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

RFP-NIH-NIAID-DMID-08-03
"Vaccine and Treatment Evaluation Units (VTEUs): Evaluation of Control Measures Against Diseases Other Than AIDS"

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:** December 15, 2006	5. **Small Bus. Set-Aside:** [ ]Yes [X] No **8(a) Set-Aside:** [ ]Yes [X] No **NAICS: 541710**
June 2, 2006	**Time:** 3:00 P.M., Local Time	(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.**	
Teresa A. Baughman 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. **Period of Performance:** 11/01/07 – 10/31/14

13. **Primary Point of Contact:**	14. **Secondary Point of Contact:**	15. **Protest Officer:**
Name : Teresa A. Baughman **Phone:** 301- 451-3690 **Fax:** 301-480-4675 **E-Mail:** tb14j@nih.gov	**Name:** Barbara A. Shadrick **Phone:** 301-496-7288 **Fax:** 301-402-0972 **E-Mail:** bs92y@nih.gov	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**
Teresa A. Baughman Office of Acquisitions DEA, NIH, NIAID 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	Teresa A. Baughman 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.

22. DETAILED TABLE OF RFP 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

This contract provides for the design and conduct of Phase 1, Phase 2, Phase 3 and Phase 4 clinical trials and clinical studies of candidate vaccines and therapeutics, as well as for other evaluations and analyses, against infectious diseases other than human immunodeficiency virus (HIV).

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. Please refer to SECTION J, List of Attachments, Attachment 12, “Proposed Advance Understandings” under this solicitation.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

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, dated June, 2006, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

1. Technical Progress Reports

   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 SECTION J, List of Attachments, Attachment 5, “Reporting Requirements and Deliverables” under this solicitation.

2. Annual Technical Progress Report for Clinical Research Study Populations

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. The Contractor shall submit this information in the format indicated in the attachment entitled, "Inclusion Enrollment Report," which is set forth in Section J of this contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report. The Contractor shall submit the report in accordance with ARTICLE F.1. DELIVERIES of this contract.

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

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

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

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR CLAUSE 52.227-11 including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040-A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer in accordance with ARTICLE F.1. DELIVERIES of this contract. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted to the Contracting Officer on or before the completion date of the contract.

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

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

SECTION D - PACKAGING, MARKING AND SHIPPING

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

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, the Project Officer identified in Article G.1., is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at, 6610 Rockledge Drive, Bethesda, Maryland 20892.

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

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

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

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 SECTION C, ARTICLE C.1. and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the items in SECTION C, ARTICLE C.2. in accordance with the stated delivery schedule. **Please refer to SECTION J, List of Attachments, Attachment 5, "Reporting Requirements and Deliverables" under this solicitation.**

The items described in SECTION C, 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 SECTION C, ARTICLE C.2. and any specification 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://acquisition.gov/comp/far/index.html

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

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

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

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

[To be specified prior to award]

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

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

The personnel specified in this contract are considered to be essential to the work to be performed hereunder. Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written consent of the Contracting Officer; provided, that the Contracting Officer may ratify in writing such diversion and such ratification shall constitute the consent of the Contracting Officer required by this article. The contract may be amended from time to time during the course of the contract to either add or delete personnel, as appropriate.

The following individuals 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. HHSN2662008xxxxxC.)

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-xxxxx.)

(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
National Institutes of Health
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892-7612

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

ARTICLE G.4. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the DHHS Publication (OS) 686, entitled, **Contractor's Guide for Control of Government Property**, which can be found at:

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

ARTICLE G.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 Contracting Officer will determine the frequency with which the interim evaluations will be performed. The final performance evaluation will be prepared at the time of completion of work.

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 calendar days to review the document and to submit any comments, 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 has been approved by the Project Officer, 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).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, 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 research.

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.

For clinical trials and other trials conducted under this contract for which the risks and complexities justify it, the Safety Oversight Structure shall be a Data and Safety Monitoring Board (DSMB); however, for most Phase 1 and Phase 2 clinical trials conducted under this contract, the Safety Oversight Structure shall be a Safety Monitoring Committee (SMC). Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan.

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

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

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

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

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

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

a. Pursuant to Public Law(s) cited in paragraph b., below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

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

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

[Applicable information to be included at award]

ARTICLE H.6. NEEDLE EXCHANGE

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

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

[Applicable information to be included at award]

ARTICLE H.7. 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 09-25-0200, which may be found at the following web site: http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm

ARTICLE H.8. OMB CLEARANCE or CLINICAL EXEMPTION

In accordance with HHSAR 352.270-7, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance has been obtained by the Project Officer and the Contracting Officer has issued written approval to proceed. In addition, in accordance with 5 CFR 1320.3(h)(5), this requirement may be eligible for a Clinical Exemption to OMB Clearance requirements subject to the approval of the NIH Clinical Exemption Review Committee (CERC). The clinical exemption must be obtained and written approval to proceed received from the Project Officer and Contracting Officer before data is collected under this contract or any subcontract.

ARTICLE H.9. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

(1) The Small Business Subcontracting Plan, dated is attached hereto and made a part of this contract.

(2) The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. Subcontracting Reports

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

(1) Individual Subcontract Reports (ISR)

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

April 30th
October 30th

(2) Summary Subcontract Report (SSR)

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

October 30th

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

[*applicable email address(es) to be included at award]*]
Contracting Officer, Office of Acquisitions, NIAID

ARTICLE H.10. SALARY RATE LIMITATION LEGISLATION PROVISIONS

[NOTE: This Article will be revised accordingly in the resultant contract to comply with applicable Fiscal Year 2008 Public Law covering the period of 10/01/2007 through 09/30/2008.]

