embryonic germ cells may begin prior to HPSCRG approval.

Offerors are encouraged to review issues pertaining to informed consent processes described in Section II.B.2.b of the NIH Guidelines. Offerors should also review the March 19, 2002, DHHS Office of Human Research Protection's document titled "Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell Derived Test Articles," at

( <http://stemcells.nih.gov/StaticResources/news/newsArchives/stemcell.pdf> )

#### 14. 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.

#### 15. 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.

## 16. 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.

## 17. Possession, Use and Transfer of Select Biological Agents or Toxins

**Notice to Offerors of Requirements of:** 42 CFR Part 73, Possession, Use, and Transfer of Select Agents and Toxins (relating to public health and safety):

( [http://www.cdc.gov/od/sap/42\\_cfr\\_73\\_final\\_rule.pdf](http://www.cdc.gov/od/sap/42_cfr_73_final_rule.pdf));

7 CFR Part 331, Possession, Use, and Transfer of Select Agents and Toxins (relating to plant health or plant products) ( [http://www.aphis.usda.gov/programs/ag\\_selectagent/FinalRule3-18-05.pdf](http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf)); and, 9 CFR Part 121, Possession, Use, and Transfer of Select Agents and Toxins (relating to human and animal health, animal health or animal products)

( [http://www.aphis.usda.gov/programs/ag\\_selectagent/FinalRule3-18-05.pdf](http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf)) - March 18, 2005.

These regulations implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and the Agricultural Bioterrorism Protection Act of 2002. They are designed to improve the ability of the United States Government to prevent, prepare for, and respond to bioterrorism and other public health emergencies. These regulations establish requirements regarding registration, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections, and notifications.

Listings of HHS select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at <http://www.cdc.gov/od/sap/> and <http://www.cdc.gov/od/sap/docs/salist.pdf>. Listings of USDA select agents and toxins as well as information about the registration process for domestic institutions are available on the APHIS/USDA website at [http://www.aphis.usda.gov/programs/ag\\_selectagent/index.html](http://www.aphis.usda.gov/programs/ag_selectagent/index.html) and

[http://www.aphis.usda.gov/programs/ag\\_selectagent/ag\\_bioterr\\_forms.html](http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_forms.html).

For foreign institutions, see the NIAID Select Agent Award information ([http://www.niaid.nih.gov/ncn/clinical/default\\_biodefense.htm](http://www.niaid.nih.gov/ncn/clinical/default_biodefense.htm)).

If the proposed contract will not involve Select Agents, the offeror must include a statement in its technical proposal that the work does not now nor will it in the future (i.e. throughout the life of the award) involve Select Agents.

#### **Domestic Institutions**

For prime or subcontract awards to domestic institutions that possess, use, and/or transfer Select Agents under this contract, the domestic institution must:

- include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.
- comply with 42 CFR part 73, 7 CFR part 331 and/or 9 CFR part 121 at: [http://www.aphis.usda.gov/programs/ag\\_selectagent/FinalRule3-18-05.pdf](http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf), as required, before using NIH funds for research involving Select Agents. No NIH funds can be used for research involving Select Agents if the final registration certificate is denied.

#### **Foreign Institutions**

For prime or subcontract awards to foreign institutions that possess, use, and/or transfer Select Agents under this contract, the foreign institution must:

- include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.
- when requested during negotiations, provide information satisfactory to the NIAID/NIH that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: [http://www.aphis.usda.gov/programs/ag\\_selectagent/FinalRule3-18-05.pdf](http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) for U.S. institutions are in place and will be administered on behalf of all Select Agent work under the resulting contract. The process for making this determination includes inspection of the foreign laboratory facility by an NIAID representative. During this inspection, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents.

An NIAID chaired committee of U.S. federal employees (including representatives of NIH grants/contracts and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will ultimately assess the results of the facility inspection, the regulations, policies, and procedures of the foreign institution for equivalence to the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at:

[http://www.aphis.usda.gov/programs/ag\\_selectagent/FinalRule3-18-05.pdf](http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf).

The committee will provide recommendations to the DEA Director, NIAID. The DEA Director will make the approval decision and notify the Contracting Officer. The Contracting Officer will inform the prime contractor of the approval status of the foreign institution. No NIH funds can be used for research involving Select Agents at a foreign institution until NIAID grants this approval.

#### **18. 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**

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.

19. **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/policies/FISMA-final.pdf>

a. Information Type

Administrative, Management and Support Information:

Mission Based Information:

b. Security Categories and Levels

Confidentiality Level:	<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
Integrity Level:	<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
Availability Level:	<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
<b>Overall Level:</b>	<input checked="" type="checkbox"/> <b>Low</b>	<input type="checkbox"/> <b>Moderate</b>	<input type="checkbox"/> <b>High</b>

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)

**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. Prospective Offeror Non Disclosure Agreement

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

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

**[ ] Level 6: Public Trust High Risk****[ ] Level 5: Public Trust - Moderate Risk**

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

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

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

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

## f. References

1. 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/policies/FISMA-final.pdf>
2. DHHS Personnel Security/Suitability Handbook: <http://www.hhs.gov/ohr/manual/pssh.pdf>
3. NIH Computer Security Awareness Training Course: <http://irtsectraining.nih.gov/>  
The following NIST publications may be found at the following site: <http://csrc.nist.gov/publications/>  
[Note: The search tool on the left side of this page provides easy access to the documents.]
4. NIST Special Publication 800-16, Information Technology Security Training Requirements; and Appendix A-D
5. NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems
6. NIST SP 800-26, Revision 1, Computer Security
7. NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems
8. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I; and Volume II, Appendices to Guide For Mapping Types of Information and Information Systems To Security Categories, Appendix C, and Appendix D
9. NIST SP 800-64, Security Considerations in the Information System Development Life Cycle
10. FIPS PUB 199, Standards for Security Categorization of Federal Information and Information Systems
11. FIPS PUB 200, Minimum Security Requirements for Federal Information and Information Systems

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 rational 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**

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.

**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 2007**

Offerors are advised that pursuant to P.L. 110-005\*\*, no NIH Fiscal Year 2006 (October 1, 2006 - September 30, 2007) 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. 110-005\*\* applies only to Fiscal Year 2007 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. 110-005\*\* 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/07tables/html/ex.asp>

**\*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 2007 Executive Level I Salary rates.

*\*\*Public Law 110-005, Revised Continuing Appropriations Resolution, 2007, extends the legislative provisions provided in the FY 2006 Appropriations Act (Public Law 109-149) through the end of FY 2007. Therefore, the provision that restricts the amount of direct salary to Executive Level I of the Federal Executive Pay Scale continues through FY 2007. The Executive Level I annual salary rate was \$183,500 for the period January 1 through December 31, 2006. Effective January 1, 2007, the Executive Level I salary rate increased to \$186,600.*

## 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 (SF 294 and SF 295) to the Government.
  11. List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

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

**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. 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.

## 9. 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.**

**Additional Note: No Government Furnished Property is offered for this acquisition.**

### 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)

**e. Facilities Capital Cost of Money, FAR 52.215-16, (June 2003)**

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

*(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.*

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

*(End of Provision)*

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

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

**[ ]Fac Cap Cost of Money (Has Not)** ***has not** specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.*

## 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 order of merit ranking 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 - TECHNICAL EVALUATION FACTORS

### 1. GENERAL

1. Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.
2. In addition, 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 points scores and written critiques. NIAID reserves the right to convene multiple SRG's to evaluate proposals.
3. The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
4. The final stage of the evaluation is the establishment of an Order of Merit Ranking in which all competing proposals are ranked on the basis of their respective relevance and scientific merit evaluations. Final selection of the awards will depend upon the availability of funds, scientific priority, and programmatic balance that the NIAID determine to exist at the time of award selection.
5. The estimated cost of an offer must be reasonable for the tasks to be performed, and, in accordance with FAR 15.305, and will be subject to a cost realism analysis by the Government.
6. Offerors must demonstrate in their proposals that they have the necessary expertise and capabilities for conducting the research as requested by this solicitation. 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 RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements and objectives of the RFP.

The evaluation will be based on the demonstrated capabilities for conducting the research as requested by this solicitation. 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. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements and objective of the BAA. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

### 2. HUMAN SUBJECT EVALUATION

This research project involves human subjects. NIH Policy requires:

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

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by 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 (for competitive proposals), 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.

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 (for competitive proposals), 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 (for competitive proposals), 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.

