U.S. Department of Health and Human Services
National Institutes of Health
National Institute of Allergy and Infectious Diseases (NIAID)

BAA NIH-NIAID-DMID-07-37
"DEVELOPMENT OF THERAPEUTIC AGENTS FOR SELECTED BIODEFENSE BACTERIAL DISEASES"

OMB Control Number 0990-0115

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

2. **SECTION A – SOLICITATION/CONTRACT FORM -- PURCHASE AUTHORITY: FAR 1.602-1**
NOTE: The issuance of this solicitation does not commit the government to an award.

3. **Issue Date:**	4. **Due Date:** Thursday, August 3, 2006	5. **Small Bus. Set-Aside:** [ ]Yes [X] No
Monday April 3, 2006	**Time:** 4:00 P.M., DST	**8(a) Set-Aside:** [ ]Yes [X] No **NAICS:** 541710 (See Part IV, Section L.)

6. **Just In Time:**	7. **Number of Awards:**	8. **Technical Proposal Page Limits:**
[X] No [ ] Yes (See Part IV, Section L.)	[ ] Only 1 Award [X] Multiple Awards	[ ] No [X] Yes (See Section J, Attachment 1, Packaging and Delivery of Proposal)

9. **Issued By:**	10. [x] **NIAID reserves the right to make awards without discussion.**	
Paul D. McFarlane Contracting Officer Office of Acquisitions, DEA, NIH, NIAID 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	11. **Options:** **[X] No** **[ ] Yes** (See Part IV, Section L.)	12. **Performance Period:** Various depending upon proposals.

13. **Primary Point of Contact:**	14. **Secondary Point of Contact:**	15. **Protest Officer:**
Name : Carl A. Newman **Phone:** 301- 496-8371 **Fax:** 301-402-0972 **E-Mail:** Cnewman@niaid.nih.gov	**Name: Paul D. McFarlane** **Phone:** 301-496-0349 **Fax:** 301-402-0972 **E-Mail:** pmcfarlane@niaid.nih.gov	Charles Grewe Director, OA Address (see Block 9.)

16. **COLLECT CALLS WILL NOT BE ACCEPTED. FACSIMILE SUBMISSIONS ARE NOT ACCEPTABLE.**

17. Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See Part III, SECTION J – Attachments)

18. **DELIVERY ADDRESS INFORMATION**

19. **Hand Delivery or Overnight Service:**	20. **U.S. Postal Service or an Express Delivery Service**
Carl A. Newman Office of Acquisitions DEA, NIH, NIAID 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	Carl A. Newman Office of Acquisitions DEA, NIH, NIAID 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612

21. The **Official Point of Receipt** for the purpose of determining timely delivery is the address provided in Block 19, above. The original paper copy with original signatures is the official copy for recording timely receipt. If the original paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with FAR 15.208 entitled "Submission, Modification, Revision, and Withdrawal of Proposals." FACSIMILE AND E-MAIL SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

DETAILED TABLE OF BAA CONTENTS

PART I - THE SCHEDULE

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 PROPOSED CONTRACT DOCUMENT. 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. HOWEVER, THE ENCLOSED CONTRACT SCHEDULE PROVIDES ALL THE NECESSARY INFORMATION FOR THE OFFEROR 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 purpose of this effort is to advance the development of candidate therapeutics with demonstrated activity against one or more of the NIAID Category A and B bacterial pathogens via a focused, staged approach, that is consistent with all applicable federal regulations and Division of Microbiology and Infectious Diseases (DMID), NIAID, NIH policies and guidelines for the conduct and oversight of research in human subjects.

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-DMID-07-37. The Offeror's statement of work may be revised during negotiations leading to award of a contract.

ARTICLE C.2. REPORTING REQUIREMENTS

a. Reporting Requirements and Deliverables

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. Please refer to Attachment 5, **Reporting Requirements and Deliverables**, under this solicitation.

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 NIAID Project Officer is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at DMID, NIAID, NIH, DHHS, 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 **52.246-5, Inspection of Services - Cost-Reimbursement** (April 1984).

   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. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in Article C.1. and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the items in Article C.2., in accordance with the stated delivery schedule.

The items described in Article C.2. will be required to be delivered F.O.B. Destination as set forth in FAR Clause 52.247-35, F.O.B. Destination, Within Consignees Premises (April 1984), and in accordance with and by the dates specified in Article C.2. and any specifications stated in SECTION D. Packaging, Marking and Shipping of the contract.

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

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. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

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

Any contract awarded from this BAA will contain the following:

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 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

Pursuant to the Key Personnel clause incorporated in this contract, 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 instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

These instructions also provide for the submission of financial and personnel reporting required by HHSAR 342.7002.

(1) Invoices/financing requests shall be submitted as follows:

(a) To be considered a "proper" invoice in accordance with FAR 32.9, Prompt Payment, each invoice shall clearly identify the two contract numbers that appear on the face page of the contract as follows:

Contract No. (This is the 17 digit number that appears in Block 2 of the SF-26, i.e. HHSN2662007xxxxxC.)

ADB Contract No. (This is the 10 digit number that appears in the upper left hand

corner of the SF-26, i.e. N01-AI-7xxxx.)

(b) An original and two copies to the following designated billing office:

Contracting Officer
Office of Acquisitions, DEA
National Institute of Allergy and Infectious Diseases, NIH, DHHS
Room 3214, MSC 7612
6700-B Rockledge Drive
Bethesda, MD 20892-7612

(2) Inquiries regarding payment of invoices should be directed to the designated billing office, (301)496-0612.

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 Contracts Management
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. 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 annually to coincide with the anniversary date of the contract.

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

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved by the NIAID, written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer 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. The human subject certification can be met by submission of the Contractor's 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.2 . REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. The information below is a summary of the NIH Policy Announcement:

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

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

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

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

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

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

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

The Data and Safety Monitoring [BOARD and PLAN] shall be established and approved prior to beginning the conduct of the clinical trial.

ARTICLE H.4. HUMAN MATERIALS

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.

ARTICLE H.5. 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.6. 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).

ARTICLE H.7. 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.8. 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.9. 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.10. PRIVACY ACT

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

The Privacy Act System of Records applicable to this project is Number ___. This document is incorporated into this contract as Attachment __.

ARTICLE H.11. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

(1) The Small Business Subcontracting Plan, dated [to be completed upon award] is attached hereto and made a part of this contract.

(2) The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8,

entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. Subcontracting Reports

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

(1) Individual Subcontract Reports (ISR)

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

April 30th
October 30th

(2) Summary Subcontract Report (SSR)

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

October 30th

For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes at the following e-mail address:

Cnewman@niaid.nih.gov
Carl Newman, Contracting Officer, OA, NIAID, DEA, DHHS

ARTICLE H.12. 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 per year 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 No.	**Fiscal Year**	**Dollar Amount of Salary Limitation***

[Applicable information to be included at award]

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

For the period 10/1/05 - 12/31/05, the Executive Level I rate is $180,100. Effective January 1, 2006, the Executive Level I rate increased to $183,500 and will remain at that rate until it is revised. See the web site listed below for the Executive Schedule rates of pay:

FOR FY-06 EXECUTIVE LEVEL SALARIES EFFECTIVE JANUARY 1, 2006:
http://www.opm.gov/oca/06tables/html/ex.asp
(Note: This site shows the FY-06 rates. For previous years, click on "salaries and wages" and then scroll down to the bottom of the page and click on the year to locate the desired Executive Level salary rates.)

ARTICLE H.13. INFORMATION SECURITY

The Statement of Work (SOW) requires the contractor to develop or access Federal automated information systems; therefore, the contractor shall comply with the "DHHS Information Security Program Policy" (http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc) as set forth below. The contractor shall include this provision in any subcontract awarded under this contract.

a. Information Type

**** *(NOTE: The resultant contract will include the Information Type(s), however for the purposes of this RFP, the Information Type(s) is specified in SECTION L.2.b. Technical Proposal Instructions of this RFP.)* ****

[ ] Administrative, Management and Support Information:

[ ] Mission Based Information:

b. Security Categories and Levels

**** *(NOTE: The resultant contract will include the Security Categories and Levels, however for the purposes of this RFP, the Security Categories and Levels are specified in SECTION L.2.b. Technical Proposal Instructions of this RFP.)* ****

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:

**** *(NOTE: The resultant contract will include the Position Sensitivity Designations, however for the purposes of this RFP, the Position Sensitivity Designations applicable to this RFP are specified in SECTION L.2.b. Technical Proposal Instructions of this RFP.)* ****

[ ] 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 and responsibility, of all IT staff working under the contract. The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 days of the effective date of the contract. Any revisions to the Roster as a result of

staffing changes shall be submitted within fifteen (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 Investigation 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 employees who have had a background investigation conducted by the U.S. Office of Personnel Management (OPM) within the last five years may only require an updated or upgraded investigation.

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

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

Level 6: In special circumstances the Project Officer may request a waiver of the preappointment investigation. If the waiver is granted, the Project Officer will provide written authorization for the contractor employee to work under the contract.

d. Systems Security Plan

The contractor shall protect Federal automated information systems that are developed or accessed by the contractor. System security shall be accomplished in accordance with the contractor's System Security Plan dated _____. The plan must:]

(1) Include a detailed plan of present and proposed systems security programs commensurate with the size and complexity of the requirements of the Statement of Work. The contractor shall use the NIH Systems Security Plan Template (detailed) at http://irm.cit.nih.gov/security/secplantemp.doc or NIH Systems Security Plan Outline (outline only) at http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc.

[OR (To be determined during negotiations)]

(1) Include a plan of present and proposed systems security programs commensurate with the size and complexity of the requirements of the Statement of Work. The minimum areas to be addressed include, but are not limited to administrative, technical, and physical security as follows:

(i) Security Awareness Training
(ii) Logical Access Control
-Network (ex: firewall)
-System (ex: network OS, tcp wrappers, SSH)
-Application (ex: S-LDAP, SSL)
-Remote Access (ex: VPN)
-Monitoring and support (ex: IDS, pager, NOC)
(iii) Protection against data loss
-OS security (ex: patch management, configuration)
-Application security (ex: patch management)
-Database security
-Back-up and recovery
-Fault tolerance, high availability
(iv) Malicious Code Protection (ex: Antivirus, filtering of e-mail attachments, etc)
(v) Physical Security

-Access control (ex: locks, guards)
-Power conditioning and/or UPS
-Air conditioning
-Fire protection

Include an acknowledgment of its understanding of the security requirements.

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

e. Rules of Behavior

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

f. Information Security Training

Each contractor employee shall complete the NIH Computer Security Awareness Training (http://irtsectraining.nih.gov/) prior to performing any contract work, and on an annual basis thereafter, during the period of performance of this contract.

The contractor shall maintain a listing by name and title of each individual working under this contract that has completed the NIH required training. Any additional security training completed by contractor staff shall be included on this listing.