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.

Effective January 1, 2006, the Executive Level I rate is $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.11. 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, however for the purposes of this RFP, the Information Type 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. **Please note that NCI points of contact do not apply to this acquisition. Contact the Contracting Officer listed on page 1 of this solicitation for applicable NIAID contact information.**

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 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

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

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

e. Rules of Behavior

The Contractor shall comply with 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 sensitive Department 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.12. 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/.

ARTICLE H.13. CONFIDENTIALITY OF INFORMATION

The following information is covered by HHSAR 352.224-70, Confidentiality of Information (MARCH 2005):

(To be determined during negotiations)

ARTICLE H.14. 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 No. HHSN2662008xxxxxC."

ARTICLE H.15. PRESS RELEASES

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

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

[Applicable information to be included at award]

ARTICLE H.16. 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.17. 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)

ARTICLE H.18. 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.19. 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.

a. Sharing of Model Organisms for Biomedical Research

The plan for sharing model organisms submitted by the Contractor is acceptable. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

ARTICLE H.20. SHARING RESEARCH DATA

The data sharing plan submitted by the Contractor is acceptable. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

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

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

ARTICLE H.21. 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.22. 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.23. 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.24. 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).

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

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. **[For Educational Institutions]**

FAR Clause **52.216-7, Allowable Cost And Payment** (December 2002), is modified in paragraph (a) to delete the words "subpart 31.2 of the Federal Acquisition Regulation (FAR)" and substitute the words "45 CFR part 74, appendix E". **[For Hospitals - Profit or Non-Profit]**

Alternate I of FAR Clause **52.216-11, Cost Contract--No Fee** (April 1984), is added.

Alternate II (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (July 2005) 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 **52.216-15, Predetermined Indirect Cost Rates** (April 1998).

(2) FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (July 2005).

"(c) Waiver of evaluation preference.....
[ ] Offeror elects to waive the evaluation preference."

(3) FAR Clause **52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting** (October 1999).

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

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

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

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

Specific data items that are not subject to paragraph (j) include: None.

(8) FAR Clause **52.227-15, Representation of Limited Rights Data and Restricted Computer Software** (May 1999).

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

(10) FAR Clause **52.230-2, Cost Accounting Standards** (April 1998).

(11) FAR Clause **52.230-3, Disclosure and Consistency of Cost Accounting Practices** (April 1998).

(12) FAR Clause **52.230-5, Cost Accounting Standards - Educational Institution** (April 1998).

(13) FAR Clause **52.230-6, Administration of Cost Accounting Standards** (April 2005).

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

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

(16) FAR Clause **52.247-63, Preference for U.S. Flag Air Carriers** (June2003).

b. 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 - LIST OF 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 **352.270-8, Protection of Human Subjects** (March 2005).

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

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

(1) **NIH (RC)-7, Procurement of Certain Equipment** (April 1984) (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 **52.222-39, 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 cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.

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

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

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

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

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

(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and
(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or

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

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

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 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 RFP:

SOLICITATION ATTACHMENTS:

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal	See Attachment Section at end of this RFP
Attachment 2:	Proposal Intent Response Sheet	See Attachment Section at end of this RFP
Attachment 3:	Background	See Attachment Section at end of this RFP
Attachment 4:	Statement of Work	See Attachment Section at end of this RFP
Attachment 5:	Reporting Requirements and Deliverables	See Attachment Section at end of this RFP
Attachment 6:	Additional Technical Proposal Instructions and Format for Technical Proposal	See Attachment Section at end of this RFP
Attachment 7:	Additional Business Proposal Instructions and Uniform Cost Assumptions	See Attachment Section at end of this RFP
Attachment 8:	Currently Funded NIAID Vaccine and Treatment Evaluation Units (VTEU) Contracts	See Attachment Section at end of this RFP
Attachment 9:	Completed and Active VTEU Studies (June 2002 - December 2005)	See Attachment Section at end of this RFP
Attachment 10:	DMID Funded Clinical Research Support Services Contracts	See Attachment Section at end of this RFP
Attachment 11:	Data Submission Requirements	See Attachment Section at end of this RFP
Attachment 12:	Proposed Advance Understandings	See Attachment Section at end of this RFP
Attachment 13:	Small Disadvantaged Business (SDB) Participation Plan	See Attachment Section at end of this RFP

TECHNICAL PROPOSAL ATTACHMENTS: (The following documents must be completed, where applicable, and submitted with the Technical Proposal. They can be located at the electronic websites listed and are therefore, not included in the Attachment Section at the end of this RFP.)

Title	Location
Targeted/Planned Enrollment Table	http://rcb.cancer.gov/rcb-internet/forms/enroll-table.pdf
Annual Technical Progress Report Format for Each Study	http://rcb.cancer.gov/rcb-internet/forms/atpr.pdf
Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
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
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. They can be located at the electronic websites listed and are therefore, not included in the Attachment Section at the end of this RFP.)

Title	Location
Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Small Business Subcontracting Plan	http://rcb.cancer.gov/rcb-internet/forms/sb-subplan-nci.pdf
Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet	http://oamp.od.nih.gov/contracts/BUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls
Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
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 RFP and will be required during contract performance. They can be located at the electronic websites listed and are therefore, not included in the Attachment Section at the end of this RFP.)