### **3. 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.

If your proposal does not include a plan or the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the order of merit ranking (for competitive proposals), or if the Government holds discussion with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered "unacceptable" by the Government after discussions, your proposal may not be considered for further award.

### **4. TECHNICAL EVALUATION CRITERIA**

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. Offerors and reviewers are advised to refer to Attachment 7 entitled "Technical Evaluation Factors" at the end of this BAA.

### **5. PAST PERFORMANCE FACTOR**

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the order of merit ranking. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the order of merit ranking on the basis of 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.

**6. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

**SDB participation will not be scored**, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government. The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the order of merit ranking. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform. Offers will be evaluated on the following sub-factors:

- a. Extent to which SDB concerns are specifically identified
- b. Extent of commitment to use SDB concerns
- c. 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.

## PACKAGING AND DELIVERY OF THE PROPOSAL

**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:

**"NIH-NIAID-BAA-08-11 Adjuvant Development Program"**

**"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>
Doris C. McClain Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20817	Doris C. McClain Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612

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

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

### 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>                      One (1) unbound SIGNED ORIGINAL.                      Six (6) unbound COPIES</p> <p><b><u>ELECTRONIC FILES ON CD</u></b>                      Three (3) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices)</p>	<b>Not to Exceed 200 pages (inclusive of all Attachments and Appendices)</b>
<b>Business Proposal</b>	<p><b><u>PAPER</u></b>                      One (1) unbound SIGNED ORIGINAL.                      Five (5) unbound COPIES</p> <p><b><u>ELECTRONIC FILES ON CD</u></b>                      Three (3) 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.</p> <p>See Section J, Attachment entitled <a href="#">Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet</a> to access the Excel Workbook.</p>	N/A

**PROPOSAL INTENT RESPONSE SHEET**

**RFP No.:** NIH-NIAID-BAA-DAIT-08-11

**RFP Title:** Adjuvant Development Program

Please review the attached Request for Proposal. Furnish the information requested below and return this page by **November 19, 2007**. 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: Doris C. McClain  
BAA-NIH-NIAID-DAIT-08-11  
FAX# (301) 402-0972  
Email: mcclainj@niaid.nih.gov

## **ATTACHMENT 3: BROAD AGENCY ANNOUNCEMENT DESCRIPTION**

### **ADJUVANT DEVELOPMENT PROGRAM BAA NIH-NIAID-DAIT-08-11**

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

You are invited to submit a proposal in accordance with the requirements of this BROAD AGENCY ANNOUNCEMENT (BAA) solicitation, BAA NIH-NIAID-DAIT-08-11, entitled "Adjuvant Development Program." The BAA is authorized by Federal Acquisition Regulation (FAR) 6.102 and further described in FAR 35.016 as well as the NIH Manual Issuance 6035, Broad Agency Announcements. A BAA is a general announcement of an agency's research interest. The intent of a BAA is to encourage the submission of creative and innovative approaches to specific research areas identified by the Government.

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

The Statement of Work, including the specific work requirements and performance specifications, is developed and defined by the Offeror, not the Government.

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

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

It is anticipated that multiple awards will result from this solicitation and these awards will be multi-year, cost-reimbursement, completion type contracts. The NIAID anticipates awarding 3-5 contracts based on technical merit, scientific priority, programmatic balance and the availability of funds. The maximum period of performance is limited to five (5) years.

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

## **ATTACHMENT 4: BACKGROUND and INTRODUCTION**

### **ADJUVANT DEVELOPMENT PROGRAM BAA NIH-NIAID-DAIT-08-11**

The National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) and other agencies in the Department of Health and Human Services (DHHS) support extramural research to develop new products to protect the public from the health consequences of biological agents that might be used in acts of bioterrorism and from emerging/re-emerging diseases, such as West Nile Virus, multi-drug resistant Tuberculosis, and Dengue Fever. The biological agents deemed to pose the greatest threat to civilian populations are prioritized in the NIAID Category A, B and C Priority Pathogens and toxins list, which is available at: [http://www3.niaid.nih.gov/Biodefense/bandc\\_priority.htm](http://www3.niaid.nih.gov/Biodefense/bandc_priority.htm).

The NIAID contributes to meeting the goals for host defense described in the NIAID Strategic Plan for Biodefense ([http://www3.niaid.nih.gov/Biodefense/Research/strat\\_plan.htm](http://www3.niaid.nih.gov/Biodefense/Research/strat_plan.htm)) by supporting the development of new candidate vaccine adjuvants that stimulate the innate immune response to: protect against pathogenic infection; specifically activate the appropriate arms of the immune response; and result in stronger, more protective vaccines against NIAID Category A, B, and C Priority Pathogens.

Currently, aluminum hydroxide/aluminum phosphate (alum) is the only licensed adjuvant for general human use in the United States. Although it has been utilized for decades, alum does not enhance immune responses to every vaccine, and therefore is not a universally effective adjuvant. Many recent findings have linked adjuvant activity with the capacity to stimulate the innate immune system effectively. Innate immunity forms the front line of defense against infection, and plays a critical role in the development of adaptive immune responses to a pathogen or vaccine, primarily by activating dendritic cells and other antigen-presenting cells (APC) to express costimulatory molecules and to take up, process, and present foreign proteins in the context of self Major Histocompatibility Complex molecules to T cells. Activation of APC through different innate immune receptors appears to shape adaptive immunity for appropriate responses to different pathogens, a capability not readily achieved with alum in many cases. A panel of adjuvants is required to stimulate the most beneficial and safe responses to a diversity of microorganisms.

Significant progress has been achieved in the last decade in defining the mammalian innate immune response to pathogens and vaccines. Host proteins such as Toll-Like Receptors (TLRs), Nod-Like Receptors, and RNA helicases are able to recognize prokaryotic pathogens and to subsequently direct an immediate innate immune response consisting of cytokines, anti-microbial peptides, and activated macrophages, dendritic cells and NK cells. TLR activation can enhance an appropriate adaptive immune response by B and T cells that can lead to immunological memory. Thus, innate immune activity forms the basis for development of new vaccine adjuvants tailored to stimulate a safe and protective immune response against specific pathogens or pathogen classes.

Clinical trials have already begun for a few novel adjuvants such as oligodeoxynucleotides (ODN), which stimulate TLR9 activation; and 4'-monophosphoryl Lipid A (MPL), which stimulates TLR4 activation. In an effort to promote the discovery of additional potential immune-stimulating molecules, the NIAID established a program in 2003 to support high throughput screening to identify and optimize lead candidates for adjuvant development (Innate Immune Receptors and Adjuvant Discovery, 2003, RFP NIH-NIAID-DAIT-BAA-03-41). Five contracts were

awarded in fiscal year 2004 and are currently developing lead candidates for adjuvants that stimulate innate immunity. Participation in the Innate Immune Receptors and Adjuvant Discovery program is not a pre-requisite to be eligible to submit a proposal in response to this solicitation.

The purpose of this solicitation is to establish a new Adjuvant Development Program to advance a novel class of vaccine adjuvants towards licensure for human use. This novel class of adjuvants stimulates the innate immune response and demonstrates strong adjuvant properties in animal models. These candidate vaccine adjuvants will be developed for human use with currently licensed or new investigational vaccines, to protect against NIAID Category A, B, or C Priority Pathogens. This initiative supports the development of candidate vaccine adjuvants through immunological characterization studies, lead compound optimization, and/or Investigational New Drug (IND)-enabling studies, for a period not to exceed five (5) years. Proposals are required to include studies on at least one Category A, B, or C Priority Pathogen. In addition, studies on other human infectious pathogens may be included with sufficient justification of an ultimate application to Biodefense. Studies with HIV will not be supported.

Candidate vaccine adjuvants eligible for support must meet the following requirements: (1) the adjuvant has been previously identified and characterized as safe; (2) functions by activating the innate immune system; (3) there is documented evidence that demonstrates a mechanism of action for the adjuvant; (4) the proposed Product Development Plan will significantly advance the development of the candidate adjuvant within the five-year period of contract performance; and (5) where possible, the adjuvant has been shown to safely augment the ability of a vaccine to protect against a NIAID Category A, B, or C Priority Pathogen upon pathogen challenge in an *in vivo* animal model.

The NIAID reserves the right to award all or any portion of the activities proposed based on technical merit, scientific priority, programmatic balance, and the availability of funds.