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

**** *[Additional courses will be listed here in the resultant contract, if applicable.]* ****

g. Personnel Security Responsibilities

The contractor shall perform and document the actions identified in the "Employee Separation Checklist", attached and made a part of this contract, when a contractor employee terminates work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request

h. Commitment to Protect Departmental Information Systems and Data

(1) Contractor Agreement

The Contractor shall not release, publish, or disclose 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 sensitive 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 employee who may have access to sensitive Department information under this contract shall complete 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.

i. References

1. DHHS Information Security Program Policy: http://www.hhs.gov/ohr/manual/pssh.pdf

2. DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf
3. NIST Special Publication 800-16, Information Technology Security Training Requirements: http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf
   Appendix A-D: http://csrc.nist.gov/publications/nistpubs/800-16/AppendixA-D.pdf
4. NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems: http://csrc.nist.gov/publications/nistpubs/index.html
5. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I: http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V1-final.pdf
6. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume II: http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V2-final.pdf
7. NIST SP 800-64, Security Considerations in the Information System Development Life Cycle: http://csrc.nist.gov/publications/nistpubs/800-64/NIST-SP800-64.pdf
8. NIH Computer Security Awareness Training Course: http://irtsectraining.nih.gov/
9. Roster of Employees Requiring Suitability Investigations: http://ais.nci.nih.gov/forms/Suitability-roster.xls
10. NCI Information Technology Security Policies, Background Investigation Process: http://ais.nci.nih.gov/
11. NIH Systems Security Plan Template (detailed): http://irm.cit.nih.gov/security/secplantemp.doc
12. NIH Systems Security Plan Outline (outline only): http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc
13. NIH Information Technology General Rules of Behavior: http://irm.cit.nih.gov/security/nihitrob.html
14. Commitment To Protect Non-Public Information - Contractor Agreement: http://irm.cit.nih.gov/security/Nondisclosure.pdf

ARTICLE H.14. ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) all Electronic and Information Technology (EIT) developed, procured, maintained and/or used under this contract shall be in compliance with the "Electronic and Information Technology Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR Part 1194. The complete text of Section 508 Final Standards can be accessed at http://www.access-board.gov/.

The standards applicable to this requirement are identified in the Statement of Work/listed below]:

ARTICLE H.15. PUBLICATION AND PUBLICITY

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 HHSN2662007xxxxxC."

ARTICLE H.16. 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 non-governmental sources.

b. **Public Law and Section No.**	**Fiscal Year**	**Period Covered**

[Applicable information to be included at award]

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. YEAR 2000 COMPLIANCE

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

1. Service Involving the Use of Information Technology:

YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY

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

(End of Clause)

2. Noncommercial Supply Items Warranty:

YEAR 2000 WARRANTY--NONCOMMERCIAL SUPPLY ITEMS

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

YEAR 2000 COMPLIANT ITEMS

All hardware and software used in performance of the resultant contract.
(End of Clause)

3. Commercial Supply Products Warranty:

YEAR 2000 WARRANTY--COMMERCIAL SUPPLY ITEMS

The contractor warrants that each hardware, software and firmware product delivered under this contract and

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

YEAR 2000 COMPLIANT ITEMS

All hardware and software used in performance of the resultant contract.

(End of Clause)

ARTICLE H.19. 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.20. 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.21. 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), 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)
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). 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 and 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).

ARTICLE H.22. 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.23. 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.24. 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.

ARTICLE H.25. CONSTITUTION DAY

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

ARTICLE H.26. SHARING RESEARCH DATA

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.

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 BAA. 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 BAA:

General Clauses for a Cost-Reimbursement Research and Development Contract
General Clauses for a Cost-Reimbursement Contract with Educational Institutions
General Clauses for a Cost-Reimbursement Contract with Non-Profit Organizations Other Than Educational Institutions

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

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

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.

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.

FAR Clause **52.216-7, Allowable Cost And Payment** (December 2002), is modified in paragraph (a). The reference to Subpart 31.2 is changed to Subpart 31.3.

FAR Clause **52.216-8, Fixed Fee** (March 1997), is deleted in its entirety and FAR Clause 52.216-11, Cost Contract–No Fee (April 1984) is substituted therefor.

Alternate II (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (July 2005) is added.

FAR Clause **52.249-14, Excusable Delays** (April 1984) is deleted and HHSAR Clause 352.249-14, Excusable Delays (April 1984) is substituted therefor.

FAR Clause **52.232-17, Interest** (June 1996) is added.

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.]**

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 **52.204-9, Personal Identity Verification of Contractor Personnel** (January 2006).

(2) FAR Clause **52.215-17, Waiver of Facilities Capital Cost of Money** (October 1997).

(3) FAR Clause **52.216-15, Predetermined Indirect Cost Rates** (April 1998).

(4) 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."

(5) FAR Clause **52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status**

and Reporting (October 1999).

(6) FAR Clause **52.222-29, Notification of Visa Denial** (June 2003).

(7) FAR Clause **52.223-3, Hazardous Material Identification and Material Safety Data (January 1997), with Alternate I** (July 1995).

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

(9) FAR Clause **52.224-2, Privacy Act** (April 1984).

(10) FAR Clause **52.227-14, Rights in Data - General** (June 1987).

(11) **Alternate III** (June 1987), FAR Clause **52.227-14, Rights in Data--General** (June 1987).

Additions to, or limitations on, the restricted rights set forth in the Restricted Rights Notice of subparagraph (g)(3) of the clause are expressly stated as follows: **TBD**

(12) **Alternate II** (June 1987), FAR Clause **52.227-14, Rights in Data--General** (June 1987).

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

(13) **Alternate III** (June 1987), FAR Clause **52.227-14, Rights in Data--General** (June 1987).

Additions to, or limitations on, the restricted rights set forth in the Restricted Rights Notice of subparagraph (g)(3) of the clause are expressly stated as follows:

(14) FAR Clause **52.227-16, Additional Data Requirements** (June 1987).

(15) FAR Clause **52.227-23, Rights to Proposal Data (Technical)** (June 1987).

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

(16) FAR Clause **52.230-2, Cost Accounting Standards** (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 **52.237-3, Continuity of Services** (January 1991).

(20) FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).

(21) FAR Clause **52.247-68, Report of Shipment (REPSHIP)** (February 2006).

(22) FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984).

(23) FAR Clause **52.246-23, Limitation of Liability** (February 1997).
AND/OR
(24) FAR Clause **52.246-24, Limitation of Liability - High-Value Items** (February 1997).

C. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 chapter 3) CLAUSES:

(1) HHSAR Clause **352.223-70, Safety and Health** (January 2001). [This clause is provided in full text in Section J - Attachments.]

(2) HHSAR Clause **352.224-70, Confidentiality of Information** (April 1984 - including revisions mandated by the 1/3/2005 Federal Register notice which was effective March 2005).

(3) HHSAR Clause **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).

(4) HHSAR Clause **352.270-8, Protection of Human Subjects** (March 2005).

(5) HHSAR Clause **352.270-9, Care of Live Vertebrate Animals** (March 2005).

(6) HHSAR Clause **352.270-5, Key Personnel** (April 1984).

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

D. 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) (OMB Bulletin 81-16).

(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 **52.204-9, Personal Identity Verification of Contractor Personnel** (January 2006).

(a) The Contractor shall comply with agency personal identity verification procedures identified in the contract that implement Homeland Security Presidential Directive-12 (HSPD-12), Office of Management and Budget (OMB) guidance M-05-24, and Federal Information Processing Standards Publication (FIPS PUB) Number 201.

(b) The Contractor shall insert this clause in all subcontracts when the subcontractor is required to have physical access to a federally-controlled facility or access to a Federal Information system.

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

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

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

(b) Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and

payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).

Notice to Employees

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

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

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

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

To locate the nearest NLRB office, see NLRB's website at http://www.nlrb.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 canceled, 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 20210, 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.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this BAA:

SOLICITATION ATTACHMENTS:

Attachment No.	Title	Location
Attachment 1	Packaging and Delivery of Proposal	Linked to the Attachment Title
Attachment 2	Proposal Intent Response Sheet	Linked to the Attachment Title
Attachment 3	Background and Introduction	Linked to the Attachment Title
Attachment 4	Research and Technical Objectives	Linked to the Attachment Title
Attachment 5	Reporting Requirements and Deliverables	Linked to the Attachment Title
Attachment 6	Appendix A - Additional Technical Proposal Instructions	Linked to the Attachment Title
Attachment 7	Appendix B - Additional Business Proposal Instructions	Linked to the Attachment Title

TECHNICAL PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable, and submitted with the Technical Proposal.)

Attachment No.	Title	Location
Attachment 8:	Targeted/Planned Enrollment Table	http://rcb.cancer.gov/rcb-internet/forms/enroll-table.pdf
Attachment 9:	Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Attachment 10:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Attachment 11:	Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
Attachment 12:	Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (formerly Optional Form 310	http://rcb.cancer.gov/rcb-internet/forms/of310.pdf
Attachment 13:	Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf

BUSINESS PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable, and submitted with the Business Proposal.)

Attachment No.	Title	Location
Attachment 14:	Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm

Attachment 15:	Small Business Subcontracting Plan	http://rcb.cancer.gov/rcb-internet/forms/sb-subplan-nci.pdf
Attachment 16:	Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet	http://www.niaid.nih.gov/contract/forms.htm http://ocm.od.nih.gov/contracts/spsh/spshexcl.xls
Attachment 17:	Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Attachment 18:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf

INFORMATIONAL ATTACHMENTS: (The following Attachments and Reports will become part of any contract resulting from this BAA and will be required during contract performance.)

Attachment No.	Title	Location
Attachment 19:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 20:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Attachment 21:	Financial Report of Individual Project/Contract, NIH 2706	http://www.niaid.nih.gov/contract/forms/nih-2706.pdf
Attachment 22:	Instructions for Completing Form NIH 2706	http://www.niaid.nih.gov/contract/forms/instructions2706.pdf
Attachment 23:	Privacy Act System of Records *System of Records No. 09-25-0200 is applicable to this BAA.*	http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm
Attachment 24:	Safety and Health, HHSAR Clause 352.223-70	http://www.niaid.nih.gov/contract/forms/form10.pdf
Attachment 25:	Research Patient Care Costs, NIH(RC)-11	http://www.niaid.nih.gov/contract/forms/nih-rc-11.pdf
Attachment 26:	Inclusion Enrollment Report	http://rcb.cancer.gov/rcb-internet/forms/inclusion-enrollment.pdf
Attachment 27:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf
Attachment 28:	Commitment To Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Attachment 29:	Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Attachment 30:	Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

SECTION K 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.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE SECTION K AND SUBMIT IT AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Provision 52.215-1 (January 2004)]

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

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

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

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

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

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

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

(c) *Submission, modification, revision, and withdrawal of proposals*.

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

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

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

(ii) (A) Any proposal, modification, or revision received at the Government office designated in

the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

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

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

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an Offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

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

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

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

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

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

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

(e) *Restriction on disclosure and use of data.*

(1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the

Offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the Offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the Offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The Offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The Offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
>
> If a contract is awarded to the Offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
>
> The Offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

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

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

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

(f) *Contract award*.

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

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

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

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the Offeror's initial proposal should contain the Offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the 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.

(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 BAA), 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 541710.

(2) The small business size standard is 500 employees.

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

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

It is anticipated that multiple awards will be made from this solicitation and that the awards will be made on/about June 5, 2007.

It is anticipated that the awards from this solicitation will be a multiple-year cost reimbursement completion type contract with a period of performance of up to 5 years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

d. **COMMITMENT OF PUBLIC FUNDS**

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

e. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

f. **RELEASE OF INFORMATION**

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

g. **COMPARATIVE IMPORTANCE OF PROPOSALS**

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

h. **PREPARATION COSTS**

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

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

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

Contracting Officer
Office of Acquisitions, DEA
National Institute of Allergy and Infectious Diseases, NIH, DHHS
Room 3214, MSC 7612
6700B Rockledge Drive
BETHESDA MD 20892-7612

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

(End of Provision)

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

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

(End of provision)

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 BAA. Your proposal shall be submitted in the number of copies, to the addresses, 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 BAA should be placed in the following order:

I. COVER PAGE

Include BAA 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 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 research and technical objectives. 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 BAA, 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 BAA.

(7) **Potential Award Without Discussions**

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

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

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

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

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

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

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

(9) **Standards for Privacy of Individually Identifiable Health Information**

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

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

(10) **Privacy Act - Treatment of Proposal Information**

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

The NIH is requesting the information called for in this BAA 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 BAA, 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. The order of merit will be comprised of all of the technically acceptable proposals. Oral or written discussions will be conducted with a selection from the order of merit.