Title	Location
Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Privacy Act System of Records *System of Records No. 09-25-0200, is applicable to this RFP.*	http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm
Safety and Health, HHSAR Clause 352.223-70	http://www.niaid.nih.gov/contract/forms/form10.pdf
Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Research Patient Care Costs, NIH(RC)-11	http://www.niaid.nih.gov/contract/forms/nih-rc-11.pdf
Inclusion Enrollment Report	http://rcb.cancer.gov/rcb-internet/forms/inclusion-enrollment.pdf
Commitment To Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf

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 competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

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

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

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

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

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

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

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

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

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

(*1*) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(*2*) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(*3*) It is the only proposal received.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

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

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

(11) 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)

b. **NAICS CODE AND SIZE STANDARD**

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

(1) The North American Industry Classification System (NAICS) code for this acquisition is 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 (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

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

It is anticipated that Multiple Awards will be made from this solicitation and that the award(s) will be made on/about November 1, 2007.

It is anticipated that the awards from this solicitation will be multiple-year cost reimbursement, completion type contracts with a period of performance of seven (7) years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

d. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 13.25 Full-Time Equivalents (FTEs) **annually**. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

Annual Estimated Professional FTEs	7.75
Annual Estimated Technical FTEs	5.50
Annual Estimated TOTAL FTEs	13.25

e. **COMMITMENT OF PUBLIC FUNDS**

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

f. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

g. **RELEASE OF INFORMATION**

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

h. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors 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.

i. **PREPARATION COSTS**

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

j. **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
National Institutes of Health
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892-7612

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

(End of Provision)

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

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 RFP. 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 RFP should be placed in the following order:

I. COVER/TITLE PAGE

Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover/title page, a table of contents, and the information requested in the Technical Proposal Instructions **and as specified in SECTION J, List of Attachments, Attachment 6 entitled, "Additional Technical Proposal Instructions and Format for Technical Proposal".**

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover/title page, a table of contents, and the information requested in the Business Proposal Instructions **and as specified in SECTION J, List of Attachments, Attachment 7 entitled, "Additional Business Proposal Instructions and Uniform Cost Assumptions".**

(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 statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

(6) **Evaluation of Proposals**

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

(7) **Potential Award Without Discussions**

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

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

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all 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 RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

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

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

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

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

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

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

(11) **Selection of Offerors**

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

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

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

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

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

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

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

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

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

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

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

EACH INSTITUTION MUST:

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

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

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

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

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

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

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

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

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

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

4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

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

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:
(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

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

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

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

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

(14) **Past Performance Information**

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

A list of the last five (5) contracts completed during the past three (3) years and the last three (3) contracts currently awarded 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 shall submit comparable information on **all subcontractors** that the offeror proposes to perform a subcontract under this effort.

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://acquisition.gov/comp/far/index.html.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

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

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

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

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

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

b. TECHNICAL PROPOSAL INSTRUCTIONS

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

In addition, refer to SECTION J, List of Attachments, Attachment 6 entitled, "Additional Technical Proposal Instructions and Format for Technical Proposal".

(1) **Technical Discussions**

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

a) **Project Objectives, NIH-1688-1**

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

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

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

b) **Statement of Work**

(1) Objectives

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

(2) Approach

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

(3) Methods

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

(4) Schedule

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

c) **Personnel**

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

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

(1) Principal Investigator/Project Director

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

(2) Other Investigators

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

(3) Additional Personnel

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

-The specific items or expertise they will provide.

-Their availability to the project and the amount of time anticipated.

-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) Resumes

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

(2) **Technical Evaluation**

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

(3) **Additional Technical Proposal Information**

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

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

(4) **Other Considerations**

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

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

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

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

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

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

IMPORTANT NOTE TO OFFERORS: The following paragraphs (5) through (15) shall be addressed 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.

(End of provision)

(6) **Instructions to Offerors Regarding Protection of Human Subjects**

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

(a) Risks to the subjects

Human Subjects Involvement and Characteristics:

- Describe the proposed involvement of human subjects in response to the solicitation.
- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
- Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.

Sources of Materials:

- Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks:

- Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.

- Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

- Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the Contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the Contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

Protection Against Risk:

- Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.

- Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.

- In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

(c) Potential Benefits of the Proposed Research to the Subjects and Others

- Discuss the potential benefits of the research to the subjects and others.

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

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

(d) Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.

- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

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

Collaborating Site(s)

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

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

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts 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.

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

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

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

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

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, List of Attachments)

NOTE: *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.*

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.

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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.

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

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

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

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

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

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

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

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

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

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

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

All offerors proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:
http://www.nih.gov/grants/guide/notice-files/not98-024.html

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

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

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

Justifications for Exclusion of Children

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

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

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

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

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

Definition of a Child

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

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

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

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

(11) **Research Involving Human Fetal Tissue**

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

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

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

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

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

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

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

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

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

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

(13) **Human Embryonic Germ Cell (HEGC) Research**

1. Guidelines.

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

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

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

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

If the offeror intends to fulfill the requirements of the Statement of Work by performing research using human embryonic germ cells, it must so state in its proposal.

If the offeror's proposal includes research using human embryonic germ cells and it receives a contract award, the Contractor may not perform any research using these human embryonic germ cells until the Human Pluripotent Stem Cell Review Group (HPSCRG) has reviewed and approved the documentation furnished as prescribed in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html) and the Contracting Officer has notified the Contractor of the approval in writing.

The resultant contract will be divided into discrete phases or option period(s). During Option Period(s)/Phase(s) N/A of the contract, the Contractor shall submit the original and two copies of the required documentation and assurances that address the areas covered in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells," at: (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html) to the Contracting Officer. This documentation will be forwarded for review and approval to the HPSCRG.