Furthermore, the NIAID recognizes that product development is an iterative process and that the progress of a candidate vaccine adjuvant through the development pathway requires ongoing evaluation to assess and reassess the likelihood that the candidate adjuvant will meet the ultimate clinical objectives. The NIAID, therefore, reserves the right to determine, at any time during the contract period, that a particular candidate vaccine adjuvant has not demonstrated sufficient potential to merit further investment by the NIAID in the development and evaluation of that candidate. The NIAID reserves the right to modify the milestones, process, schedule, or budget; to add or delete process or schedule as need may arise. Because of the nature of this contract and complexities inherent in this and prior programs, at designated milestones the NIAID will evaluate whether work should be redirected, removed, or whether schedule or budget adjustments should be made. In any event, the NIAID reserves the right to change process, schedule, or event, to add or delete part or all of these elements as needed.

The NIAID is aware that no single organization or institution may have the expertise and facilities required to perform all parts of their Statement of Work. Therefore, it may be necessary for the Contractor to subcontract a portion of the work. The Contractor shall be responsible for ALL work performed under this contract including that performed by any subcontractor(s).

## ATTACHMENT 5: RESEARCH AND TECHNICAL OBJECTIVES

### ADJUVANT DEVELOPMENT PROGRAM BAA NIH-NIAID-DAIT-08-11

#### RESEARCH and TECHNICAL OBJECTIVES

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

#### (I) SCOPE:

The overall objective of the contracts awarded under this BAA is to further develop promising vaccine adjuvant candidates known to function by signaling through receptors of the innate immune system.

- (A) For the purposes of this solicitation, candidate vaccine adjuvants eligible for support must meet the following requirements:
- (1) The candidate vaccine adjuvant has been previously discovered, identified and characterized to stimulate the innate immune response.
  - (2) There is documented evidence that demonstrates a mechanism of action for the candidate vaccine adjuvant and describes a profile of immunological responses stimulated by the adjuvant.
  - (3) The candidate vaccine adjuvant safely augments the ability of a vaccine against a NIAID Category A, B, or C Priority Pathogen to produce protective immunity as shown by pathogen challenge in an *in vivo* animal model. The evidence of protection must be obtained from studies performed under well-controlled and documented experimental conditions, with a statistically significant better outcome than found under appropriate control conditions. If protection studies have not been conducted because appropriate containment facilities are not available, evidence of immune responses to the candidate vaccine adjuvant that may be surrogates of immune responses for the protection *in vivo* will be acceptable.
- (B) The Offeror shall propose a well-defined and feasible Product Development Plan that advances the development of one candidate vaccine adjuvant toward licensure for human use within the five-year contract period of performance through carrying out one or more of the following activities as specified in the negotiated Statement of Work:
- (1) optimization of one candidate compound for enhanced safety and efficacy;
  - (2) establishment of an immunological profile of activity and immunotoxicity that will be of use to evaluate the capability of the candidate vaccine adjuvant to advance to human testing;
  - (3) preclinical IND-enabling studies;
  - (4) pilot lot manufacturing of cGMP adjuvant or adjuvant:vaccine combinations for IND-enabling studies.
- (C) Proposals may be submitted for more than one candidate vaccine adjuvant; however, separate Technical and Business Proposals are required for each candidate vaccine adjuvant.

**(D) NOTE: Contracts awarded under this solicitation will NOT support:**

- **The design and conduct of clinical trials (see <http://www.niaid.nih.gov/ncn/glossary/default2.htm#clintrial> for the NIH definition of a clinical trial).**
- **The discovery and initial characterization of adjuvant candidates.**
- **The development of HIV candidate adjuvant or vaccines.**
- **The discovery or development of adjuvants or vaccines to treat cancer or allergic or autoimmune diseases.**
- **Platform development such as vehicle or delivery systems.**
- **The development and/or optimization of a pathogen-specific vaccine component.**

(E) Upon completion of the proposed work, Contractors may apply for clinical trial support through independent NIH grant mechanisms such as the Small Business Innovation Research (SBIR) program (<http://grants.nih.gov/grants/guide/pa-files/PA-07-280.html>) or the NIAID Clinical Trial Planning Grant (R34) program (<http://grants.nih.gov/grants/guide/pa-files/PAR-06-384.html> )

**(II) TECHNICAL REQUIREMENTS:**

The Contractor shall be required to perform the following activities and provide the following resources as appropriate to the scope of the negotiated Statement of Work.

**(A) Product Development Plan**

Provide a Product Development Plan (PDP) for the candidate vaccine adjuvant selected for further development and its intended use and specifications, approaches for carrying out each stage of the overall product development pathway, and clearly defined milestones and timelines necessary to complete and deliver a candidate vaccine adjuvant suitable for clinical studies within the 5-year contract period of performance.

**(1) Product Development Plan – Overview** shall include:

- (a) The intended use/indication for the candidate vaccine adjuvant and the biodefense/public health gap the candidate vaccine adjuvant is intended to fill.
- (b) The intended product profile including potential stability, bioavailability, dosing and safety.
- (c) The performance specifications and features the candidate vaccine adjuvant should have in order to provide immunological protection.
- (d) A description of the candidate vaccine adjuvant as it is currently configured and evaluation of its potential for further development.
- (e) A description of vaccine(s) chosen for study with the candidate vaccine adjuvant, and the rationale for the choice of vaccine(s) selected.
- (f) Evidence to support the characterization and selection of the candidate adjuvant for further development. Specifically, supporting evidence shall include:
  - (i) A summary of data that demonstrate that the candidate vaccine adjuvant safely augments the ability of a vaccine against a NIAID Category A, B, or C Priority Pathogen or other model pathogens to produce protective immunity as shown by pathogen challenge in an *in vivo* animal model. The evidence of protection must be obtained from studies performed under well-controlled and documented experimental conditions, with a statistically significant better outcome than found under appropriate control conditions.

- (ii) A detailed description of the relevant assays, animal models, and pathogens.
- (iii) The rationale for the choice of animal model, adjuvant candidate, pathogen challenge protocol, strain and route, as well as for the outcome/endpoints selected.
- (iv) Data that the candidate vaccine adjuvant is safe.
- (g) Evidence of approval and clearance of facilities and personnel for utilizing the selected pathogen(s).
- (h) Documentation of availability of the candidate vaccine adjuvant, vaccine, and other materials required to carry out the research provided for in the negotiated Statement of Work. Examples of demonstrated access include, but are not limited to letters of commitment or commercial availability.
- (i) Summaries of discussions with the FDA, if any, that are relevant to the development activities for the proposed candidate adjuvant through the submission of an IND application. Summaries should include any key agreements, correspondence, and requirements that resulted from discussions with the FDA.

## (2) Product Development Plan – Technical Approach

(a) The Technical Approach shall include:

- (i) Activities and stages of candidate vaccine adjuvant development to be carried out with contract funding including the milestones to be met at each stage of the Product Development Plan.
- (ii) Key development objectives for each developmental stage.
- (iii) Clearly defined decision points during the product development process where proceed or not to proceed (“Go/No Go”) decisions will be made. These should be distinct stages of the product development pathway that are critical decision points for Go/No Go decisions for advancing to the next stage of the Product Development Plan. For each decision point, also delineate the qualitative and quantitative criteria and accompanying data elements to be used to assess the merit and feasibility of proceeding to the next stage of product development.
- (iv) A detailed discussion of the technical approach to achieve the project objectives, with sufficient detail to fully explain and justify the scientific/technical rationale for the proposed approach, experiments, and methodologies, reflecting a clear understanding of the scope and nature of the work being undertaken.
- (v) A detailed Gantt Chart organized by each specific stage of product development, with milestones. Schedules shall be shown in terms of where each stage fits into the overall timeline of the project.
- (vi) Approaches to integrate adverse experimental or production results or new scientific findings into the proposed goals and timelines.
- (vii) A budget of direct costs for each stage of product development proposed for funding, linked to a timeline for completion of each stage; and a budget of direct costs for each subcontract, listed by activity (e.g., animal challenge studies, cGMP manufacture, IND-enabling toxicological studies).