It is NIAID's policy to conduct discussions with all or a portion of the offerors in the order of merit. 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 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 BAA. In addition, the BAA may be amended or canceled as necessary to meet NIAID requirements. Synopses of awards exceeding $25,000 will be published in FedBizOpps.

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

EACH INSTITUTION MUST:

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

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

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

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

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

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

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

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

funding is sought from the NIH;

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

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

4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

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

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

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

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

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

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

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

(14) **Past Performance Information**

a) Offerors shall submit the following information as part of their BUSINESS proposal.

A list of the last three contracts completed during the past THREE years and THE LAST <u>three</u>

CONTRACTS AWARDED currently in process that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

Include the following information for each contract or subcontract:

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

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

b) Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

(15) **Electronic and Information Technology Accessibility**

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that:

a. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

b. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards.

Further information about Section 508 is available via the Internet at http://www.section508.gov .

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

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

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

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The

offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).

b. TECHNICAL PROPOSAL INSTRUCTIONS

(1) **Technical Discussions**

See Appendix A at the end of this BAA.

A proposal submitted in response to this BAA must present separate detailed technical and cost proposals 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 NIAID. The Statement of Work **should not exceed fifteen (15) single-spaced pages** in length within the Technical Proposal.

(2) **Technical Evaluation**

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

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:"**

(3) **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 (Revised 1986, Reprinted 2000)

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER, OLAW. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance

is required. The Contracting Officer will request that OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at http://www.grants.nih.gov/grants/olaw/olaw.htm.

b. 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.

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

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

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

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

(a) **Sharing Research Data**

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

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the Offeror must submit a plan in its technical proposal for data sharing or state why data sharing is not possible. If data sharing is limited, the Offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:

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

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

(b) **Sharing of Model Organisms for Biomedical Research**

The NIH Research Tools Policy, also referred to as Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research 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, dated May 7, 2004, and the September 10, 2004 extension of this policy NOT-OD-04-066,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) (http://ott.od.nih.gov/NewPages/Rtguide_final.html#sla)for the transfer of materials or the Uniform Biological Material Transfer Agreement (UBMTA) (http://ott/od/nh/gov/NewPages/UMTA.pdf)?

- 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.

IMPORTANT NOTE TO OFFERORS: The following [10/11/12] paragraphs [(5) through (14)/(15)/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 (MARCH 2005)

(a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office 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 Department.

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

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

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The 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: 301-496-7005), 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 may be found at:

http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html

(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.

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

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

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named

personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

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

http://www.centerwatch.com/order/pubs_profs_protect.html.

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

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

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

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

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

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

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

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

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**[1] require that*:* a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Justifications for Exclusion of Children

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

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

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

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

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

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

Definition of a Child

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

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

(9) **Research Involving Prisoners as Subjects**

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

b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

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

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

1. The sole purposes are:

   a) to describe the prevalence or incidence of a disease by identifying all cases, or
   b) to study potential risk factor associations for a disease, and

2. The Institution responsible for the conduct of the research certifies to the OHRP that the Institutional Review Board (IRB) approved the research and fulfilled its duties under 45 CFR 46.305(a)(2-7) and determined and documented that:

   a) the research presents no more than minimal risk, and
   b) no more than inconvenience to the prisoner-subjects, and
   c) prisoners are not a particular focus of the research.

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

(10) **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.

(11) **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);
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); 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) - 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 and 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).

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, 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 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.
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.

(12) **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 Statement of Work (SOW) requires the successful offeror to develop or access Federal automated information systems. Pursuant to the DHHS Information Security Program Policy (http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc), the following requirements apply:

(a) Information Type

[ ] Administrative, Management and Support Information:

[X] Mission Based Information:

(b) Security Categories and Levels

Confidentiality	Level:	**[ ]** Low	**[ ]** Moderate	**[X]** High
Integrity	Level:	**[ ]** Low	**[ ]** Moderate	**[X]** High
Availability	Level:	**[ ]** Low	**[ ]** Moderate	**[X]** High
Overall	**Level:**	**[ ] Low**	**[ ] Moderate**	**[X] High**

(c) Position Sensitivity Designations

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

[ ] Level 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).

[X] 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 IT staff working under the contract. The Government will determine the appropriate level of suitability investigation required for each staff member.

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

(d) Systems Security Plan

The offeror's proposal must:

- Include a detailed plan of its present and proposed systems security programs commensurate with the size and complexity of the requirements of the Statement of Work. Offerors must use:
  NIH Systems Security Plan Template (detailed) at:
  http://irm.cit.nih.gov/security/secplantemp.doc; or
  NIH Systems Security Plan Outline (outline only) at:
  http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc.

OR

(1) Include a plan commensurate with the size and complexity of the requirements of the Statement of Work. The minimum areas to be addressed include, but are not limited to administrative, technical, and physical security as follows:

(i) Security Awareness Training
(ii) Logical Access Control
-Network (ex: firewall)
-System (ex: network OS, tcp wrappers, SSH)
-Application (ex: S-LDAP, SSL)

-Remote Access (ex: VPN)
-Monitoring and support (ex: IDS, pager, NOC)

(iii) Protection against data loss
-OS security (ex: patch management, configuration)
-Application security (ex: patch management)
-Database security
-Back-up and recovery
-Fault tolerance, high availability

(iv) Malicious Code Protection (ex: Antivirus, filtering of e-mail attachments, etc)

(v) Physical Security
-Access control (ex: locks, guards)
-Power conditioning and/or UPS
-Air conditioning
-Fire protection

Include an acknowledgment of its understanding of the security requirements.
Provide similar information for any proposed subcontractor developing or accessing an AIS.

The SSP that the offeror must submit with its proposal shall be finalized in coordination with the Project Officer no later than 90 calendar days after contract award.

(e) Information Systems Security Training

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

The successful offeror will be responsible for assuring that each contractor employee has completed the NIH Computer Security Awareness Training course(http://irtsectraining.nih.gov/) prior to performing any contract work, and on an annual basis thereafter, 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.

(f) Prospective Offeror Non-Disclosure Agreement

The Government has determined that prospective offerors will require access to 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
[X] Level 5: Public Trust - Moderate Risk

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

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

Prospective offerors are required to process their requests for access, receive Government approval, and then access the 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.

(g) References

(1) DHHS Information Security Program Policy: http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc
(2) DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf
(3) NIH Systems Security Plan Template: http://irm.cit.nih.gov/security/secplantemp.doc
(4) NIH Systems Security Plan Outline: http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc
(5) NIH Computer Security Awareness Training Course: http://irtsectraining.nih.gov/
(6) NIST Special Publication 800-16, Information Technology Security Training Requirements: http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf
Appendix A-D:
http://csrc.nist.gov/publications/nistpubs/800-16/AppendixA-D.pdf
(1) NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems:
http://csrc.nist.gov/publications/nistpubs/index.html
(1) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I: http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V1-final.pdf
(2) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume II: http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V2-final.pdf
(3) NIST SP 800-64, Security Considerations in the Information System Development Life Cycle:
http://csrc.nist.gov/publications/nistpubs/800-64/NIST-SP800-64.pdf

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) Salary Rate Limitation in Fiscal Year 2006

Offerors are advised that pursuant to P.L. 109-149, no NIH Fiscal Year 2006 (October 1, 2005 - September 30, 2006) 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. 109-149 applies only to Fiscal Year 2006 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 109-149 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/06tables/indexSES.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 2006 Executive Level I Salary rates.*

(4) **Small Business Subcontracting Plan**

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

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

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

c) The Offeror understands that:

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

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

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

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

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

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

d) Each plan must contain the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(5) **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.

(6) **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 Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled “Extent of Small Disadvantaged Business Participation” as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes.

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) code, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). TheNAICS 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 Subsector(s). The applicable authorized NAICS Subsector(s) for this project is (are) identified elsewhere in this BAA. 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 Subsector 223

SDB Percentage of Total Contract Value	**SDB Dollars**

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

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

(7) **Total Compensation Plan - Instructions**

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

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

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

(8) **Total Compensation Plan - Evaluation**

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

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

b) **Cost (Professional Compensation)**

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

c) **Other (Labor Relations)**

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

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

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

(9) **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this BAA, 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 BAA**

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 BAA. 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 BAA.

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 BAA.

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 BAA; 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 BAA. 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 BAA requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(10) **Other Administrative Data**

a) **Property**

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

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

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

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

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

b) **Royalties**

The Offeror shall furnish information concerning royalties which are anticipated to be paid in connection with performance of work under the proposed contract.

c) **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.

d) **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.

e) **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 BAA, the Offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

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

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

(End of provision)

f) **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.

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

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

(11) **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 BAA 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

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

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

OR

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

(13) **Representations and Certifications**

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

(14) **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 BAA shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

All offerors included within the order of merit 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.

(15) **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.

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

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

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

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

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

1. **Direct Labor**

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

2. **Materials**

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

3. **Subcontracted Items**

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

4. **Raw Materials**

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

5. **Purchased Parts**

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

6. **Fringe Benefits**

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

7. **Indirect Costs**

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

8. **Special Equipment**

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

9. **Travel**

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

10. **Other Costs**

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

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

(a) Exceptions from cost or pricing data.

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

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

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

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the

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

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

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

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

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

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

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

(End of provision)

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

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

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

SECTION M - EVALUATION FACTORS FOR AWARD

I. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against five (5) factors. The factors in order of importance are: technical, programmatic balance, cost, past performance, and Small and Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, programmatic balance, cost/price, past performance 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 awards to those Offerors whose proposals provide the best overall value to the Government.

All technical proposals will undergo evaluation by a peer review group also known as a Scientific Review Group (SRG). The 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 objectives of the BAA. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

The final stage of the evaluation is the establishment of the 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 factors set forth above and are contingent upon successful negotiations as determined by NIAID at the time of award selection.

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

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 GLP, cGMP, GCP and QC/QA 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 records, including previous regulatory inspection reports, and staff, available in response to a pre-award site visit or audit by the NIAID or its designee.

II. TECHNICAL EVALUATION CRITERIA

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.

CRITERION	**WEIGHT**
1. TECHNICAL APPROACH/PLAN	**40**

A. Therapeutic Candidate Selection and Product Development Plan Feasibility (10)

a) The suitability of the proposed therapeutic candidate/product for further development as described in the Comprehensive Staged Product Development Plan, (e.g. the biodefense/public health gap that is being addressed, potential for licensure for a treatment indication, for formulation with long term stability, oral bioavailability, simple dosing regimen, safety in diverse populations, broad spectrum activity).

b) The soundness of the assays used and the data to support therapeutic activity of the proposed candidate/product in a relevant animal model.

c) The soundness and feasibility of the Comprehensive Staged Product Development Plan for advancing the therapeutic candidate/product toward a licensed product for the proposed indication.

d) The soundness and feasibility of the Strategic Staged Product Development Plan for advancing the therapeutic candidate/product toward a licensed product for the proposed indication within the requested period of funding.

e) The feasibility of completing a Phase 1 clinical trial and the Final Clinical Study Report within the five (5)-year contract period (if a Phase 1 clinical trial has not already been completed at the time of review).

f) The soundness, feasibility, suitability and completeness of the proposed decision gates for Go/No Go evaluation of the therapeutic candidate/product, including the qualitative and quantitative criteria to be used to reach Go/No Go decisions at the various stages of product development and the budget for each stage of product development.

B. Implementation of the Strategic Staged Product Development Plan (20)

a) The soundness, appropriateness and feasibility of the technical methods proposed in the Work Plan (e.g. non-clinical studies, medicinal chemistry, manufacturing, assay development, animal model development, performance of animal studies, clinical evaluation, NDA or BLA-enabling activities).

b) The suitability and adequacy of the plans for quality control, quality assurance, and data management for the conduct of activities proposed in the Work Plan.