If the HPSCRG disapproves the documentation presented by the Contractor, the Contracting Officer may elect to either terminate the contract in accordance with the Termination for Convenience clause of the contract OR determine not to exercise subsequent option(s) as appropriate based the terms of the specific contract. Otherwise, when the HPSCRG approves the documentation, the Contracting Officer will notify the Contractor in writing that research using the human embryonic germ cells may commence.

Research involving the use of human embryonic germ cells shall not be conducted under the contract until the HPSCRG review and approval have been obtained, and the Contracting Officer has provided written notice of such approval to the Contractor.

(14) **Human Embryonic Stem Cell (HESC) Research**

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

1. The derivation process (which commences with the removal of the inner cell mass from the blastocyst) must have already been initiated prior to August 9, 2001;
2. Prior to August 9, 2001, the embryo from which the stem cell line was derived no longer had the possibility of development as a human being;
3. The stem cells must have been derived from an embryo that was created for reproductive purposes;
4. The embryo was no longer needed for these purposes;
5. Informed consent must have been obtained for the donation of the embryo;
6. No financial inducements were provided for the donation of the embryo.

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

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

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

(15) **Data and Safety Monitoring in Clinical Trials**

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

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

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

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

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

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

For clinical trials and other trials conducted under this contract for which the risks and complexities justify it, the Safety Oversight Structure shall be a Data and Safety Monitoring Board (DSMB); however, for most Phase 1 and Phase 2 clinical trials conducted under this contract, the Safety Oversight Structure shall be a Safety Monitoring Committee (SMC). Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan.

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

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

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

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

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

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

(16) **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.

(17) **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.

(18) **Information Technology Systems Security**

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

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

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

Upon award, the Contractor will be required to submit a roster of all 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:

(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.

(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
(7) NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems: http://csrc.nist.gov/publications/nistpubs/index.html
(8) 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
(9) 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
(10) 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

In addition to the requirements below, refer to SECTION J, List of Attachments, Attachment 7 entitled, "Additional Business Proposal Instructions and Uniform Cost Assumptions".

(1) Basic Cost/Price Information

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

(2) Proposal Cover Sheet

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

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

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

(3) Information Other than Cost or Pricing Data

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

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

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.

(4) **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.

(5) **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.*

(6) **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, Attachment 21 to this RFP 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 RFP in SECTION J.

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

30% for Small Business;
11% for Small Disadvantaged Business;
5% for Women-Owned Small Business;
3% for HUBZone Small Business; and
3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

(7) **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.

(8) **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). The NAICS codes can be found at:
http://www.sba.gov/size/indextableofsize.html

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 RFP. A total target for SDB participation by the prime Contractor, that includes any joint ventures and team arrangements*, 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 their proposed targets. **This information shall be provided in the format prescribed in SECTION J, List of Attachments, Attachment 25 entitled “Small Disadvantaged Business (SDB) Participation Plan, or in a similar format developed by the offeror.** Where participation of SDB concerns in the performance of the contract is not feasible, the offeror shall provide specific rationale for this exclusion. **This information shall be provided in one clearly marked section of the Business Proposal.** Targets for SDB participation will be incorporated into and become a part of 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.

*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.

(9) **Qualifications of the Offeror**

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

a) **General Experience**

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

b) **Organizational Experience Related to the RFP**

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

c) **Performance History**

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

d) **Pertinent Contracts**

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

e) **Pertinent Grants**

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

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

(10) **Other Administrative Data**

a) **Property**

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

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

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

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

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

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

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

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.

(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) **Financial Capacity**

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

d) **Incremental Funding**

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

HHSAR 352.232-75, Incremental Funding (January 2001)

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

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

(End of provision)

(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 RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:
http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

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

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

(13) **Representations and Certifications - SECTION K**

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

(14) **Travel Costs/Travel Policy**

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

(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.

SECTION M - EVALUATION FACTORS FOR AWARD

1. **GENERAL**

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

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

2. **HUMAN SUBJECT EVALUATION**

This research project involves human subjects. NIH Policy requires:

a) **Protection of Human Subjects from Research Risks**

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

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

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

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

b) **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. ***For clinical trials and other trials for which the risks and complexities justify it, the Safety Oversight Structure shall be a Data and Safety Monitoring Board (DSMB); for most Phase 1 and Phase 2 clinical trials, the Safety Oversight Structure shall be a Safety Monitoring Committee (SMC).*** 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 elects to conduct discussions and includes your proposal in the competitive range, 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.

c) **Women and Minorities**

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

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

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

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

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants. Reviewers will consider the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

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

  - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
  - overriding factors dictate selection of subjects); or
  - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.

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

  - inclusion of those groups would be inappropriate with respect to their health; or
  - inclusion of those groups would be inappropriate with respect to the purpose of the research.

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

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

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

If the Government elects to conduct negotiations and includes your proposal in the competitive range, 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.

d) **Children**

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

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' 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 wit h 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 elects to conduct negotiations and includes your proposal in the competitive range, you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion of children is still found to be unacceptable, then your proposal may not be considered further for award.

3. **EVALUATION OF DATA SHARING PLAN**

The offeror's plan for the sharing of final research data 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 elects to conduct negotiations and includes your proposal in the competitive range, 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.