(b) Although it is the responsibility of the Offeror to propose a Statement of Work, **EXAMPLES** of the types of product development activities that are within the scope of this BAA include:

- (i) Research and Development: design, conduct and complete all non-clinical research and development studies to:
  - Evaluate the safety, pharmacokinetics/pharmacodynamics, bioavailability, formulation, dose, route of administration, and dose schedule of the candidate adjuvant:vaccine combination, including *in vitro* and *in vivo* testing in animal model(s), including non-human primates if appropriate, following FDA guidance

and Good Laboratory Practice guidelines (GLP: as defined in the U.S. Code of Federal Regulations- 21CFR:58). FDA guidance for non-clinical studies may be found at the following sites: <http://www.fda.gov/cber/gdlns/reprotox.htm> and <http://www.fda.gov/cber/gdlns/dvpexcp.htm>. Animal studies must comply with the requirements as stated in the U.S. Code of Federal Regulations – CFR 601.90-95, Subpart H, “Approval of Biological Products When Human Efficacy Studies Are Not Ethical or Feasible.”

- Develop, characterize, and qualify and/or validate reagents and assays required for evaluation of the candidate adjuvant:vaccine combination.
- Establish immunological parameters and methods to predict and evaluate safety and efficacy *in vitro* and in human subjects.
- Modify the candidate vaccine adjuvant to improve its immunological activity and reduce potential toxicity in humans.

(ii) Process Development and Pilot Lot Manufacturing

- Develop and establish master and working cell banks in compliance with current Good Manufacturing Practices guidelines (cGMP: as defined in the U.S. Code of Federal Regulations-21 CFR:58, 210, 211, 610, 820 and applicable guidance's, such as Draft Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals (1993) (<http://www.fda.gov/cber/gdlns/ptccell.pdf>)).
- Conduct process development activities that lead to the manufacture of cGMP grade candidate vaccine adjuvant and candidate adjuvant: vaccine combination.
- Establish a well-documented and controlled production process.
- Manufacture non-cGMP pilot lots to demonstrate the reliability and reproducibility of the production process, and produce cGMP pilot lots of the candidate adjuvant and the candidate adjuvant:vaccine combination in amounts sufficient to carry out required non-clinical studies.
- Conduct long-term stability studies of cGMP candidate vaccine adjuvant or candidate adjuvant: vaccine.

Within 14 calendar days of the effective date of the contract, the Contractor shall submit, for review and approval by the Project Officer and Contracting Officer, an updated Product Development Plan. The updated Product Development Plan shall be revised, in accordance with Project Officer comments, within 14 calendar days of receipt of Project Officer comments. Implementation of the activities provided for in the approved Product Development Plan shall be initiated no later than 7 calendar days after receipt of Project Officer and Contracting Officer approval. The Product Development Plan shall be updated annually and upon any change in stage or milestone. Annual updates and changes to the Product Development Plan shall be approved by the Project Officer and Contracting Officer.

### **(3) Product Development Plan - Regulatory Compliance, Quality Assurance and Data Management Systems**

As required for the implementation of the Product Development Plan, the Contractor shall:

- (a) Ensure strict adherence to FDA regulations and guidance, including requirements for the conduct of animal studies and assays under GLP and the manufacturing of the candidate vaccine adjuvant or candidate adjuvant:vaccine combination under cGMP. The Contractor shall maintain quality assurance documentation to support adherence in these areas.
- (b) Arrange for independent regulatory audits, as needed or as requested by the Project Officer and the Contracting Officer. Audits may be requested to ensure that Contractor and/or subcontractor facilities and all planned procedures comply with the FDA regulations and guidance that are required to meet GLP and cGMP standards. In addition,

the Contractor shall ensure that all Contractor and/or subcontractor records and staff are available for site visits or audits. The Contractor shall provide interim and final audit reports to the Project Officer and the Contracting Officer within thirty (30) calendar days of the completion of the audit. The NIAID reserves the right to conduct independent audits of the Contractor and its subcontractors as needed to evaluate compliance with the FDA regulations and guidance, including those required to meet GLP and cGMP standards.

- (c) Be responsible for the development and implementation of data management and quality control systems/procedures, including the transmission, storage, confidentiality, and retrieval of all study data.
- (d) Provide for the statistical design and analysis of data resulting from the research undertaken.
- (e) Provide raw data or specific analyses of data generated with contract funding to the Project Officer.

## **(B) SCIENTIFIC AND TECHNICAL PERSONNEL**

The Contractor shall provide a scientific and technical team of investigators with the expertise needed for the implementation of the Product Development Plan to be performed under this contract, including research, manufacturing, regulatory, statistical, management, and administrative activities. The Contractor's team must include strong scientific leadership, as well as significant experience and expertise in the management, design, and execution of a research and development program focused on product development, manufacturing, and testing in vertebrate animals.

## **(C) PROJECT MANAGEMENT**

The Contractor shall provide:

### **(1) Overall Project Management**

- (a) The overall management, integration, and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, direction, and completion of all contract activities.
- (b) A plan for effective communication with the Project Officer and the Contracting Officer.
- (c) A Principal Investigator (PI) with responsibility for overall project management and communication, tracking performance and cost, monitoring and reporting on project status and progress, and recommending modifications to project requirements and timelines, including projects undertaken by subcontractors.
- (d) A Project Manager with responsibility for monitoring and tracking day-to-day progress and timelines, and coordinating communication, project activities, and costs incurred.
- (e) Administrative staff with responsibility for financial management by the Contractor and any subcontractors.

### **(2) Intellectual Property Agreements**

The Contractor shall be solely responsible for the timely acquisition of all appropriate proprietary rights, including intellectual property rights, and all materials needed to perform the project. Before, during, and subsequent to the award, the U.S. Government is not required to obtain for the Contractor any proprietary rights, including intellectual property rights, or any materials needed by the Contractor to perform the project. The Contractor is required to report to the U.S. Government all inventions made

in the performance of the project, as specified at FAR 52.227-11 (Bayh-Dole Act). Contractors are encouraged to reach early consensus with any proposed partners regarding any appropriate intellectual property or other legal issues that may arise during the project. In addition, Contractors are expected to exercise their Bayh-Dole rights in a manner that does not conflict with the goals of this award or the intent of the Bayh-Dole Act to promote the utilization, commercialization and availability of U.S. Government-funded inventions for public benefit. Finally, Contractors are expected to make new information and materials known to the research community in a timely manner through publications, web announcements, and reports to the NIAID or other mechanisms consistent with laws, regulations, and NIH policies.

### (3) Reports and Deliverables

The Contractor shall prepare and provide all reports and other deliverables listed in the "Reporting Requirements and Other Deliverables" section of this BAA as they relate to the Contractor's specific Statement of Work. The Contractor, the Project Officer, and the Contracting Officer shall agree in the final contract negotiations on which reports and deliverables are relevant to the awarded contract Statement of Work and shall, therefore, be required as deliverables.

## **(D) FACILITIES, EQUIPMENT, TRAINING AND OTHER RESOURCES**

The Contractor shall provide the equipment, facilities, training and other resources required to implement the Product Development Plan in compliance with all Federal and NIH regulations. Depending on the stage of development of the candidate vaccine adjuvant, this may include:

- (1) The performance of IND-enabling assays and animal studies under GLP.
- (2) Production, characterization and release testing of the candidate adjuvant or the candidate adjuvant:vaccine combination under cGMP conditions.
- (3) The care and housing of laboratory animals, including appropriate veterinary coverage, the physical plant housing all animals and laboratories, and required safety procedures.
- (4) Adherence to NIH regulations on the use of human subjects.
- (5) The use of facilities and resources to conduct work in accordance with the Biosafety Level (BSL) 2 and 3 guidelines (<http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm>) and in accordance with the Biosafety in Microbiology and Biomedical Laboratories (BMBL) Guidelines, Centers for Disease Control and Prevention and the National Institutes of Health, fifth Edition <http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm>.
- (6) The handling, storing, and shipping of potentially dangerous biological and chemical agents, including Select Agents, under biosafety levels required for working with the biological agents under study. The Biosafety in Microbiology and Biomedical Laboratories, 5<sup>th</sup> edition is available at: <http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm>. The Centers for Disease Control and Prevention (CDC) Select Agent program can be found at: <http://www.cdc.gov/od/sap>.

The Contractor is required to undertake all studies with approval from its Institutional Biosafety Committee. The Contractor shall provide copies of materials submitted for Institutional Biosafety Committee Review and documentation of approval of experiments to the Project Officer with each annual report.