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 modifying the Strategic Staged Product Development Plan/Work Plan based on adverse experimental or production results, or on new scientific findings along the development path.

e) The adequacy of the clinical trial Protocol Synopsis and documented experience in performing human subjects research in accordance with Federal regulations for the conduct of clinical trials.

f) Adequacy of the plan to communicate and meet with the FDA and to share FDA communications with the Project Officer.

g) Adequacy of previous experience of the Offeror and any proposed subcontractors in conducting studies in compliance with GLP, cGMP and GCP guidelines as documented by the Offeror and provision of audit history and reports.

h) Adequacy of the plan to audit facilities and maintain compliance with GLP, cGMP, and/or GCP guidelines, where appropriate, and the inclusion of letters allowing pre-award site visits to Offeror and subcontractor facilities.

C. Proposed Statement of Work (10)

a) 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 to perform the proposed work plan.

b) 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.

2. QUALIFICATIONS/AVAILABILITY OF PROPOSED PERSONNEL 20

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

a) Appropriateness of the documented qualifications, knowledge, experience, education, competence, and availability of the PI to carry out the proposed Statement of Work.

b) Appropriateness of the documented qualifications, knowledge, experience, education, competence and availability of the Project Manager to carry out the proposed Statement of Work.

c) Appropriateness of the documented qualifications, knowledge, experience, education, competence and availability of the other key personnel, provided by the Contractor or by subcontractors or consultants (e.g. manufacturing, regulatory, clinical, animal models, assay development, etc.) to carry out the proposed Statement of Work.

d) Appropriateness of the responsibilities and level of effort of all proposed staff of the Offeror and any proposed subcontractors and consultants.

e) Adequacy of the proposed mix of staff, expertise, experience, and training (e.g., research, manufacturing, clinical, regulatory, statistical, management, administrative) to carry out the Work Plan.

3. FACILITIES, EQUIPMENT AND OTHER RESOURCES 20

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

a) Availability and adequacy of facilities, equipment, and other resources to safely perform all phases of the proposed project.

b) Availability and adequacy of biocontainment facilities, as needed.

c) Availability and suitability of facilities to conduct assays and animal studies in accordance with FDA regulations and guidelines, including GLP guidelines; to manufacture therapeutic candidates/products according to cGMP guidelines; and to perform clinical trials in accordance with GCP guidelines.

d) Suitability and feasibility of the plan for obtaining, adding or deleting facilities as necessary due to progress during the course of the product development.

e) Suitability of the provisions for the conduct of work in accordance with the DHHS regulations regarding the transfer of Select Agents.

f) Adequacy of occupancy of facility, including documentation of lease or ownership for the period of performance of the contract.

4. PROJECT MANAGEMENT 20

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

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

b) Suitability of systems proposed for tracking project activities and monitoring progress, timelines, and budgets.

c) 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.

d) Suitability of the plan for soliciting, evaluating, negotiating, awarding and managing any proposed subcontracts in accordance with Federal regulations.

e) Adequacy of the plan to identify and remediate problems in subcontractor performance.

f) Completeness of Letter(s) of Understanding between collaborating parties to address intellectual property, facilitate development of commercialization, and resolve disputes.

g) Adequacy of the plan to protect and share confidential information with the External Advisory Group members.

h) Suitability of the plan to organize the Annual Review Meetings and provide for a thorough assessment of contract status, progress, problems, and approaches to their resolution, and future plans.

TOTAL POINTS: 100

III. PAST PERFORMANCE FACTOR

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

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

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

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

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

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends n 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.

IV. 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.

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) Complexity and variety of the work SDB concerns are to performed. Greater emphasis will be given for the arrangements where the SDB shall be performing work appropriate to the scientific objectives expressed in the Offeror's proposed Statement of Work.

(b) Extent of participation of SDB concerns in terms of the value of the total acquisition.

V. HUMAN SUBJECT EVALUATION

This research project involves human subjects. NIH policy requires:

(1) 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 in the proposed research plan, 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.

(2) Data and Safety Monitoring

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

any further technical evaluation criteria in this Section M, as applicable, for the solicitation's specific requirements for data and safety monitoring.

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

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

(3) Women and Minorities

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

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

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

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

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

Reviewers will 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 offerors selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or

    - overriding factors dictate selection of subjects); or

    - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.

- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:

    - inclusion of those groups would be inappropriate with respect to their health,;or

    - inclusion of those groups would be inappropriate with respect to the purpose of the research.

- For NIH-defined Phase III clinical trials, reviewers will also consider whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is <u>not</u> expected in the primary analyses.

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

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

If the Government includes your proposal in the order of merit ranking (for competitive proposals), or if the Government holds discussions with the selected source, 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.

(4) <u>Children</u>

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, 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.

If the information provided in your proposal about the inclusion of children is rated "unacceptable" and the Government includes your proposal in the order of merit ranking (for competitive proposals), or if the Government holds discussions with the selected source, you will be afforded the opportunity to further discuss, clarify or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion of children is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

VI. EVALUATION OF DATA SHARING PLAN

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

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

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

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

If your proposal does not include a plan or if 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 discussions with the selected source, you will be afforded the opportunity to further discuss, clarify or modify your plan for sharing model organisms during discussions and in your Final Proposal Revision (FPR). If your plan for sharing model organisms is still considered "unacceptable"by the Government after discussions, your proposal may not be considered further for award.

SOLICITATION ATTACHMENTS INCLUDED WITH THE BAA

The following pages include Attachments applicable to this BAA as specified in SECTION J - List of Attachments

ATTACHMENT 1

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 IS NOT ACCEPTABLE.

A. EXTERNAL PACKAGE MARKING:

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

BAA NIH-NIAID-DMID-07-37
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. PAPER COPIES and CD-Rom to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Carl A. Newman Contracting Officer Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214 Bethesda, Maryland 20817	Carl A. Newman Contracting Officer 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:

TECHNICAL PROPOSAL PAGE LIMITS (see table below).

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

TOTAL PAGE COUNT DOES NOT INCLUDE: 1 Cover and 1 Back Page; 1 Table of Contents; Section Dividers that do not contain information other than title of Section.

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.

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

ATTACHMENT 1

Document	Number of Copies	Page Limits
Technical Proposal	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** Sixteen (16) Compact Disks containing an electronic copy of the Technical Proposal in a Portable Document Format (PDF) [NOTE: 1 file on each disk.]	Limited to not-to-exceed 200 pages **including all appendices.**
Technical Proposal Appendices Any materials not available electronically (i.e. SOPs, Pertinent Manuals, Non-scannable Figures or Data, and Letters of Collaboration/Intent also count in the page limit).	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** Sixteen (16) Compact Disks containing an electronic copy of the Appendices in a Portable Document Format (PDF) [NOTE: 1 file on each disk.] If any Appendices are not available electronically, 16 hard copies of each page must be provided.	[NOTE: Included in the 200 total page count.]
Business Proposal	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** One (1) Compact Disks containing an electronic copy of the Business Proposal in a Portable Document Form (PDF).	N/A
Breakdown of Proposed Estimated Cost	This Attachment should be submitted also as a separate Excel file on the Business Proposal Compact Disk.	N/A

ATTACHMENT 2

PROPOSAL INTENT RESPONSE SHEET

BAA No.: BAA NIH-NIAID-DMID-07-37
BAA Title: Development of Therapeutic Agents for Selected BioDefense Bacterial Diseases

Please review the attached Broad Agency Announcement. Furnish the information requested below and return this page by June 30, 2006. 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:

Office of Acquisitions, NIAID, NIH, DHHS
Room 3214
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Carl A. Newman
BAA NIH-NIAID-DMID-07-37
FAX# (301) 480-2622
Email: cnewman@niaid.nih.gov

BROAD AGENCY ANNOUNCEMENT
"DEVELOPMENT OF THERAPEUTIC AGENTS FOR SELECTED BIODEFENSE BACTERIAL DISEASES"
BAA NIH-NIAID-DMID-07-37

BROAD AGENCY ANNOUNCEMENT DESCRIPTION

You are invited to submit a proposal in accordance with the requirements of this BROAD AGENCY ANNOUNCEMENT (BAA), NIH-NIAID-DMID-07-37, entitled: "Development of Therapeutic Agents for Selected Biodefense Bacterial Diseases." The BAA is authorized by 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 and constitutes a solicitation. The intent of a BAA is to encourage the submission of creative and innovative approaches to specific research areas identified by the U.S. Government.

A proposal submitted in response to this BAA must present separate detailed technical and cost proposals 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 U.S. Government.

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

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

Negotiations are conducted with those Offerors in the Order of Merit Ranking whose proposals would comprise the best group of contractors to fill the Government's needs for this research program based on technical merit, scientific priority, programmatic balance and the availability of funds. During negotiations, there is an opportunity to refine and update the proposed Statement of Work in consultation with the Project Officer, including the incorporation of the comments of the SRG, as appropriate. At the conclusion of negotiations with the Offerors selected from the Order of Merit Ranking, those Offerors are allowed the opportunity to submit a Final Proposal Revision (FPR) to address weaknesses in the proposal, based on issues identified by the SRG, 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 up to four (4) contracts based on technical merit, scientific priority, programmatic balance and the availability of funds. Awards are expected to be made on or about June 12, 2007. The NIAID estimates that the annual total costs (direct and indirect cost combined) will range from $2.0 million to $5.0 million per contract. However, it is anticipated that the total costs of each award may vary substantially depending upon the scope of the

project and the technical objectives of the award. The length of time for which funding is requested should be consistent with the nature and complexity of the proposed research. The maximum period of performance is 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.

BACKGROUND

Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), strives to understand, treat and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports extramural research to control and prevent diseases caused by virtually all infectious agents, with the exception of the human immunodeficiency virus (HIV). This includes basic and applied research to develop and evaluate therapeutics, vaccines and diagnostics, which are funded through a variety of research grants and contracts. In this context, the NIAID's mission includes the development of new medical countermeasures against the biological agents that are most likely to be used in a terror attack on civilian populations. These biological agents have been prioritized by NIAID as Category A, B, and C (http://www3.niaid.nih.gov/Biodefense/bandc_priority.htm). Through this solicitation, the NIAID is seeking to advance, via a focused, staged approach, the development of candidate therapeutics with demonstrated activity against one or more of the NIAID Category A and B bacterial pathogens listed below. Existing treatments for these pathogens are limited in number and effectiveness, as well as threatened by the emergence of antimicrobial resistance and the creation of antimicrobial resistance through intentional genetic engineering of pathogens.

- *Bacillus anthracis*
- *Yersinia pestis*
- *Francisella tularensis*
- *Burkholderia pseudomallei*
- *Burkholderia mallei*
- *Rickettsia prowazekii*

Pathogens, excluding sexually-transmitted organisms (see http://www3.niaid.nih.gov/biodefense/anti_stis.htm for list of excluded organisms), resistant to antimicrobial agents were recently added to the NIAID Biodefense Category C priority pathogens list. This solicitation will also support the development of candidate therapeutics with broad spectrum activity against NIAID Category C antimicrobial resistant bacterial pathogen(s) and at least one of the selected Category A or B bacterial pathogens (*B. anthracis, Y. pestis, F. tularensis, B. pseudomallei, B. mallei and R. prowazekii*).

INTRODUCTION

Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), strives to understand, treat and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports extramural research to control and prevent diseases caused by virtually all infectious agents, with the exception of the human immunodeficiency virus (HIV). This includes basic and applied research to develop and evaluate therapeutics, vaccines, and diagnostics, which are funded through a variety of research grants and contracts.