4. **EVALUATION OF PLAN FOR SHARING MODEL ORGANISMS FOR BIOMEDICAL RESEARCH**

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

If your proposal does not include a plan, appropriate reasons for restricting sharing, or, if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your plan for sharing model organisms during discussions and in your Final Proposal Revision (FPR). If your plan for sharing model organisms is still considered "unacceptable," or your justification for restricting sharing is still considered inappropriate by the Government after discussions, your proposal may not be considered further for award. The following web site provides guidance on sharing model organisms and additional information about this policy: http://grants.nih.gov/grants/policy/model_organism/index.htm.

5. **TECHNICAL EVALUATION CRITERIA**

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

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

CRITERA	**WEIGHT**
A. TECHNICAL PLAN/APPROACH	**35**

The offeror's overall understanding of the objectives and requirements of the RFP, ability to identify problems and suggest solutions, and the ability to enhance the achievement of the scientific goals of the overall program will be evaluated for the following elements.

1. Clinical Trials, Clinical Studies and Other Evaluations and Analyses: Ability to design and conduct clinical trials and clinical studies, as well as other evaluations and analyses, as evidenced by the soundness, appropriateness, adequacy and feasibility of the scientific, technical and operational plans for the three case studies:

    a. Case Study 1: Phase 1 Clinical Trial of West Nile Virus Vaccine
    b. Case Study 2: Phase 3 Clinical Trial of an Inactivated Influenza Vaccine
    c. Case Study 3: Phase 1 Clinical Trial of a Meningitis Vaccine

2. Study Populations and Enrollment Requirements:

    a. General Population:

        1) Adequacy of documentation with respect to access to the number and type of populations required to serve as study participants, and ability to recruit and retain study participants from the general population;
        2) Ability to identify anticipated recruitment and retention problems and difficulties that may arise and adequacy of proposed approaches to overcome or minimize anticipated problems and difficulties.

b. Additional Populations:

1) Adequacy of documentation with respect to access to the scope of additional populations to serve as study participants, including women of child-bearing age, pregnant women, immunocompromised populations, non-U.S. populations, and populations with underlying medical conditions;
2) Ability to recruit and retain additional study populations; and;
3) Ability to identify anticipated recruitment and retention problems and difficulties that may arise and adequacy of proposed approaches to overcome or minimize anticipated problems and difficulties.

3. Demonstrated ability to adhere to Good Clinical Practices (GCP).

B. PROTOCOL IMPLEMENTATION AND OVERSIGHT **15**

Ability to implement and provide oversight for clinical trials, clinical studies and other evaluations/analyses as evidenced by the appropriateness and adequacy of proposed plans for the following:

1. Internal procedures for assuring safety oversight for study participants and compliance with all safety guidelines and regulations at the VTEU institution and all affiliated clinical sites;
2. System for reporting data and information from safety and efficacy testing of candidate vaccines and therapeutics;
3. System of records for all documentation required for the conduct of clinical trials and clinical studies;
4. Plans for accommodating clinical site monitoring activities and developing and implementing remedial actions to address deficiencies and problems identified through the clinical site monitoring process;
5. Procedures for receiving, labeling, storing and tracking study products and for monitoring storage conditions, and sample Standard Operating Procedure for inventory control system;
6. Procedures for classification, labeling, documentation, shipping and tracking of clinical specimens and demonstrate ability to meet requirements of the International Transport Association for shipping of dangerous goods; and
7. Quality assurance/quality control plan, including data management and quality control systems/procedures and plans to accommodate independent auditors.

C. PERSONNEL **20**

1. Principal Investigator: Appropriateness and adequacy of the training, experience, expertise and level of effort of the proposed Principal Investigator with respect to the following:

a. The design, conduct and analysis of clinical trials, clinical studies and other evaluations and analyses for testing the safety and efficacy of vaccine and therapeutic candidates for infectious diseases;
b. The management and oversight of clinical trials and clinical studies, including multi-site trials and studies, with respect to ensuring adherence to Federal regulations, Good Clinical Practice, and protocol-specific requirements for the conduct of research involving human subjects, including the development and implementation of standard operating procedures and plans for quality

assurance/quality control, the identification of performance problems and deficiencies, and the implementation of remedial actions to address performance problems and deficiencies; and

c. Collaborating with industry and clinical research support services contractors with respect to study design, statistical analysis, preparation of and reporting study data for Investigational New Drug (IND) applications, data management and quality control, and clinical site monitoring.
d. Documented active physician's licensure in the United States.

2. Other Scientific and Technical Personnel: Appropriateness and adequacy of the training, experience, expertise and level of effort of other proposed scientific and technical personnel of the offeror and all proposed subcontractors, including the adequacy of the proposed mix of staff, expertise, experience, and training to carry out contract requirements with respect to the following:

a. The conduct of clinical trials and clinical studies of candidate vaccines and therapeutics for infectious diseases in accordance with Federal regulatory requirements, protocol-specific requirements, and Good Clinical Practice;
b. The receipt, packaging, distribution and tracking of study products;
c. The collection and processing of clinical specimens and the conduct of protocol relevant tests to determine patient eligibility and safety evaluations;
d. The packaging, labeling and transport of clinical specimens; and
e. Data entry, management and quality control.

D. FACILITIES AND OTHER RESOURCES **20**

1. The availability, adequacy and suitability of the clinical research facilities, equipment and other resources of the Offeror and all proposed subcontractors for the conduct of clinical trials, clinical studies and other evaluations and analyses in accordance with Federal regulatory requirements and guidelines, including Good Clinical Practice, NIH, NIAID and DMID policies and procedures, and the scope and requirements of the RFP. This includes:

a. Outpatient and inpatient clinical research facilities;
b. Clinical laboratory and clinical research laboratory facilities;
c. Research pharmacy facilities; and
d. General clinical research facilities.