## **(E) CONTRACT REVIEW MEETINGS**

- (1) Annual Review Meetings

At the end of each contract year, the Project Officer will plan, conduct and be responsible for logistical arrangements for an annual review meeting of all Contractors, to be held at a site chosen by the Project Officer. All Contractor PIs, Project Managers, key investigators including subcontractor personnel, the Project Officer, the Contracting Officer, and other designated NIAID staff shall attend these meetings. The Project Officer may invite other Extramural Program Staff from NIH to attend these meetings. The agenda will be prepared by the Project Officer. Meetings will be closed to the general public and shall involve oral and electronic presentations by the Contractors, including: updates on results of activities undertaken or completed since the last review meeting; updates on the predicted timeline, including an updated Gantt chart; a description of any problems encountered or anticipated; a discussion of approaches to overcoming problems; and a description of activities to be undertaken in the coming year.

## (2) Site Visits

Within sixty (60) calendar days of the effective date of the contract, the Contractor shall plan, conduct and be responsible for the logistical arrangements for a post-award kick-off meeting at the Contractor's site. The Principal Investigator, Project Manager, all key investigators, key subcontractor personnel, the Project Officer and the Contracting Officer shall attend this meeting. Other NIAID staff, as designated by the Project Officer, may also attend this meeting. The purpose of this meeting shall be to review the Product Development Plan and to coordinate activities and communication between the Contractor and the NIAID. The PI shall provide a copy of any slide presentations to the Project Officer. The Contracting Officer and Project Officer may request site visits at the Contractor site(s) annually or as needed.

## (3) Quarterly Teleconferences

The Contractor shall plan and conduct a teleconference meeting with the Project Officer each quarter of the contract period of performance, to discuss technical progress and financial invoices. One (1) week prior to the teleconference, the Contractor shall submit an agenda to the Project Officer. Within one (1) week after the teleconference, the Contractor shall provide a meeting summary of the teleconference to the Project Officer. The timing of the Quarterly Teleconference meetings may be altered or adjusted by the Project Officer as needed to address progress on the contract.

## (4) Additional Contract Meetings/Teleconferences

The Principal Investigator, Project Manager, key investigators, and key subcontractor personnel shall attend additional meetings or teleconferences at the request of the Project Officer. Such meetings will be requested, as necessary, to discuss contract specific issues and to review recommended changes or deviations from milestones and timelines in the Product Development Plan.

## **(F) PUBLICATIONS**

Any manuscript or scientific meeting abstract containing data generated under this contract shall be submitted for Project Officer review no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts before submission for public presentation or publication. NIAID contract support shall be acknowledged in all such publications. A "publication" is defined as an issue of printed or electronic material offered for distribution or any communication or oral presentation of information. The Project Officer will review all manuscripts and abstracts in a period of time not to exceed thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstract from receipt, and will either agree to

the publication/disclosure or recommend changes. If Project Officer comments are not provided within these timelines, the Contractor may proceed with public presentation or publication.

**(G) IT AND NETWORK SYSTEMS**

Provide and maintain a secure, internal IT systems and network architecture, software development environment and computational infrastructure to support the data and computational needs of the activities conducted under the Adjuvant Development Program. The Contractor's institution's security policies and guidelines must be followed. Provide a System Security Plan (SSP) of the program infrastructure to the Project Officer within 3 months of contract award. A template for the SSP can be found in NIST Special Publication SP-800-37 Guide for the Security Certification and Accreditation of Federal Information Systems (<http://www.csrc.nist.gov/publications/nistpubs/800-37/SP800-37-final.pdf>).

## ATTACHMENT 6: REPORTING REQUIREMENTS AND OTHER DELIVERABLES

### ADJUVANT DEVELOPMENT PROGRAM BAA NIH-NIAID-DAIT-08-11

#### 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 and two (2) hardcopies to the Project 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) Quarterly Teleconference Agenda and Minutes

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 quarter of performance plus any fractional part of the initial month. Thereafter, the reporting period shall be quarterly.

On a date and time agreed upon by the Contractor and the Project Officer, the Contractor shall conduct a teleconference meeting with the Project Officer each quarter until the end of the contract to review technical progress and financial invoices. One (1) week before the teleconference, the Contractor shall deliver an agenda to the Project Officer. Within one (1) week after the teleconference, the Contractor shall provide minutes of the teleconference to the Project Officer. The timing of the Quarterly Teleconference meetings may be altered or adjusted by the Project Officer as needed to address progress on the contract.

##### (2) Quarterly Technical Progress Written Report shall include the following sections:

- a) A Cover page that includes the contract number and title; the type of report and period covered; the Contractor's name, address, telephone number, fax number, and email address; and the date of submission.
- b) SECTION I - An Introduction covering the purpose and scope of the contract effort.

- c) SECTION II – PROGRESS
  - i) SECTION II Part A: OVERALL PROGRESS - A brief summary of the overall progress.
  - ii) SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A summary of all meetings, teleconferences, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating, and managing subcontractor performance).
  - iii) SECTION II Part C: TECHNICAL PROGRESS - For each activity, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project.
  - iv) SECTION II Part D: PROPOSED WORK - A summary of work proposed for the next reporting period; including any updates to the Product Development Plan.
  - v) References of directly related papers and abstracts published that quarter.
  - vi) A summary of any inventions developed or patents filed during the quarter.

A Quarterly Technical Progress Report shall not be required in the same month that the Annual Technical Progress Report is submitted.

**(3) Annual Technical Progress Report shall include the following sections:**

- a) A Cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and email address; and the date of submission.
- b) SECTION I: EXECUTIVE SUMMARY - A brief overview of the work completed, and the major accomplishments achieved during the current reporting period.
- c) SECTION II – PROGRESS
  - i) SECTION II Part A: OVERALL PROGRESS - A brief summary of the overall progress.
  - ii) SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, teleconferences, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating and managing subcontractor performance; regulatory compliance audits).
  - iii) SECTION II Part C: TECHNICAL PROGRESS - A detailed description of the work performed, structured to follow the activities and milestones outlined in the approved Product Development Plan. Any problems (technical or financial) that occurred or were identified during the reporting period, and how these problems were resolved.
  - iv) SECTION II Part D: PROPOSED WORK - A summary of work proposed for the next year period; including any updates to the Product Development Plan.
  - v) References of published manuscripts and abstracts, and copies of any protocols or methods developed specifically under the contract during the reporting period.
  - vi) A summary of any inventions developed and patents filed during the course of the contract year.

An Annual Technical Progress Report shall not be required at the time that the Final Technical Progress Report is submitted.

**(4) Draft Final Technical Progress Report and Final Technical Progress Report**

The Draft Final and Final Technical Progress Reports shall document and summarize the results of the entire contract period of performance. These reports shall conform to the following format:

- a) Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address and submission date.
- b) SECTION I: EXECUTIVE SUMMARY – Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.
- c) SECTION II: RESULTS - A detailed description of the work performed, the results obtained, and the impact of the results on the scientific and/or public health community, including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance, and a summary of all patents and inventions.

**(5) Draft Final Technical Progress Report**

The Contractor is required to submit the Draft Final Progress Report to the Project Officer and Contracting Officer one hundred-twenty (120) calendar days before the completion date of the contract. The Project Officer and Contracting Officer will review the Draft Final Progress Report and provide the Contractor with comments within forty-five (45) calendar days after receipt.

**(6) Final Technical Progress Report**

The Contractor shall deliver the Final Technical Progress Report as specified in the Article F.1 within **thirty (30) calendar days** before the completion date of the contract.

**(7) Summary of Salient Results**

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

**(8) 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) .

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 and Deliverables**

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.

### **(1) Audit Reports**

Within thirty (30) calendar days of completion of an audit related to conformance to FDA regulations and guidance, including adherence to GLP and cGMP guidelines, the Contractor shall provide copies of the audit report and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP and cGMP guidelines as identified in the final audit report.

### **(2) Updated Product Development Plan**

The Contractor shall be required to update the Product Development Plan to incorporate progress since the submission date of the proposal. Within fourteen (14) calendar days after the award date of the contract, the Contractor shall submit an updated Product Development Plan for approval, unless otherwise negotiated with the Project Officer and the Contracting Officer.

### **(3) Copies of FDA Correspondence and Meeting Summaries**

Within thirty (30) calendar days of receiving correspondence from or meeting with the FDA, submit copies of the correspondence or meeting minutes/summaries to the Project Officer.

### **(4) Invention Report Requirement**

The Contractor shall submit all reports and documentation required by FAR Clause 52.277-13 to the Officer of Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Dr., Rm. 1040A, MSC 7980, Bethesda, MD 20892-7980 (telephone 301-435-1986). Examples of reports and documents include, but are not limited to the invention disclosure report, the confirmatory license, and the government support certification. In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the NIAID Contracting Officer. The final invention statement (see FAR 27.303 (a) (2)(ii)) shall be submitted not later than the expiration date of the contract to the NIAID Contracting Officer.