The NIAID also has a mission to advance the development of new medical countermeasures against the biological agents that are most likely to be used in a terror attack on civilian populations. The NIAID has prioritized these biological agents as Category A, B, and C (http://www2.niaid.nih.gov/Biodefense/bandc_priority.htm) based on associated morbidity and mortality; potential for person-to-person transmission or by vector transmission; infectivity; ability to contaminate food and water supplies; lack of a specific diagnostic and/or effective treatment; lack of a safe and effective vaccine; potential to cause anxiety in the public and in health care workers; and their potential to be weaponized. Treatment options for the Category A and B bacterial pathogens, *Bacillus anthracis, Yersinia pestis, Francisella tularensis, Burkholderia pseudomallei, Burkholderia mallei and Rickettsia prowazekii*, are both limited and vulnerable to emerging antimicrobial resistance and genetically engineered threats. Many antimicrobial resistant pathogens represent a public health threat and, in the context of biodefense, are classified as Category C pathogens. Within this framework, the development of new antimicrobial agents with broad spectrum activity for the selected Category A and B bacterial pathogens and Category C antimicrobial resistant bacterial pathogens is a high priority.

Through this solicitation, the NIAID is seeking to advance the development of candidate therapeutics, with demonstrated activity against one or more of the following selected bacterial pathogens, toward the product stage:

- *B. anthracis*
- *Y. pestis*
- *F. tularensis*
- *B. pseudomallei*
- *B. mallei*
- *R. prowazekii*

This solicitation will also support the development of candidate therapeutics with broad spectrum activity against an NIAID Category C antimicrobial resistant bacterial pathogen(s) and at least one of the selected Category A and/or B bacterial pathogens.

Offerors are invited to submit proposals that request funding to advance the development of a promising therapeutic candidate/product with activity against one or more of the selected bacterial pathogens listed above through a well-defined product development path that must include completion of a Phase 1 clinical trial prior to or within the five (5) years of contract award. The performance of studies in vertebrate animals and clinical studies must be consistent with all applicable Federal regulations and the DMID, NIAID, and NIH policies and guidelines for the conduct and oversight of research in vertebrate animals and human subjects. This solicitation will also support post-Phase 1 product development activities which are enabling for a biologic license application (BLA) or a new drug application (NDA), including: a) manufacturing scale-up leading to consistency lot manufacturing; b) Phase 2 clinical trials; c) animal studies to support licensure under the U.S. Food and Drug Administration (FDA) “Animal

Rule" (New Drug and Biological Drug Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible: http://www.fda.gov/cber/rules/humeffic.htm). All proposed activities must reasonably be expected to be completed within the maximum five (5)-year contract period. Plans for advancing therapeutic candidates/products through the product development path shall be proposed, implemented and funded in stages with specific decision points/gates and well defined criteria for determining the merit and feasibility of advancing to the next stage.

NOTE: Contracts awarded under this solicitation will not support the design and conduct of Phase 3 clinical trials.

The NIAID is particularly interested in the development of therapeutic candidates/products with the potential to be licensed for a treatment indication; however, proposals to advance therapeutics for a post-exposure prophylactic indication are also encouraged. In addition, the NIAID is interested in the development of therapeutics formulated for long-term stability, oral bioavailability, simple dosing regimens, and acceptable safety in diverse populations. Broad spectrum activity against multiple bacteria, including antimicrobial resistant bacteria, is also highly desirable.

Offerors may submit proposals for more than one therapeutic candidate/product; however, separate Technical and Business Proposals are required for each therapeutic candidate/product. If a therapeutic candidate/product is being proposed for activity against more than one of the selected bacterial pathogens within the scope of this BAA, a single Technical and Business Proposal is required.

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. In addition, the NIAID may elect to terminate funding of a contract at any time due to changes based on 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/product through the development pathway requires ongoing evaluation to assess and reassess the likelihood of the candidate/product to meet the desired therapeutic/post-exposure prophylactic objectives. The NIAID, therefore, reserves the right to determine, at any time during the contract period, that a particular candidate therapeutic has not demonstrated sufficient potential to merit further investment by the NIAID in the development and evaluation of that candidate/product.

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).

RESEARCH AND TECHNICAL OBJECTIVES

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

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

OVERALL SCOPE AND REQUIREMENTS

The purpose of this solicitation is to fund organizations with product development experience from the public or private sector, either domestic or foreign, that have:

1) Identified a "promising candidate therapeutic agent"

a) For the purposes of this BAA, a "promising candidate therapeutic agent" is defined as an agent that meets the following three criteria/definitions.

i) A drug (synthetic or natural product) or a biological product (i.e., monoclonal antibody or a derivative of a monoclonal antibody) intended for use in the cure, mitigation, treatment, or as post-exposure prophylactic, and is the type of agent that is within the regulatory purview of the Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA); AND .

ii) An agent with demonstrated therapeutic or post-exposure prophylactic activity in an appropriate animal model against one or more of the selected bacteria. "Therapeutic or post-exposure prophylactic activity in an animal model" is defined as an agent that mediates a statistically significantly better outcome/endpoint than relevant controls under well-controlled and documented experimental conditions; AND

iii) An agent that either has completed or will have completed evaluation in a Phase 1 clinical trial within the five (5) year contract period. Phase 1 clinical trial completion is defined as completion of a Final Clinical Study Report following International Conference on Harmonization (ICH) Guidelines on Structure and Content of Clinical Study Reports E3 (http://www.pharmacontract.ch/support/su_ich_liste.htm).

2) Devised a <u>Comprehensive</u> Staged Product Development Plan

A Comprehensive Staged Product Development Plan is expected to <u>summarize</u>:

a) The intended use/indication of the proposed therapeutic candidate/product and the biodefense/public health gap the product is intended to fill (e.g. potential for licensure for a treatment indication, for formulation with long term stability, oral bioavailability, simple dosing regimen, safety in diverse populations, broad spectrum activity).
b) The intended product profile.
c) The performance specifications and features the product should have in order to provide therapeutic benefit.
d) A description of the therapeutic candidate/product as it is currently configured.

e) A description and developmental status of the assays for product release and characterization, including activity and efficacy.
f) Data to support the characterization and selection of the therapeutic candidate/product for further development. Specifically, a summary of data that demonstrates therapeutic activity (treatment or post-exposure prophylactic activity) in appropriate animal models and assays against one or more of the selected bacteria is required. This includes: a detailed description of the assays and animal models, the choice of bacterial challenge, strain and route, and a rationale for the choice of animal model, bacterial challenge, strain and route, as well as for the outcome/endpoints selected; documentation that the animal infection experiments were performed under well-controlled experimental conditions and data that supports whether and how the candidate therapeutic specifically addresses antimicrobial resistance, engineered threats, or broad spectrum activity.
g) Discussions with CDER, FDA, if any, that are relevant to development activities for the proposed therapeutic candidate/product through submission of a biologic license application (BLA), or new drug application (NDA),and are investigational new drug (IND)-, BLA- or NDA-enabling or activities required to support the execution of IND-, BLA-, or NDA-enabling studies.

The NIAID recognizes that the regulatory path to licensure for therapeutics for the selected bacterial pathogens within the scope of this BAA may not be well defined. The regulatory requirements are likely to be defined in an iterative decision-making process with the CDER, FDA based on candidate/product-specific data as it emerges. Despite this uncertainty, based on current data and/or discussions with the CDER, FDA, a critical path to licensure for product must be devised, recognizing risks and areas of significant uncertainty. Risk mitigation strategies are desired.

3) Devised a Strategic Staged Product Development Plan

A Strategic Staged Product Development Plan is expected to detail:

a) Activities and stages of product development that the Offeror is proposing to perform under contract funding.
b) Distinct stages of the product development pathway that are decision gates for Go/No Go decisions for advancing to the next stage of the Strategic Staged Product Development Plan.
c) The qualitative and quantitative criteria and accompanying data elements to be used to assess the scientific merit and feasibility of proceeding to the next stage of product development.
d) Timelines for the initiation, conduct and completion of product development activities for each stage with a budget (direct costs) linked to each stage.

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

Non-Clinical Research and Development – Conduct research to: (1) evaluate the safety, pharmacokinetics/pharmacodynamics, bioavailability, solubility, formulation, dose, route and schedule of the therapeutic candidate/product *in vitro* and in animal models following Good Laboratory Practice guidelines (GLP: as defined in the U.S. Code of Federal Regulations – 21CFR §58); (2) optimize the therapeutic candidate/product through medicinal chemistry; (3) develop, characterize, and qualify and/or validate reagents and assays required for the clinical and non-clinical evaluation of the therapeutic candidate/product; and/or (4) develop animal models to support the evaluation of therapeutic products where efficacy cannot be evaluated in humans. Animal models should be developed in the context of the anticipated indication for which the therapeutic candidate/product is being developed (e.g. post-exposure prophylaxis delivered orally, treatment delivered subcutaneously).

Pilot Lot Manufacturing of Therapeutics – Product development activities in this area include: (1) development of master and working cell banks under current Good Manufacturing Practice guidelines (cGMP: as defined in the U.S. Code of Federal Regulations – 21 CFR §211); (2) conduct of process development for the manufacture of cGMP therapeutic product; (3) manufacture of non-cGMP and of cGMP pilot lots of therapeutic product in amounts sufficient to carry out required/proposed non-clinical and Phase 1 and/or Phase 2 clinical trials; and/or 4) conduct of long-term stability studies of cGMP product.

Phase 1 Clinical Evaluation – Product development activities in this area include: (1) designing a Phase 1 clinical trial to evaluate the safety and pharmacokinetics of the therapeutic candidate/product in humans; (2) preparing and submitting an IND application to the U.S. FDA; and/or (3) conducting a Phase 1 clinical trial in accordance with all federal guidelines, Good Clinical Practice guidelines (GCP: as defined by 21 CFR §312 and ICH Guidelines document E6 (http://www.pharmacontract.ch/support/su_ich_liste.htm) and DMID, NIAID, NIH policies and guidelines.

Post-Phase 1 BLA- or NDA-Enabling Activities – Activities in this area include: (1) conduct of scale-up leading to consistency lot manufacturing of the therapeutic candidate /product; (2) design and conduct of a Phase 2 clinical trial in accordance with all federal guidelines, Good Clinical Practice guidelines (GCP: as defined by 21 CFR §312 and ICH Guidelines document E6 (http://www.pharmacontract.ch/support/su_ich_liste.htm) and DMID, NIAID, NIH policies and guidelines; and/or (3) conduct of animal studies to support licensing under the "Animal Rule" (New Drug and Biological Drug Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible: http://www.fda.gov/cber/rules/humeffic.htm).

SPECIFIC TECHNICAL REQUIREMENTS

Independently, and not as an agent of the U.S. Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, as needed to provide the services delineated in the negotiated Statement of Work. The specific components of the Statement of Work and the scope of the product development activities to be undertaken will depend on the status of the individual therapeutic candidate/product as part of an overall Strategic Staged Product Development Plan, as well as regulatory requirements. The Contractor shall carry out activities within the contract's Statement of Work only as requested and approved by the Project Officer, and may not conduct work on the contract without prior approval from the Project Officer. Approval to carry out specific activities will be linked to approval by the Project Officer of the Strategic Staged Product Development Plan following contract award, approval of Monthly and Annual Progress Reports, review and approval of a Clinical Trial Protocol and supporting materials, and approval of Decision Gate Reports or Decision Gate Change or Deviation Requests (see reporting requirements for a description of these reports).