2. Adequacy and appropriateness of plans for accessing the facilities and other resources of VTEU-affiliated clinical sites and plans for adding or deleting facilities as necessary due to progress or performance issues that arise during the course of the contract.

E. PROJECT MANAGEMENT **10**

1. Overall Project Management

   a. Adequacy of the plans for the staffing, organization, distribution of responsibilities, leadership and lines of authority for carrying out contract requirements;
   b. Suitability of systems proposed for tracking contract activities and monitoring progress, timelines and budgets;
   c. Suitability of plan for how the Principal Investigator will communicate with the Project Officer and the Contracting Officer, as well as established lines of communication among all performance sites and activities; and
   d. Suitability of the plan for how the Contractor will safeguard data and materials provided by third parties or the Government, as well as data generated during the contract.

2. Subcontract Acquisition and Management

   Adequacy and suitability of subcontract acquisition and management with respect to:

   a. Plan for soliciting, evaluating, awarding and managing subcontracts;
   b. Plans and methods to assess subcontractor performance, identify performance problems and approaches for their remediation, including non-compliance with subcontract terms and conditions, and implement corrective actions when necessary; and
   c. Experience and expertise of proposed staff responsible for the management of subcontracts.

TOTAL **100**

6. **PAST PERFORMANCE FACTOR**

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the competitive range on the basis of the results of the evaluation of factors other than past performance.

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

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

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

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence

to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

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

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

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

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

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

Offers will be evaluated on the following sub-factors:

(a) Extent to which SDB concerns are specifically identified
(b) Complexity and variety of the work SDB concerns are to perform
(c) Extent of participation of SDB concerns in terms of the value of the total acquisition.

SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP

The following pages include those Attachments incorporated into this RFP as specified in SECTION J - List of Attachments

PACKAGING AND DELIVERY OF THE PROPOSAL

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

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

A. EXTERNAL PACKAGE MARKING:

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

"**RFP NO. NIH-NIAID-DMID-08-03**
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
Teresa A. Baughman Contracting Officer Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20817	Teresa A. Baughman 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:

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

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

FORMATTING AND LAYOUT:
Use your usual word processing and spreadsheet programs to prepare and format the technical and business proposals. *If documents are submitted using Adobe .pdf, the document should be submitted using a* ***.pdf searchable*** *format.*

- Type size must be 10 to 12 points.
- Type spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
- Print margins must be at least one inch on each edge of the paper.
- Print setup should be single-sided on standard letter size paper (8.5 x 11" in the U.S., A4 in Europe).
- Proposals shall NOT include links to Internet Web site addresses (URLs) or otherwise direct readers to alternate sources of information.

CREATING AND NAMING ELECTRONIC FILES:

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

Company name / RFP number / technical / ** /date

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

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

Company name / RFP number / business / ** / date

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

EXAMPLE: XYX Company/07-16/Business/Staffing/3-6-06

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

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

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

Document	Number of Copies	Page Limits
Technical Proposal and all Appendices and Case Studies	**PAPER** One (1) unbound SIGNED ORIGINAL. Seven (7) unbound COPIES **ELECTRONIC FILES ON CD** Thirty (30) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices and Case Studies)	**Not to Exceed 280 pages**
Business Proposal	**PAPER** One (1) unbound SIGNED ORIGINAL. Seven (7) unbound COPIES **ELECTRONIC FILES ON CD** Seven (7) Compact Disks containing an electronic copy of the Business Proposal	N/A
Breakdown of Proposed Estimated Cost using Electronic Cost Proposal EXCEL Workbook	This Attachment to the Business Proposal should be submitted as a separate EXCEL file on the Business Proposal Compact Disk. **See Section J, Attachment entitled Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet to access the Excel Workbook.**	N/A

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DMID-08-03
RFP Title: Vaccine and Treatment Evaluation Units (VTEUs): Evaluation of Control Measures Against Infectious Disease Other Than AIDS

Please review the attached Request for Proposal. Furnish the information requested below and return this page by August 2, 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:
OA, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

Attn: Teresa A. Baughman
RFP-NIH-NIAID-DMID-08-03
FAX# (301) 480-4675
Email: tb14j@nih.gov

Vaccine and Treatment Evaluation Units (VTEUs): Evaluation of Control Measures Against Infectious Diseases Other than AIDS
RFP NIH-NIAID-DMID-08-03

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) (www.niaid.nih.gov/dmid/clinresearch) supports extramural research to control and prevent diseases caused by virtually all infectious agents other than 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 evaluation of new and improved vaccine and therapeutic candidates in clinical trials/studies is an essential element of the efforts of DMID. The Vaccine and Treatment Evaluation Units (VTEUs), supported by DMID since the 1960's, have conducted a broad range of studies including Phase 1, Phase 2, Phase 3, and Phase 4 clinical trials of bacterial, viral and parasitic vaccines, therapeutics, and other biologics and drugs as preventive and therapeutic measures against infectious diseases in people of all ages and risk categories. The VTEUs have also undertaken a variety of other studies, including: targeted surveillance for pathogens of interest in study populations; evaluations of novel investigational product delivery systems; and reevaluation of current vaccine formulations, schedules and modes of delivery.