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

### **(6) 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.

**System Security Plan**

Unless otherwise specified herein, the Contractor shall deliver to the Government, within 3 months of contract award, a System Security Plan for the IT infrastructure used to meet the requirements of this contract. The plan should detail, at minimum, the architecture, policies, procedures, and interconnections of the infrastructure.

**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]:

**Article F. Technical Progress Reports**

Item	Reports	Recipients	Delivery Schedule
1.	Quarterly Teleconference Agenda and Minutes	1 electronic copy to the PO	The agenda is due one week before each teleconference. The minutes are due within one week after the teleconference
2.	Quarterly Technical Progress Report	1 original to CO 2 paper and 1 electronic copy to PO	The 15 <sup>th</sup> of the month following each reporting period. First report is due following the third full month of contract performance. Quarterly Technical Progress Reports shall not be required when an Annual Technical Progress Report is due.
3.	Annual Technical Progress Report	1 Original to CO 2 hard copies to PO 1 electronic copy to PO	15 <sup>th</sup> of the month following the end of each 12 month performance period. The Annual Technical

		and CO	Progress Report shall not be required when the Final Technical Progress Report is due.
4.	Draft Final Technical Progress Report	1 Original to CO 2 hard copies to PO 1 electronic copy to PO and CO	120 calendar days prior to completion date of the contract
5.	Final Technical Progress Report	1 Original to CO 2 hard copies to PO 1 electronic copy to PO and CO	Due within 30 days of the completion date of the contract
6.	Summary of Salient Results	1 hard copy to PO 1 original to CO 1 electronic copy to PO and CO	Due within 30 days the completion date of the contract with the Final Technical Progress Report
7.	Annual Technical Progress Report for Clinical Research Study Populations	1 Original to CO 2 hard copies to PO 1 electronic copy to PO and CO	Due on/before the 15 <sup>th</sup> of the month following each anniversary date of the contract
8.	Final Invention Statement	1 copy to CO	Due on/before completion date of the contract
9.	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.

## B. Other Reports

Item	Deliverables	Recipient	Delivery Schedule
1.	Audit Reports	1 Original to CO 2 hard copies to PO 1 electronic copy to PO and CO	Within 30 calendar days of the audit.
2.	Updated Product Development Plan	1 Original to CO 2 hard copies to PO 1 electronic copy to PO and CO	Within 14 calendar days after contract award
3.	FDA Correspondence and Meeting Summaries	1 Original to CO 2 hard copies to PO 1 electronic copy to PO and CO	Within 30 calendar days of receiving correspondence or meeting with the FDA
4.	System Security Plan	1 hard copy to PO, CO 1 electronic copy to PO, CO	Due within 3 months from contract award. An update is due within 1 month after any major change to the infrastructure.

## (C) Other Deliverables

- 1) Samples of Candidate Vaccine Adjuvant: The Contractor may be required to submit samples of non-cGMP candidate vaccine adjuvants alone and in combination with the vaccines proposed in the Statement of Work, and cGMP material manufactured with contract funding. The Contractor will be advised by the Project Officer if samples are to be submitted.
- 2) Animal Models: Technology Transfer packages that include complete protocols and critical reagents for animal models developed and/or improved with contract funding must be submitted at the request of the Project Officer.
- 3) Other Reports: the Project Officer may request copies of other reports generated during the contract period related to performance of the contract, including: Process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, and Certificate of Analysis.
- 4) Institutional Biosafety Approval: The Contractor shall provide documentation of materials submitted for Institutional Biosafety Committee Review and documentation of approval of experiments at the request of the Project Officer.
- 5) Data: the Contractor shall provide raw data or specific analyses of data generated with contract funding at the request of the Project Officer.

**ATTACHMENT 7: SECTION M - TECHNICAL EVALUATION FACTORS**

**ADJUVANT DEVELOPMENT PROGRAM  
BAA NIH-NIAID-DAIT-08-11**

**GENERAL**

The final stage of the evaluation is the establishment of an Order of Merit Ranking in which all competing proposals are ranked on the basis of their respective relevance and scientific merit evaluations. Final selection of awards will depend upon the availability of funds, scientific priority, and programmatic balance that the NIAID determines to exist at the time of award selection.

**PRE-AWARD SITE VISIT OR SITE AUDIT**

Offerors determined, upon completion of the scientific/technical peer review, to be in the Order of Merit Ranking may be subject to auditing of their facilities and 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 a factor 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.**

**TECHNICAL EVALUATION CRITERIA:**

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

OFFERORS AND REVIEWERS ARE ADVISED TO REFER TO – Attachment 8-Additional Technical Proposal Instructions – OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATION RELATED TO THE PREPARATION OF TECHNICAL PROPOSALS.

Proposals submitted in response to this BAA will be evaluated based on the following factors, as they are relevant to the Offeror's specific Statement of Work, weighted according to their relative importance.

**CRITERIA**

**WEIGHT**

**CRITERION 1: PRODUCT DEVELOPMENT PLAN**

**(A+B) =55**

**A. PRODUCT DEVELOPMENT PLAN – OVERVIEW, TECHNICAL APPROACH, and REGULATORY COMPLIANCE, QUALITY ASSURANCE AND DATA MANAGEMENT (45)**

**1) Overview:**

- a. The suitability of the proposed candidate vaccine adjuvant for further development with a vaccine as described in the Product Development Plan Overview, (e.g. the biodefense/public health gap that is being addressed, demonstrated safety and efficacy in animal models, likelihood of safety and efficacy in man, potential for licensure for a treatment indication).

- b. The soundness of the assays used and the preliminary data to support the efficacy of the proposed candidate adjuvant in an appropriate animal model.
- c. The soundness and feasibility of the Product Development Plan for advancing the candidate adjuvant toward a licensed product.

**2) Technical Approach:**

- a. The soundness, appropriateness, and feasibility of the technical approaches and methods proposed in the Product Development Plan – Technical Approach (e.g. immune profiling studies, protection studies, medicinal chemistry, manufacturing, assay development, performance of animal studies, IND-enabling activities) for advancing the candidate adjuvant toward a licensed product,
- b. Clarity of defined decision points and criteria for Go/No Go decisions along the product development pathway.
- c. The feasibility of performing the proposed activities within the stated timelines for initiation, conduct, completion, and analysis of data.
- d. The suitability and feasibility of the plans for changing the Product Development Plan based on adverse experimental or production results, or on new scientific findings along the development path.

**3) Regulatory Compliance, Quality Assurance and Data Management:** The suitability and adequacy of the plans for regulatory compliance, quality assurance and data management for the conduct of activities proposed in the Product Development Plan; and adequacy of previous experience of the Offeror and any proposed subcontractors in conducting studies in compliance with GLP and cGMP guidelines as documented by the Offeror and provision of audit history and reports.

**B: PROPOSED STATEMENT OF WORK** (10)

- 1) The adequacy of the Statement of Work to describe all the necessary activities, services, personnel, materials, equipment, and facilities to be provided by the Offeror and any proposed subcontractors to perform the proposed work.
- 2) The suitability, completeness, and timeliness of the list of deliverables provided in the Statement of Work and the description of the deliverables to be provided to the Government during the performance of the contract.

**CRITERION 2: SCIENTIFIC AND TECHNICAL PERSONNEL** 25

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

- 1) Principal Investigator (PI): Appropriateness of the documented qualifications, knowledge, experience, education, competence, and availability of the PI to carry out the proposed Statement of Work.
- 2) Scientific and Technical Personnel: Appropriateness of the documented qualifications, knowledge, experience, education, competence and availability of the Project Manager and all proposed scientific and technical personnel, including proposed subcontractors, with respect to manufacturing, regulatory, pharmacology, toxicology, animal models, statistical analysis, assay development, management, and administrative duties as described in the proposed Statement of Work.

**CRITERION 3: PROJECT MANAGEMENT** 10

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

- 1) Adequacy of the Project Management Plan in terms of staffing, organization, responsibilities, leadership, and lines of authority.

- 2) Suitability of systems proposed for tracking project activities and monitoring progress, timelines, milestones, and budgets.
- 3) Suitability of the plan for how the PI will communicate with the Project Officer and the Contracting Officer, as well as establish lines of communication between all performance sites and activities.
- 4) Suitability of the plan for soliciting, evaluating, negotiating, awarding, and managing any proposed subcontracts in accordance with Federal regulations.
- 5) Adequacy of the plan to identify and remediate problems in subcontractor performance.