Each Contractor shall be required to perform the following activities and provide the following resources as appropriate to the scope of its specific negotiated Statement of Work:

1. STRATEGIC STAGED PRODUCT DEVELOPMENT

The Contractor shall prepare and implement a Strategic Staged Product Development Plan to aggressively advance the therapeutic candidate/product along a well-defined development path leading to a therapeutic product suitable for testing in humans in a Phase 1 clinical trial and/or for post-Phase 1 BLA- or NDA-enabling activities within the maximum five (5)-year period of the contract award. The Contractor shall perform all technical, regulatory, management, and administrative activities that are required to

implement the Strategic Staged Product Development Plan. The Strategic Staged Product Development Plan shall include:

a) Clearly defined goals, stages of product development and product development activities.
b) Go/No-Go decision gates.
c) Quantitative and qualitative criteria for assessing the scientific merit and feasibility of moving to the next stage of product development.
d) A detailed timeline for each stage covering the initiation, conduct and completion of product development activities and a budget (direct costs) linked to each stage.

The Strategic Staged Product Development Plan shall be approved by the Project Officer and the Contracting Officer prior to initiation of any activities related to its implementation. On completion of a stage of product development, as defined in the approved Strategic Staged Product Development Plan, the Contractor shall prepare and submit to the Project Officer and the Contracting Officer a Decision Gate Report that contains: (a) sufficient detail, documentation and analysis to support successful completion of the stage according to the predetermined qualitative and quantitative criteria that have been established for Go/No Go decision-making; (b) costs incurred; and (c) a description of the next stage of product development to be initiated and a request for approval to proceed to the next stage of product development.

2. CLINICAL TRIAL PROTOCOL DEVELOPMENT AND IMPLEMENTATION

The Contractor shall develop all clinical trial protocols and shall have ultimate responsibility for the conduct of all clinical trials and adherence to Federal regulations and the DMID, NIAID, NIH policies and guidelines for the conduct of research involving human subjects. Copies of Department of Health and Human Services (DHHS) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protections (OHRP), Office of the Secretary (OS), DHHS – http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm . DMID policies, guidelines, templates and other important information regarding performing human subjects research are available at: http://www.niaid.nih.gov/dmid/clinresearch/. It is required that the information contained in the DMID Serious Adverse Event (SAE) Report Form be included in the Contractor's SAE Report Form, and it is recommended that the Contractor use the DMID SAE Report Form located at http://www.niaid.nih.gov/dmid/clinresearch/. SAE Reports must be submitted to the DMID Office of Clinical Research Affairs, according to the Clinical Terms of Award (see below). In addition, the Contractor shall develop and implement a Clinical Trials Monitoring Plan as part of the DMID Clinical Protocol.

The Contractor shall be required to: (a) comply with all Federal and NIAID Clinical Terms of Award (http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf); (b) submit clinical trial protocols and supporting documentation (e.g. investigators brochures, informed consent templates, manuals of procedures, local Institutional Review Board committee approvals) and amendments to the Project Officer for review and approval by the appropriate NIAID review committee (the Clinical Trials Monitoring Plan is part of the DMID protocol template and is also subject to approval by the Project Officer); and (c) obtain from the Project Officer final approval of protocols to be undertaken prior to FDA IND submission and participant enrollment.

The Contractor shall be the product sponsor and shall be responsible for: (a) preparing materials for and requesting, scheduling and participating in all meetings with the CDER, FDA, including meetings to review IND, NDA and BLA packages; (b) submitting all documentation to the FDA in a timely manner, consistent with timelines set out in the contract and by the FDA; (c) including NIAID staff, as designated by the Project Officer, in meetings and teleconferences with the FDA; and (d) providing copies of all

FDA correspondence and meeting minutes that are relevant to the therapeutic candidate/product to the Project Officer.

NOTE: PHASE 3 CLINICAL TRIALS WILL NOT BE FUNDED UNDER THIS SOLICITATION.

3. REGULATORY COMPLIANCE AND DATA MANAGEMENT

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

a) 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.
b) Provide for the statistical design and analysis of data resulting from the research undertaken.
c) Provide raw data or specific analyses of data generated with contract funding to the Project Officer.
d) Ensure strict adherence to FDA regulations and guidances, including requirements for the conduct of animal studies and assays under GLP, the manufacturing of the therapeutic candidate/product under cGMP, and the conduct of clinical trials under GCP standards. The Contractor shall maintain quality assurance documentation to support adherence in these areas.
e) Arrange for independent audits, as needed or as requested by the Project Officer and as concurred in by the Contracting Officer. Audits may be requested to assure that Contractor and/or subcontractor facilities and all planned procedures meet the FDA regulations and guidances that are required to meet GLP, cGMP and GCP 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 guidances, including those required to meet GLP, cGMP or GCP standards. Such audits may also be conducted prior to contract award as a part of the technical evaluation of the Offeror's Technical Proposal.

4. TECHNICAL, MANAGEMENT, AND ADMINISTRATIVE TEAM

The Contractor shall provide all expertise needed for the implementation of the Strategic Staged Product Development Plan to be performed under this contract including: research, manufacturing, regulatory, clinical, 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 humans and in vertebrate animals. The Principal Investigator (PI) shall be responsible for all aspects of project performance and communication with the Project Officer and the Contracting Officer. In addition, the Contractor shall provide Project Manager(s) who are responsible for the day-to-day monitoring and tracking of progress and timelines, the coordination of project activities and costs incurred.

5. FACILITIES, EQUIPMENT AND OTHER RESOURCES

The Contractor shall provide the equipment, facilities, and other resources required for the implementation of the Strategic Staged Product Development Plan. Depending on the stage of development of the therapeutic candidate/product, this may include: (1) the performance of IND-enabling

assays and animal studies under GLP; (2) production, characterization and release testing of therapeutic agent under cGMP conditions; and (3) performance of clinical trial(s) in humans under GCP.

This shall also include the equipment and facilities, training, and resources to comply with all Federal and NIH regulations, including: (a) the humane care and use of vertebrate animals; and (b) 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, 4th edition is available at: http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.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 their Institutional Biosafety Committee. At the request of the Project Officer, the Contractor shall provide copies of materials submitted for Institutional Biosafety Committee Review and documentation of approval of experiments.

6. PROJECT MANAGEMENT

The Contractor shall provide for: (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) effective communication with the Project Officer and the Contracting Officer; and (c) a 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) Project Manager(s) with responsibility for monitoring and tracking day-to-day progress and timelines, coordinating communication, project activities and costs incurred; and (e) administrative staff with responsibility for financial management and reporting on all activities conducted by the Contractor and any subcontractors.

The Contractor is 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).

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.

7. EXTERNAL ADVISORY GROUP

In consultation with the Project Officer, the Contractor shall establish an External Advisory Group with the relevant expertise to critically evaluate technical progress in meeting product development objectives and established timelines. Contractor performance shall be subject to periodic review by this External Advisory Group as described under the "Reporting Requirements and Other Deliverables" section of this BAA. The membership of the External Advisory Group will be jointly proposed and agreed to by the Contractor and the Project Officer and approved by the Project Officer post-award.

8. CONTRACT REVIEW MEETINGS

Post-Award Kick-Off Meeting: Within thirty (30) calendar days after contract award, the Contractor shall plan, conduct and be responsible for the logistical arrangements for a post-award kick-off meeting to be held at a site proposed by the PI and approved by the Project Officer. The PI, Project Manger(s), all key investigators, and 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 Strategic Staged Product Development Plan and the Work Plan and to coordinate activities and communication. The PI shall provide slide presentations and a detailed summary of meeting discussions to the Project Officer and the Contracting Officer within twenty-one (21) calendar days following the date of the meeting. External Advisory Group members may attend the meeting if they have been named within the first thirty (30) calendar days of the contract.

Annual Review Meetings: At the 12 month mark of each contract year, the Contractor shall plan, conduct and be responsible for logistical arrangements for an annual review meeting, to be held at a site proposed by the PI and approved by the Project Officer, for NIAID contract and program staff and the External Advisory Group. The PI, Project Manger(s), all key investigators, and key subcontractor personnel shall attend these meetings. The agenda will be prepared by the Project Officer in consultation with the PI. Meetings will be closed to the public and shall involve oral and electronic presentations, including: a) updates on results of activities undertaken or completed since the last review meeting; b) updates on progress toward or reaching a decision gate; c) interim reports on active preclinical or clinical protocols; d) a description of any problems encountered or anticipated; e) a discussion of approaches to overcoming problems; and f) a description of activities to be undertaken in the coming year. The PI shall provide slide presentations and a detailed summary of meeting discussions to the Project Officer and the Contracting Officer within twenty-one (21) calendar days following the date of the meeting.

For Contractors with domestic or foreign subcontracts, this annual review meeting shall also report on approvals for manufacturing, preclinical or clinical testing that have been obtained from both the U.S. and/or foreign governments.

The PI, Project Manager(s), key investigators, and key subcontractor personnel shall attend additional meetings in Bethesda, Maryland at the request of the Project Officer. Such meetings will be requested, as necessary, to discuss contract specific issues.

9. 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 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.

REPORTING REQUIREMENTS AND OTHER DELIVERABLES

Some reports and other deliverables are relevant to specific activities that may or may not be performed during the contract period of performance. The Contractor, the Project Officer and the Contracting Officer shall agree in the final contract negotiations on which reports and other deliverables are relevant and shall be required as deliverables as determined by the negotiated Statement of Work.

As part of the work to be performed under this BAA, the Contractor shall prepare and deliver the following reports throughout the period of performance. For all reports the Contractor shall submit two (2) paper copies and one (1) electronic copy to the Project Officer and one (1) paper copy and one (1) electronic copy to the Contracting Officer.

A. PROGRESS REPORTS

1) Monthly Technical Progress Reports

On the due date specified in the contract, the Contractor shall submit a Monthly Technical Progress Report that includes the following:

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 description of overall progress;
    ii) SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, 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; and
    v) Copies of preprints and reprints of papers and abstracts.

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

2) Annual Technical Progress Reports

Annual Technical Progress Reports shall be submitted by the 15th of the month following the end of each 12 months of the contract period of performance. Each Annual Technical Progress Report shall include:

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 description of overall progress;
    ii) SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, 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 decision gates outlined in the approved Strategic Staged 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.
    v) Copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting period; and
    vi) A summary of any inventions developed during the course of the contract.

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

3) 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 inventions.

Draft Final Technical Progress Report: The Contractor is required to submit the Draft Final Progress Report to the Project Officer and Contracting Officer. This report is due 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 45 calendar days after receipt.

Final Technical Progress Report: The Contractor shall deliver the Final Technical Progress Report as specified in the Article F.1 within **15 calendar days** prior to completion of the contract period.

Summary of Salient Results: The Contractor shall prepare and submit, with the Final Technical Progress Report, a summary of salient result (not to exceed 200 words) achieved during the

performance of the contract. This report shall be required on or before the expiration date of the contract.

B. TECHNICAL REPORTS

1) **Decision Gate Report**

A Decision Gate Report shall be submitted when the Contractor has completed a stage of product development and has reached a Go/No Go decision point, as defined in the approved Strategic Staged Product Development Plan. These reports shall be in sufficient detail to explain comprehensively the results achieved. The description shall also include pertinent data and/or conclusions resulting from the analysis and scientific evaluation of data accumulated to date under the project.

Decision Gate Reports shall include the following specific information:

a) Cover page that lists the contract number and title, the period of performance being reported, the Contractor's name and address, telephone number, fax number, email address, and the date of submission;
b) An introduction covering the purpose, the scope of the contract effort, and the specific Decision Gate that has been reached;
c) Document and summarize the results of work undertaken that supports the completion of the stage of product development, including an analysis of the data as it relates to the qualitative and quantitative criteria established for Go/No Go decision-making;
d) Actual costs incurred in relation to costs estimated in the original approved budget; and
e) A description of the next stage of product development to be initiated and a request for Project Officer approval to proceed to the next stage of product development.