This Request for Proposal (RFP) provides for the recompetition of the VTEU clinical research program. Approximately fifty clinical studies have been conducted during the past three years under these contracts. Several of these studies were performed in a compressed time frame to address emergent public health research needs. The contracts to be awarded under this RFP will support the conduct of clinical trials/studies to evaluate vaccine and therapeutic candidates, which may include the following components: safety, immunogenicity, reactogenicity, pharmacokinetics, optimal dose and schedule, degree of virulence or attenuations and transmissibility. It is anticipated that up to eight (8) cost reimbursement, completion type contracts will be awarded for a seven (7)-year period of performance beginning on or about November 1, 2007. All projects carried out under this program must be conducted in a manner consistent with all applicable Federal regulations and the DMID, NIAID, NIH policies and guidelines for the conduct and oversight of research involving human subjects. Moreover, the NIAID is aware that no single organization or institution may have the expertise and facilities required to perform all parts of the Statement of Work. Therefore, it may be necessary for the Contractor to subcontract a portion of the work. The Contractor shall, however, be responsible for all work performed under this contract including that performed by any subcontractor(s).

Vaccine and Treatment Evaluation Units (VTEUs): Evaluation of Control Measures Against Infectious Diseases Other than AIDS
RFP NIH-NIAID-DMID-08-03

STATEMENT OF WORK

OBJECTIVE AND SCOPE

This contract provides for the design and conduct of Phase 1, Phase 2, Phase 3 and Phase 4 clinical trials and clinical studies of candidate vaccines and therapeutics, as well as for other evaluations and analyses, against infectious diseases other than human immunodeficiency virus (HIV). The Contractor shall interact with companies under contract to DMID who provide regulatory, clinical site monitoring and data management and analysis to support the VTEUs. See Appendix E attached to this RFP for more information on these companies.

Scope of Infectious Diseases: The Contractor shall evaluate candidate vaccines and therapeutics, as well as conduct other types of evaluations and analyses, for viral (other than HIV), bacterial, parasitic and fungal pathogens, including National Institute of Allergy and Infectious Diseases (NIAID) priority biodefense pathogens (http://www3.niaid.nih.gov/Biodefense/bandc_priority.htm).

Scope of Investigational Vaccine and Therapeutic Candidates: The scope of investigational candidates to be evaluated by the Contractor shall include live, attenuated, killed, vectored, DNA and combination vaccines, adjuvants, novel therapeutic agents such as immunomodulatory agents, and approaches to vaccine or therapeutic delivery, dose finding, schedule, routes and modes of delivery. The Contractor is expected to incorporate novel vaccine and therapeutic approaches as they are developed.

Scope of Clinical Research: The scope of clinical research shall include the conduct of Phase 1 and Phase 2 clinical studies and trials of candidate vaccines and therapeutics to evaluate safety, immunogenicity, reactogenicity, optimal dose and schedule, infectivity, degree of virulence or attenuations, transmissibility and genetic stability and when warranted, shall include pharmacogenomic studies. The range of characteristics to be evaluated by the Contractor will vary depending on the candidate being tested. When requested by the Project Officer, the Contractor shall initiate and maintain targeted surveillance for pathogens of interest in study populations as background information in the context of protocol development to interpret vaccine and therapeutic response, initiate clinical studies and trials at a time when the wild type pathogen is not at its peak, and determine the impact of a particular pathogen in selected high-risk populations. The scope of clinical research shall also include the conduct of Phase 3 and 4 clinical trials and studies in cases where such efficacy evaluations are feasible and includes evaluations of novel investigational product delivery systems and evaluations of current vaccines or therapeutics with new formulations, schedules or routes of delivery. Candidate vaccines and therapeutics to be evaluated by the Contractor will be provided by or through the NIAID.

Scope of Study Populations: Vaccine and therapeutic products shall be evaluated by the Contractor, as appropriate, in general populations, including pediatric, adult and elderly subjects. In order to accommodate urgent and compelling needs and opportunities as determined by the Government, the Contractor may be required to access additional populations such as women of reproductive age, pregnant women, immunocompromised populations, non-U.S. populations, and populations with underlying medical conditions.

TECHNICAL REQUIREMENTS

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, healthy volunteer and patient populations, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work below:

1. STUDY POPULATIONS AND ENROLLMENT REQUIREMENTS

a. General Population

1) Provide subjects from pediatric, adult and elderly populations, utilizing subcontracts with affiliated clinical sites as necessary. This shall include the recruitment and enrollment in clinical trials and studies of the following minimum number of eligible healthy subjects on an annual basis:

- 300 pediatric subjects (birth-18 years of age),
- 1,200 adult subjects (>18-45 years of age), and
- 300 mature adult and elderly subjects (>45 years of age and up).

2) Provide for the rapid expansion of enrollment of appropriate subjects to accommodate enrollment targets. Rapid expansion shall be accommodated directly by the Contractor and may include subcontracts with affiliated clinical sites to meet necessary target enrollment.

b. Additional Populations

Access, either directly or through subcontracts with affiliated clinical sites, additional study populations, including women of reproductive age, pregnant women, immunocompromised populations, non-U.S. populations, and populations with underlying medical conditions, to accommodate urgent and compelling needs and opportunities, as determined by the Government.

2. AFFILIATED CLINICAL SITES (SUBCONTRACTORS)

a. Solicit for, evaluate, award and manage subcontracts to provide for VTEU-affiliated clinical sites when necessary and appropriate to meet the requirements of the contract. All such subcontracts shall be approved in writing prior to protocol implementation by the Contracting Officer based on review and recommendation from the Project Officer.

b. Affiliated clinical sites may be used for one or more of a variety of purposes in order to carry out the requirements of the contract, including providing access to and ensuring enrollment of adequate numbers of study participants in the following areas:

1) Phase 1, Phase 2, Phase 3 and Phase 4 clinical trials involving general populations (i.e., pediatric, adult and elderly subjects).