**CRITERION 4: FACILITIES, EQUIPMENT AND OTHER RESOURCES**

**10**

As required and/or appropriate for the Offeror's proposed Statement of Work, assess the availability and adequacy of facilities, equipment, biocontainment facilities (as needed), and other resources to suitably and safely perform all phases of the proposed project, including:

- 1) Availability and suitability of facilities to conduct assays and animal studies in accordance with NIH and FDA regulations and guidelines, including GLP guidelines and manufacturing the adjuvant candidate according to cGMP guidelines.
- 2) Suitability and feasibility of the plan for obtaining, adding, or deleting facilities as necessary due to progress during the course of product development.
- 3) Suitability of the provisions for the conduct of work regarding the transfer of Select Agents (if appropriate) in accordance with all required federal regulatory agencies, including the Department of Health and Human Services and the United States Department of Agriculture.
- 4) Adequacy of occupancy of facility, including documentation of lease or ownership for the period of performance of the contract.

**TOTAL POSSIBLE POINTS:**

**100**

**ATTACHMENT 8: ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS,  
FORMAT FOR TECHNICAL PROPOSAL, and TABLE OF CONTENTS**

**ADJUVANT DEVELOPMENT PROGRAM  
BAA NIH-NIAID-DAIT-08-11**

**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 200 pages** including the Offeror's Statement of Work, 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. Proposals shall NOT include links to Internet Web site addresses (URLs) or otherwise direct readers to alternate sources of information.

**TECHNICAL PROPOSAL – TABLE OF CONTENTS**

**GENERAL NOTES**

The NIAID recognizes that the regulatory path to licensure for a candidate adjuvant: vaccine for a selected NIAID Category A, B, or C Priority Pathogen within the scope of this solicitation may not be well-defined. Regulatory requirements are likely to be defined in an iterative decision-making process with the FDA based on candidate adjuvant-specific data as they emerge. Despite this uncertainty, based on current data and/or discussions with the FDA, the Offeror must develop a Product Development Plan that could ultimately lead to licensure, recognizing risks and areas of significant uncertainty. Offerors are strongly encouraged to develop risk mitigation strategies. The Technical Proposal should discuss areas of significant uncertainty and propose likely alternatives.

## **SECTION I:**

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

- a. 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.
  - b. PROJECT OBJECTIVES, NIH FORM 1688
  - c. GOVERNMENT NOTICE FOR HANDLING PROPOSALS
  - d. PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)
  - e. TABLE OF CONTENTS
- 

## **SECTION II: TECHNICAL PROPOSAL REQUIREMENTS**

### **(A) PRODUCT DEVELOPMENT PLAN**

#### **(1) OVERVIEW**

Technical Proposals shall include a Product Development Plan Overview that describes the candidate vaccine adjuvant and candidate adjuvant:vaccine combination proposed for further development, the rationale for selection of the candidate vaccine adjuvant, and the justification for the investment in the further development of the proposed candidate vaccine adjuvant toward licensure for human use. Provide a detailed description of the following:

- (a) The intended use/indication for the candidate vaccine adjuvant and the biodefense/public health gap that the candidate vaccine adjuvant is intended to fill.
- (b) The intended candidate vaccine adjuvant profile including potential stability, bioavailability, dosing and safety.
- (c) The performance specifications and features the candidate vaccine adjuvant should have in order to provide immunological protection.
- (d) A description of the candidate vaccine adjuvant as it is currently configured and evaluation of its potential for further development.
- (e) A description of the vaccine(s) chosen for study with the candidate vaccine adjuvant, and the rationale for the choice of the vaccine(s) selected to be used with the adjuvant.
- (f) Evidence of access to all required materials.
- (g) Evidence to support the characterization and selection of the candidate vaccine adjuvant for further development. Specifically, supporting evidence shall include:
  - (i) A summary of data that demonstrate that the candidate vaccine adjuvant safely augments the ability of a vaccine against a NIAID Category A, B, or C Priority Pathogen or other model pathogen to produce protective immunity as shown by pathogen challenge in an *in vivo* animal model. The evidence of protection must be obtained from studies performed under well-controlled and documented experimental conditions, with a statistically significant better outcome than found under appropriate control conditions.
  - (ii) A detailed description of the assays, animal models, and pathogen.
  - (iii) The rationale for the choice of animal model, adjuvant candidate, pathogen challenge protocol, strain and route, as well as for the outcome/endpoints selected.
  - (iv) Data that support that the candidate vaccine adjuvant is safe.

- (h) Summaries of discussions with the FDA, if any, that are relevant to the development activities for the proposed candidate adjuvant through the submission of an IND application. Summaries should include any key agreements, correspondence, and requirements that resulted from discussions with the FDA.

## **(2) TECHNICAL APPROACH**

Technical Proposals shall provide a Product Development Plan Technical Approach that describes the overall product development pathway, the proposed methodologies and technical approaches to be used at each product developmental stage, the milestones and timelines to accomplish each stage of product development. Provide a detailed description of the following:

- (a) Activities and stages of product development that the Offeror is proposing to accomplish with contract funding including the milestones to be met at each stage of the Product Development Plan.
- (b) Key development objectives for each developmental stage.
- (c) Clearly defined decision points during the product development process where proceed or not to proceed (“Go/No Go”) decisions will be made. These should be distinct stages of the product development pathway that are critical decision points for Go/No Go decisions for advancing to the next stage of the Product Development Plan. For each decision point, also delineate the qualitative and quantitative criteria and accompanying data elements to be used to assess the merit and feasibility of proceeding to the next stage of product development.
- (d) A detailed discussion of the proposed technical approach to achieve the project objectives, with sufficient detail to fully explain and justify the scientific/technical rationale for the proposed approach, experiments, and methodologies, reflecting a clear understanding of the scope and nature of the work being undertaken.
- (e) A detailed Gantt Chart organized by each specific stage of product development, with milestones. Schedules shall be shown in terms of where each stage fits into the overall timeline of the project.
- (f) Approaches to integrate adverse experimental or production results or new scientific findings into the proposed goals and timelines. Offerors are urged to highlight anticipated pitfalls and alternative solutions to problems.
- (g) A budget of direct costs for each stage of product development proposed for funding, linked to a timeline for completion of each stage; and 2) a budget of direct costs for each subcontract, listed by activity (e.g., animal challenge studies, cGMP manufacture, IND-enabling toxicological studies).

## **(3) REGULATORY COMPLIANCE, QUALITY ASSURANCE AND DATA MANAGEMENT**

The Technical Proposal shall include the following, as appropriate to the offeror’s proposed Statement of Work:

- (a) A plan to develop and maintain quality assurance documentation to support adherence to FDA regulatory standards and guidance that bear on the conduct of assays under GLP and manufacturing under cGMP, as relevant to the Product Development Plan. Include data management plans and procedures for GLP and cGMP activities.
- (b) Documentation of organizational experience of the Offeror and any proposed subcontractors with performing studies in accordance with FDA regulations and guidance, including GLP and cGMP guidelines.
- (c) A description of the process that will be used to audit facilities and maintain compliance with GLP and cGMP guidelines, including a plan to: determine when audits need to be performed; schedule audits in a timely fashion; perform audits; respond to audit reports; and communicate the results of audits to the Project Officer.

- (d) Documentation that the proposed facilities of the offeror and any subcontractors have been audited and comply with GLP and cGMP regulations and requirements.
- (e) Letters signed by the appropriate authority allowing for pre-award site visits to the Offeror's facility and proposed subcontractors' facilities. Site visits may include GLP and cGMP audits (as appropriate) performed by independent auditors contracted by NIAID.
- (f) A description of the proposed data management and quality control systems and procedures that will be used for: for data entry and validation, documentation of data corrections, routine maintenance and backup, transmission of data, data reporting and exporting system, access control and confidentiality, and data retrieval and disaster recovery.
- (g) A description of the statistical design and analysis resources that will be used to support contract activities.
- (h) Plans and procedures to ensure that data can be transferred to the Project Officer without corruption of data or figures. The NIAID is connected to the INTERNET and uses IBM-compatible computers that currently run on the Microsoft XP operating system and Microsoft Office 2003 software.