2) Decision Gate Change or Deviation Request

The Contractor shall submit a written request for a change in the agreed timelines and/or decision gate as approved in the Strategic Staged Product Development Plan. This request shall include the following:

a. A discussion of the justification/rationale for the request based on current data and a description of those data;
b. Options for addressing the needed change/deviation from the approved timelines and/or decision gates, including a cost-benefit analysis of each option; and
c. A recommendation for the preferred option that includes a full analysis and discussion of the effects of the change on the entire product development program, timelines, and budget.

3) Audit Reports

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

4) Clinical Trial Protocols

The NIAID has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in NIAID-funded clinical trials. Therefore, as described in the NIAID Clinical Terms of Award (http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf), the Contractor shall develop a protocol for each clinical trial and submit all protocols and protocol amendments for approval by the Project Officer. Protocols must be submitted using the approved DMID template and include a sample Informed Consent and Clinical Trials Monitoring Plan. The DMID templates and other important information

regarding performing human subjects research are available at http://www.niaid.nih.gov/dmid/clinresearch/.

5) Final Clinical Study Report

The Final Clinical Study Report shall follow the ICH guidelines on Structure and Content of Clinical Study Reports E3 (http://www.pharmacontract.ch/support/su_ich_liste.htm). Final Clinical Study Reports shall be provided within thirty (30) calendar days of the completion of the analysis of all data generated in the clinical trial.

6) Final Animal Efficacy Report

The Final Animal Efficacy Study Report shall include a complete description of the experimental design, protocol, methods, reagents, data analysis, and conclusions of studies performed to demonstrate efficacy of therapeutic product for the indication (i.e., post-exposure prophylaxis or treatment) being sought.

C. Other Reports

1) Strategic Staged Product Development Plan

The Contractor shall be required to update the Strategic Staged Product Development Plan to incorporate progress since proposal submission. Within fourteen (14) calendar days after contract award and prior to initiation of product development activities, unless otherwise negotiated with the Project Officer and the Contracting Officer, the Contractor shall submit an updated Strategic Staged Product Development Plan for approval. This Plan shall include:

a) Clearly defined goals, product development stages and product development activities;
b) Go/No Go decision gates;
c) Quantitative and qualitative criteria for assessing the scientific merit and feasibility of moving to the next stage of product development; and
d) A detailed timeline for each stage covering the initiation, conduct and completion of product development activities and a budget (total costs) linked to each stage.

2) Contract Review Meeting Reports

A report of the Post-Award Kick-Off Meeting and the Annual Review Meetings shall be prepared by the Contractor and submitted within twenty-one (21) calendar days following the date of the meeting. These reports shall include the slide presentations and all other meeting materials as well as summaries of all discussions.

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.

Type of Report	No. of Copies	Addresses/Distribution	Due Date
PROGRESS			
Monthly Technical Progress Report	3 paper 2 electronic	Original hardcopy and one (1) electronic copy: Contracting Officer (CO), NIAID 6700 Rockledge Drive Bethesda, MD 20817 Two (2) paper and one (1) electronic: Project Officer (PO), NIAID 6610 Rockledge Drive Bethesda, MD 20817	The 15th of each month. First report is due following the first full month of contract performance, including any portion of the prior month since award. The Monthly Technical Progress Report shall not be required on months when an Annual Technical Progress Report is due.
Annual Technical Progress Report	3 paper 2 electronic	Same as CO and PO above	15th of the month following the end of each 12 months of the performance period. The Annual Technical Progress Report shall not be required when the Final Technical Progress Report is due.
DRAFT Final Technical Progress Report	3 paper 2 electronic	Same as CO and PO above	One hundred twenty calendar days prior to completion date of the contract
Final Technical Progress Report	3 paper 2 electronic	Same as CO and PO above	Fifteen calendar days before completion of the contract period
TECHNICAL			
Decision Gate Report	3 paper 2 electronic	Same as CO and PO above	Following completion of a pre-defined stage of product development and prior to initiation of a new stage.
Decision Gate Change or Deviation Request	3 paper 2 electronic	Same as CO and PO above.	As soon as the Contractor has sufficient data to

			support the need for a change from the approved Strategic Staged Product Development Plan..
Audit Reports	3 paper 2 electronic	Same as CO and PO above.	Within 30 calendar days of the audit.
Clinical Trials Protocols	3 paper 2 electronic	Same as CO and PO above	To be negotiated with the NIAID Project Officer and prior to IND submission or enrollment of human subjects.
Final Clinical Study Report	3 paper 2 electronic	Same as CO and PO above	Thirty (30) calendar days after completion of analysis of clinical trial data.
Final Animal Efficacy Study Reports	3 paper 2 electronic	Same as CO and PO above	Thirty (30) calendar days after completion of all analysis of animal efficacy study data.
OTHER REPORTS			
Strategic Staged Product Development Plan	3 paper 2 electronic	Same as CO and PO above	Within fourteen (14) calendar days after contract award and prior to initiation of product development activities
Annual Review Meeting Report	3 paper 2 electronic	Same as CO and PO above	Within twenty-one (21) calendar days following the date of the Annual Review Meeting.
FDA Correspondence and Meeting Summaries	3 paper 2 electronic	Same as CO and PO above	Within thirty (30) calendar days of receiving correspondence or meeting with the FDA.
Annual Progress Report for Clinical Research Study Populations	3 paper 2 electronic	Same as CO and PO above	Due on or before the 30th of the month following each anniversary of the contract. The first report is due on July 30, 2007

D. Other Deliverables

1) Samples of Therapeutics: The Contractor shall submit samples of non-GMP candidate therapeutics and GMP material manufactured with contract funding. The type of material and the amount will be specified in the contract. The Contractor will be advised by the Project Officer how samples are to be packaged and where samples are to be shipped.

2) Animal Model: 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) 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, Certificate of Analysis at the request of the Project Officer.

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: Provide raw data or specific analysis of data generated with contract funding at the request of the Project Officer.

6) Annual 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.

APPENDIX A:
ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS
BAA NIH-NIAID-DMID- 07-37
FORMAT FOR TECHNICAL PROPOSAL-TABLE OF CONTENTS

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.

The following additional Technical Proposal instructions reflect the requirements of the BAA and are meant to provide additional instructions as well as a uniform format for Technical Proposals. The information requested in these instructions should be used as a guide for formatting and preparing the proposal. Offerors should follow the instructions in Section L of the solicitation and include the information requested in this appendix.

Offerors are advised to give careful consideration to the Broad Agency Announcement Description, Background, Introduction, Research and Technical Objectives, all reference material, appendices and attachments, the technical evaluation criteria, and, the BAA as a whole, in the development of their proposal.

Offerors that propose 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 between the prime and subcontractor(s), and the expected advantages of such an approach.

THE TOTAL MAXIMUM NUMBER OF PAGES FOR THE ENTIRE TECHNICAL PROPOSAL MAY NOT EXCEED **200** PAGES, INCLUDING ALL APPENDICES. PAGES IN EXCESS OF THE LIMIT WILL BE REMOVED AND WILL NOT BE REVIEWED.

PAGES THAT ARE 2-SIDED WILL BE COUNTED AS 2 PAGES. TOTAL PAGE COUNT DOES NOT INCLUDE THE FOLLOWING: 1 COVER PAGE AND 1 BACK PAGE, 1 TABLE OF CONTENTS PAGE, REFERENCES, OR ANY SECTION DIVIDERS THAT DO NOT CONTAIN INFORMATION OTHER THAN TITLE OF SECTION.

OFFERORS ARE ADVISED THAT FULL SOPs, INVESTIGATOR BROCHURES, OR OTHER PERTINENT BROCHURES, ETC. DO NOT NEED TO BE SUBMITTED WITH THE TECHNICAL PROPOSAL. IN THE INTEREST OF KEEPING TO THE PAGE LIMIT, A SUMMARY OF THE PERTINENT PORTIONS OF THESE DOCUMENTS IS PREFERRED.

SECTION 1: SYNOPSIS (maximum 2 pages)

Provide a brief description of the proposed product development plan, including:

a) A 1-2 sentence summary describing the therapeutic candidate/product the Offeror is proposing to advance, the intended indication, and the BioDefense/public health gap the product is intended to fill;
b) A summary describing the scope of product development activities proposed;

c) A description of the activities to be performed by the Offeror and those that shall be provided by any proposed subcontractors, including the identification of the proposed subcontractors and a list of key personnel of the Offeror and the proposed subcontractors with degrees and titles;
d) A brief description of the facilities and other resources to be made available by the Offeror and any proposed subcontractors; and
e) The period of contract funding requested and the total budget for each year.

SECTION 2: COMPREHENSIVE STAGED PRODUCT DEVELOPMENT PLAN

Technical Proposals shall include a Comprehensive Staged Product Development Plan that describes the critical path for the proposed therapeutic candidate/product to eventual licensure and identifies the decision points/gates for progressing the candidate/product through the critical path.

Technical Proposals shall provide background information to justify the investment in the further development of the proposed therapeutic candidate/product. The Comprehensive Staged Product Development Plan shall include a summary of the following:

a) The intended use/indication of the proposed therapeutic candidate/product and the biodefense/public health gap the product is intended to fill (e.g. post-exposure treatment, post-exposure prophylaxis; broad spectrum, narrow spectrum).
b) The intended product profile including potential stability, bioavailability, dosing, and safety.
c) The performance specifications and features the product should have in order to provide therapeutic benefit.
d) A description of the therapeutic candidate/product as it is currently configured.
e) Data to support the characterization and selection of the therapeutic candidate/product for further development. Specifically, a summary of the data that demonstrate therapeutic activity (treatment or post-exposure prophylactic activity) in an appropriate animal model against one or more of the selected bacteria is required. Include a detailed description of the animal model and the choice of bacterial challenge, and a rationale for the choice of animal model and bacterial challenge, as well as for the outcome/endpoints selected. Document that the animal infection experiments were performed under well-controlled experimental conditions.
f) Discussions with the CDER, FDA, if any, that are relevant to development activities for the proposed therapeutic candidate/product.
g) A description of activities that are part of the critical product development path through submission of a BLA or NDA, and are IND-, BLA- or NDA-enabling or activities that are required to support the execution of IND-, BLA-, or NDA-enabling studies.

The NIAID recognizes that the regulatory path to licensure for therapeutics for the selected bacterial pathogens within the scope of this BAA may not be well defined. The regulatory requirements are likely to be defined in an iterative decision-making process with the CDER, FDA based on candidate/product-specific data as it emerges. Despite this uncertainty, Offerors must propose, to the best of their ability and based on current data and/or discussions with the CDER, FDA, a critical path to licensure for their product. The Technical Proposal should discuss areas of significant uncertainty and propose likely alternatives.

SECTION 3: STRATEGIC STAGED PRODUCT DEVELOPMENT PLAN

Technical Proposals shall include a Strategic Staged Product Development Plan. This plan shall include the specific tasks and stages of the Comprehensive Staged Product Development Plan that the Offeror is proposing to perform with contract funding and that can reasonably be completed within the five (5) year maximum period of performance. The Strategic Staged Product Development Plan must detail:

a) Activities and stages of product development that the Offeror is proposing to perform under contract funding.
b) Distinct stages of the product development pathway that are decision gates for Go/No Go decisions for advancing to the next stage of the Strategic Staged Product Development Plan.
c) 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) Timelines for the initiation, conduct and completion of product development activities for each stage and a budget (direct costs) linked to each stage. If a Phase 1 clinical trial has not been completed, the Offeror should clearly note the time line for completing the Phase 1 clinical trial and the Final Clinical Study Report within the five (5) year contract period.