**(4) OFFEROR'S PROPOSED STATEMENT OF WORK** (limit fifteen (15) pages)

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 advance the development of the candidate vaccine adjuvant towards licensure for human use during the contract period of performance. 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 rest of the Technical Proposal in that it describes what the Contractor shall provide, while the Technical Approach describes the specific detailed plan for the development of the candidate adjuvant:vaccine, including any IND-enabling studies and Pilot Lot production of the product.

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:

- Activity: The Contractor shall provide the equipment, facilities, and other resources required for conducting IND-enabling studies in animal models.
  - Sub-activity: The Contractor shall conduct Administration, Distribution, Metabolism, and Excretion studies of the candidate adjuvant:vaccine.
  - Sub-activity: The Contractor shall conduct Pharmacology/Toxicology studies of the candidate adjuvant:vaccine.
- Activity: The Contractor shall develop and maintain a data management system.

In addition, the Statement of Work shall acknowledge the Government's right to modify the milestones, progress, schedule, budget, or product to add or delete products, process, or schedule as need may arise. The Statement of Work shall also acknowledge that the Contractor shall carry

out activities within the contract's Statement of Work only as requested and approved by the Project Officer and the Contracting Officer; may not conduct work on the contract without prior approval from the Project Officer and Contracting Officer; and approval to carry out specific activities will be linked to approval by the Project Officer of the Product Development Plan following contract award, and approval of Quarterly and Annual Technical Progress Reports.

## **(B) 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. Proposals should include a Staffing Plan for the conduct of the Statement of Work with role descriptions and level of effort of scientific and technical personnel, including scientific and technical personnel of all proposed subcontractors. 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)**, including experience and qualifications of the PI to plan, manage, and direct the activities to be carried out under this contract.

**(2) Scientific and Technical Personnel:** Experience, expertise, and qualifications of the Project Manager and all proposed scientific and technical personnel to conduct manufacturing, regulatory, pharmacology, toxicology, animal models, statistical analysis, and assay development activities; and experience and expertise in the management, design, and execution of a research and development program focused on product development, manufacturing, and testing in vertebrate animals.

## **(C) PROJECT MANAGEMENT**

The Technical Proposal must include a Project Management Plan addressing the following:

- (1) Describe how the project will be staffed, organized, and managed, including a detailed description of the responsibilities for all proposed personnel who will be assigned to the contract, and an administrative framework indicating clear lines of authority and responsibility for all personnel including proposed subcontractors and consultants.
- (2) Describe project management systems that will be used to track activities and to keep multiple activities on time and budget.
- (3) Outline how the PI will communicate and interact with the Project Officer and the Contracting Officer and how the PI will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).
- (4) Provide a plan for soliciting, evaluating, negotiating, awarding, and managing subcontracts in accordance with FAR Clause 52.244-2.
- (5) Describe experience and education of contract management staff in the acquisition and management of subcontracts under Federal contracts.
- (6) Describe experience with identification and remediation of subcontractor performance problems or noncompliance with subcontract terms and conditions.

## **(D) FACILITIES, EQUIPMENT AND OTHER RESOURCES**

As appropriate to the Offeror's proposed Statement of Work, the Technical Proposal must:

**(1)** Document the availability and adequacy of facilities, equipment and other resources available for performance of the contract, including:

- (a) Detailed laboratory layouts.
  - (b) Information regarding ownership/lease of the facility (ies), including documentation of the availability of proposed facilities for the duration of the contract.
  - (c) Plans for and procedures to be utilized to ensure compliance with all safety guidelines and regulations, including training and monitoring of personnel.
  - (d) Plans for obtaining, adding, or deleting facilities as necessary due to progress or performance issues that arise during the course of product development.
- (2) Document the availability of appropriate facilities for performing assays and animal studies under GLP standards and production of therapeutic material under cGMP guidelines as required implementing the Product Development Plan.
- (3) Describe provisions for complying with NIH guidelines for the housing and humane care and use of laboratory animals as delineated by the Office of Laboratory Animal Welfare (OLAW; <http://grants.nih.gov/grants/olaw/olaw.htm>).
- (4) Describe provisions for ensuring safe facilities and resources and for conducting work in accordance with the Biosafety in Microbiological and Biomedical Laboratories guidelines, Centers for Disease Control and Prevention and the National Institutes of Health, 5th edition, (<http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm>) and interim guidelines for influenza, 5<sup>th</sup> edition (<http://www.cdc.gov/flu/h2n2bsl3.htm>), as well as Department of Health and Human Services (DHHS) regulations regarding the transfer of select agents (42 CFR Part 72; <http://www.cdc.gov/od/ohs/biosfty/shipregs.htm>). Safety and Health HHSAR 352.223-70 clauses shall apply.
- (5) Describe provisions for ensuring safe facilities for the conduct of work in accordance with Recommendations for the Safe Handling of Cytotoxic Drugs, NIH Publication No. 92-2621 and the NIH Guidelines for the Laboratory use of Chemical Carcinogens, NIH Publication No. 81-2385 (<http://grants2.nih.gov/grants/guide/notice-files/not92-070.html>).

## **(E) 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.

### **(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.

**ATTACHMENT 9: ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND  
UNIFORM COST ASSUMPTIONS**

**ADJUVANT DEVELOPMENT PROGRAM  
BAA NIH-NIAID-DAIT-08-11**

**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 COVERSHEET** (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**

**(A) Technical Cost Assumptions:** None

**(B) Travel**

Annual Review Meeting: Budget for travel and per diem for the Principal Investigator, Project Manager, key investigators, and key subcontractor staff to attend Annual Review Meetings, to be held at a site chosen by the Project Officer. Assume that this meeting will be held in Bethesda, Maryland, and will require a two-night stay.

Site Visits: Budget for an initial one-day site visit within sixty (60) calendar days of the effective date of the contract, and subsequent annual site visits, to discuss the initiation and progress of the contract, to be held at the Contractor's site. Key personnel should attend this meeting.

General Scientific Meetings: Propose a travel budget annually for up to five (5) individuals for travel to general scientific meetings for presentations of work conducted under this contract. Assume a 3% escalation rate in Years 2 through 5.

**(C) Special Shipping and Packaging:** None

**(D) Storage:** None

**(E) Government Furnished Equipment (GFE)**

Government Furnished Equipment available to be transferred from incumbent contractor.

The purchase of Government Furnished Equipment will not be authorized as a direct charge under this contract.

The purchase of Government Furnished Equipment will be allowed under this contract, up to \$250,000.

**(F) Alterations and Renovations**

Support will NOT be provided for alterations and renovations under this contract.

**SECTION 4 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION: 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.

**Information Technology Systems Security  
Prospective Offeror Non-Disclosure Agreement**

Request For Proposal (RFP) No: \_\_\_\_\_  
(fill in RFP Number)

Project Title: \_\_\_\_\_

\_\_\_\_\_  
(Fill in Title from RFP)

\_\_\_\_\_  
(Organization's name), intends to respond to the Government's Solicitation/Project title indicated above. The Government has determined that the solicitation requires prospective offerors to have access to sensitive information in order to prepare an offer.

I, \_\_\_\_\_ (Offeror Official name and title),  
of \_\_\_\_\_ (Organization's name),  
on this \_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_, on behalf of my organization hereby request access to the sensitive information described in Section L.III. of the RFP sited above.

I, the undersigned, understand that the Government has determined that any individual having access to the sensitive information described in the RFP must possess a valid and current Suitability Determination at the Level identified in Section L.III. of the RFP sited above.

I, the undersigned, do hereby affirm the following:

- I have a valid and current Suitability Determination sufficient to access the sensitive information (copy of suitability determination attached).
- I will be the corporate official solely responsible for appropriately safeguarding the sensitive information while in the possession of \_\_\_\_\_ (Organizations's name);
- The sensitive information will be used solely for the purpose of preparing an offer;
- I will not release, publish, or disclose the sensitive information to unauthorized personnel; and
- I will protect the sensitive information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of sensitive information;
  - 18 U.S.C. 641 (Criminal Code: Public Money, Property of Records)
  - 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
  - Public Law 96-511 (Paperwork Reduction Act)

Signature of Prospective Offeror Official: \_\_\_\_\_

Name of Prospective Offeror Official: \_\_\_\_\_

Name of Prospective Offeror: \_\_\_\_\_

Date: \_\_\_\_\_

Signature of Witness: \_\_\_\_\_

Name of Witness: \_\_\_\_\_

Date: \_\_\_\_\_

Copies Retained by: Contractor Official & Contracting Officer