SECTION 4: WORK PLAN FOR IMPLEMENTATION OF THE STRATEGIC STAGED PRODUCT DEVELOPMENT PLAN

Technical Proposals shall include a Work Plan describing each step that the Offeror proposes to perform after contract award that is required to implement the Strategic Staged Product Development Plan and complete all proposed work within the five-(5) year period of performance:

The Work Plan shall include:

a) Key development objectives and defined decision points for the development of the therapeutic candidate/product.
b) A detailed discussion of the proposed technical approach for each activity to be performed to achieve the project objectives. The Work Plan shall contain sufficient detail to fully explain and justify the scientific/technical rationale for the proposed approach and/or methodologies and should reflect a clear understanding of the scope and nature of the work being undertaken.
c) A detailed Gantt Chart organized by each specific decision gate/stage of product development proposed, as well as the overall product development program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, the date of a stated event, as for example receipt of a required approval from the Project or Contracting Officer.
d) For each decision gate proposed, a description of the process for making decisions to proceed or not proceed (Go/No-Go), including specific qualitative and quantitative criteria for advancement of therapeutic candidates/products through each stage of the product development process. For example, decision to proceed or not to proceed vis a vis human safety, pharmacokinetic (PK) and pharmacodynamic (PD) testing.
e) Plans for quality control over the implementation, coordination and conduct of the activities set forth in the Strategic Staged Product Development Plan, including plans to conduct regulatory audits.
f) Approaches to integrate adverse experimental or production results, or new scientific findings into the proposed goals and timelines.
g) A plan for sharing data, reagents, and animal model resources developed with contract funding with the scientific research community; and
h) A Technical Proposal Cost Summary to include: a list of all subcontracts by activity (e.g., GMP manufacture, IND-enabling toxicologic studies, formulation and fill, etc.), and a budget for each stage of product development proposed for funding – linked to a timeline for completion of each stage..
i) A list and description of all items to be delivered to the Government during the performance of the contract and the timeline for delivery.

SECTION 5: CLINICAL TRIAL PROTOCOL DEVELOPMENT AND IMPLEMENTATION

Work Plans that propose clinical trials must include:

a) A description of previous experience in the conduct of human subjects research that demonstrates the Offeror's expertise and/or thorough knowledge of Federal regulations for the conduct of human subjects research. A description of experience in the conduct of human subjects research in accordance with DMID, NIAID, NIH policies and guidelines or a statement acknowledging willingness to conduct clinical research according to DMID, NIAID, NIH policies and guidelines.
b) A clinical trial Protocol Synopsis for each proposed trial. The Synopsis should include: the name(s) of the individual(s), organization(s) and site(s) that will perform the clinical trial, and documentation of their capability and willingness to perform the trial; primary and secondary objectives of the trial, trial design, and assays to be performed. The Offeror shall also address issues of human subjects protection, provisions for data and safety monitoring, recruitment and retention of study participants, informed consent, the quality management plan, clinical monitoring plan and the statistical analysis plan.
c) A plan that specifies at which points in the Strategic Staged Product Development Plan it will be critical to engage in written communications and meetings with the FDA.
d) A plan that specifies the frequency and methods by which NIAID will be kept apprised of progress and provided with documentation of communications with the FDA, including correspondence from the FDA and minutes/summaries of meetings with the FDA.

SECTION 6: REGULATORY COMPLIANCE, QUALITY ASSURANCE AND DATA MANAGEMENT

a) Data Management and Quality Assurance:

i. The Technical Proposal must describe the data management and quality control systems/procedures that will be used for all studies and procedures 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.
ii. The Technical Proposal must also describe the statistical design and analysis resources that will be used to support contract activities.
iii. 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. MAC users must guarantee that data can be transferred to the Project Officer without corruption of data or figures.

b) Regulatory Compliance:

i. The Technical Proposal must provide a plan to develop and maintain quality assurance documentation to support adherence to FDA regulatory standards and guidances that bear on the conduct of assays under GLP, manufacturing under GMP, and performance of clinical trials under GCP standards, as relevant to the Work Plan. Include information on data management for GLP, cGMP, and GCP activities.
ii. Offerors should document experience with performing studies in accordance with FDA regulations and guidances, including GLP, cGMP, and/or GCP guidelines as appropriate to their proposed Statement of Work.
iii. The Technical Proposal must include a plan to determine when audits need to be performed, timely scheduling of audits, performance of audits, and responding to audit reports.

iv. The Technical Proposal must include an audit history of the facilities proposed for use in carrying out contract activities that will be performed under GLP, GMP and/or GCP.

v. The Technical Proposal must include letters signed by the appropriate authority allowing for pre-award site visits to the Offeror's facility and proposed subcontractor's facilities. Site visits may include GLP, cGMP, or GCP audits (as appropriate) performed by independent auditors contracted by NIAID.

SECTION 7: PERSONNEL: RESEARCH, PRODUCTION, REGULATORY, CLINICAL, STATISTICAL, MANAGEMENT and ADMINISTRATIVE TEAM

The Technical Proposal shall describe in detail the responsibilities and level of effort of all personnel who will be assigned to the contract.

The Technical Proposal shall provide documentation of the qualifications, knowledge, experience, education, competence, availability, and decision-making authority of the PI, as well as research, production, regulatory, clinical, project management, statistical and administrative staff. Resumes, endorsements, and documentation of previous relevant efforts provided on behalf of the PI and other investigators(s) shall clearly demonstrate relevant knowledge, training, experience, and specific accomplishments. Resumes should be limited to three (3) pages, single-spaced.

The Technical Proposal must also identify all proposed subcontractors and consultants and provide the same information and documentation as noted above with respect to the qualifications, knowledge, training, experience, education, availability, level of effort, and specific responsibilities, including documentation of previous work relevant to the proposed tasks to be carried out by all such subcontractors and consultants.

SECTION 8: FACILITIES, EQUIPMENT AND OTHER RESOURCES

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

a) Document the availability and adequacy of facilities, equipment and other resources available for performance of the contract, including: (1) detailed laboratory layouts; (2) information regarding ownership/lease of the facility(ies), including documentation of the availability of proposed facilities for the duration of the contract; (3) plans for and procedures to be utilized to insure compliance with all safety guidelines and regulations, including training and monitoring of personnel; and (4) plans for obtaining, adding or deleting facilities as necessary due to progress or performance issues that arise during the course of product development.

b) Document the availability of appropriate facilities for performing assays and animal studies under GLP standards, production of therapeutic material under GMP guidelines, and performance of clinical studies following GCP guidance as required to implement the Strategic Staged Product Development Plan.

c) 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).

d) 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, 4th edition, May 1999 (http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm) and interim guidelines for influenza, 5th 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/ncidod/srp/speciments/shippin-packing.html). Safety and Health HHSAR 352.223-70 clauses shall apply.

e) 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 (http://www.nih.gov/od/ors/ds/pubs/cyto/) 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).

SECTION 9: PROJECT MANAGEMENT

The Technical Proposal must include a Project Management Plan:

a) Describe how the project will be staffed, organized and managed, including a detailed description of the responsibilities and the level of effort 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.
b) Describe project management systems that will be used to track activities and to keep multiple activities on time and budget.
c) Outline how the PI will communicate and interact with the NIAID Project Officer and the NIAID Contracting Officer and how the PI will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).
d) Provide a plan for soliciting, evaluating, negotiating, awarding, and managing subcontracts in accordance with FAR Clause 52.244-2.
e) Describe experience and education of contract management staff in the acquisition and management of subcontracts under Federal contracts.
f) Describe experience with identification and remediation of subcontractor performance problems or noncompliance with subcontract terms and conditions.
g) Provide a Letter of Understanding (LOU) signed by persons with authority to bind each collaborating party involved in the proposed work. The LOU must describe how the collaborating parties will coordinate their efforts to 1) protect intellectual property arising in the performance of the contract, 2) facilitate the development for commercialization of the resulting therapeutic product, and 3) resolve disputes among the collaborating parties should such disputes arise in performance of the contract.

SECTION 10: EXTERNAL ADVISORY GROUP

The Technical Proposal must include a plan that describes the agreements to be put in place with members of the External Advisory Group in order to safeguard confidentiality of data and information that may be shared with these external advisors at the Annual Review Meeting.

DO NOT CONTACT POTENTIAL MEMBERS PRIOR TO AWARD OR PROPOSE MEMBERS OF THE EXTERNAL ADVISORY GROUP IN THE TECHNICAL PROPOSAL.

SECTION 11: ANNUAL REVIEW MEETINGS

The Technical Proposal must include a plan for how the Contractor will plan, organize and conduct Annual Review Meetings that will include the Project Officer and Contracting Officer, the External Advisory Group, the PI, Project Manager(s), key subcontractor staff, and principal scientists involved on the contract.

SECTION 12: OFFEROR'S PROPOSED STATEMENT OF WORK (limit fifteen (15) pages)

In contracts awarded under this BAA, the Statement of Work will be the Statement of Work proposed by the Offeror and negotiated and accepted by the NIAID. This section of the Offeror's Technical Proposal should outline the activities to be performed by the Contractor during performance of the contract using an outline format. The Offeror's proposed Statement of Work should begin as follows: "Independently, and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below. Specifically, the Contractor shall:" The opening paragraph should be followed by a full Statement of Work describing each activity that the Contractor shall perform after the award of the contract. The Statement of Work shall include all activities required to effectively implement the Strategic Staged Product Development Plan. 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 Work Plan in that it describes what the Contractor will provide, while the Work Plan describes the specific detailed plan for the implementation of the Strategic Staged Product Development Plan (See instructions for Section 4: Work Plan: Implementation of the Strategic Staged Product Development Plan).

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 the implementation of the Strategic Staged Product Development Plan.
    - Sub-activity: The Contractor shall provide ABSL 3 facilities for the performance of animal efficacy studies.
    - Sub-activity: The Contractor shall provide AALAC accredited facilities for the performance of studies that include vertebrate animals.
    - Sub-activity: The Contractor shall provide equipment and facilities for the synthesis of the therapeutic agent in accordance with cGMP.
- Activity: The Contractor shall provide for the nonclinical evaluation of the candidate therapeutic agent
    - Sub-activity: The Contractor shall perform studies to evaluate the solubility and bioavailability of the therapeutic agent
    - Sub-activity: The Contractor shall perform studies to determine the most effective dose and route of delivery for the therapeutic agent.
- Activity: The Contractor shall evaluate the therapeutic candidate/product in a Phase 1 clinical study
    - Sub-activity: Perform a Phase 1 Clinical Study
- Activity: Project Management
    - Sub-activity: Management of Subcontracts;
    - Sub-activity: Project Oversight.

APPENDIX B: ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS

DEVELOPMENT OF THERAPEUTIC AGENTS FOR SELECTED BIODEFENSE BACTERIAL DISEASES
BAA NIH-NIAID-DMID-07-37

In addition to the format requirements for the Business Proposal that are contained in Section L of the solicitation, the information provided in this Appendix is intended to provide uniform cost assumptions and business clarifications.

Offerors are advised to give careful consideration to the Broad Agency Announcement Description, Background, Research and Technical Objectives, all reference material provided as appendices and attachments, the Technical Evaluation Criteria, and the BAA as a whole in the development of their 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 in this appendix as well as any other information that will benefit the proposal.

Budget Presentation

a) Annual Budget: Provide a budget itemizing the costs for all proposed activities for each year of requested funding.

b) Stage-Specific Budget: Provide a budget for each stage of the Strategic Staged Product Development Plan that is proposed to be performed with contract funding.

Purchase of Equipment: Support will NOT be provided for the purchase of equipment under this contract.

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

Kick-off Meeting and Annual Review Meetings: Budget for travel and per diem for the External Advisory Group (four (4) members), the Principal Investigator, Project Manager(s), key investigators, and key subcontractor staff to attend a 1.5 day Kick-Off Meeting and Annual Review Meetings, the location of which will alternate between Bethesda, Maryland and the Contractor's site.