2) Clinical trials and studies requiring rapid expansion of enrollment.

3) Clinical trials and studies involving additional populations, including, women of child bearing age, pregnant women, immunocompromised populations, non-U.S. populations, and populations with underlying medical conditions.

4) Clinical trials and studies determined by the Government to be necessary and important to meet urgent and compelling needs and opportunities.

c. Ensure that all affiliated clinical sites provide the following personnel, facilities and services as necessary:

1) Qualified clinical investigators, nurse managers, study coordinators, data managers and data entry personnel, research pharmacy personnel, and other clinical research support staff, including staff with experience and expertise in clinical trials and studies of candidate vaccines and therapeutics for infectious diseases, including experience in complying with Good Clinical Practice (GCP) guidelines and other regulatory requirements governing the safe conduct of research involving human subjects, and experience in the screening, recruitment and retention of study participants.

2) Access to necessary study populations, including both general populations and additional populations as defined in the Statement of Work.

3) Clinical facilities for the screening, enrollment, treatment and follow-up of study participants.

4) Research laboratory facilities, equipment and personnel for the conduct of protocol-specific laboratory tests, including cultures and/or immunologic assays (humoral and cellular) to determine participant eligibility, baseline levels upon study entry, and response to candidate vaccines being evaluated, and for the processing and storage of clinical specimens.

5) Clinical laboratory facilities/services, clinical facilities and general pharmacy services.

3. PROTOCOL DEVELOPMENT

a. Concept Proposal

1) Develop a Concept Proposal with a corresponding budget estimate for each proposed clinical study and sub-study as the initial step in the protocol development process. The development and submission of Concept Proposals and corresponding budgets shall be either at the request of the Project Officer or at the initiation of the Contractor's Principal Investigator.

2) All Concept Proposals shall be submitted to the Project Officer for review and determination of DMID interest in supporting the study under this contract.

3) All Concept Proposals require written approval by the Project Officer and the Contracting Officer prior to initiation of protocol development.

4) The Concept Proposal shall include:

a) Study Objective(s)

- indication(s) of the investigational product and stage of development,
- study population(s),
- a brief overview of the proposed study design, including estimated sample size, primary and secondary endpoints, and product information, including available risk information, and
- the stage of development of the proposed assays to be used to support the primary and secondary endpoints.

b) Rationale for the Proposed Clinical Trial or Study

- a brief description of the scientific and public health significance of the proposed study and supporting references.

c) Recruitment and Site Plan

- identification of proposed clinical site(s),
- target enrollment for each proposed clinical site including documentation of access to study populations,
- a plan for the recruitment and retention of eligible study participants, and
- a description of the capacity of the proposed clinical site(s) to undertake and complete the study successfully.

d) Protocol Timeline

A timeline and specific milestones for protocol development and initiation, including:

- completion of screening and enrollment of study participants,
- completion of the clinical trial or study, and
- analysis of study data.

e) Personnel and Percentage of Effort

A list of all personnel who will be assigned to the clinical trial or study, including:

- percentage of effort for each,
- a description of prior experience and expertise of the personnel specific to the proposed clinical trial or study, and
- prior experience with studies of a similar type, size and complexity.

f) Proposed Budget

1) A breakdown of proposed study-specific personnel by:

- function,
- position title, and
- level of effort

2) Total estimated costs for:

- supplies,
- clinical and research laboratory,
- research pharmacy,
- study participant expenses,
- study participant incentives,
- travel
- advertising costs only as they relate to recruitment from existing patient population databases
- miscellaneous costs, and
- costs for any proposed subcontracts.

b. Protocol Development

1) Protocol Development Processes and Templates

In developing protocols for clinical trials and studies to be conducted, adhere to DMID standardized protocol development processes and templates (http://www.niaid.nih.gov/dmid/clinresearch/#resources). Only those Concept Proposals approved for implementation by the Project Officer shall proceed to the protocol development stage. The processes and requirements delineated below shall be implemented by the Contractor during the protocol development stage. All final clinical protocols require approval by the Project Officer in order to proceed to the protocol implementation stage.

2) Protocol Team

Each protocol shall be developed by a Protocol Team, coordinated by the DMID Protocol Champion (e.g., DMID Program scientist with expertise in the area of protocol focus) and consisting of:

- the Principal Investigator;
- clinical investigators from the VTEU and any affiliated clinical sites;
- industry collaborators, when appropriate;
- DMID scientific, clinical and regulatory personnel; and
- statistical, data management, medical writing, pharmacovigilance and other personnel supplied by the DMID clinical research support services contractors.

3) Draft and Final Protocol

a) Develop the Draft Protocol for Project Officer review, with assistance from the Protocol Team, and make any necessary revisions based on Project Officer comments. The protocol shall be considered final only upon receipt of written approval from the Project Officer.

b) Following approval of the Final Protocol, the Case Report Forms and Manual of Operations shall be developed by either the Contractor, the DMID Data Coordinating Center, or other collaborators at the direction of the Project Officer. The Case Report Forms and Manual of Operations shall be provided by DMID to the Contractor.

4) Protocol Timeline

a) If necessary, revise the Protocol Timeline provided in the Concept Proposal (see paragraph 4)d),above under Section 3. PROTOCOL DEVELOPMENT) to accommodate any changes with respect to protocol implementation, study completion and analysis and publication of study results, including the rationale for the proposed changes.

b) All such modifications to the Protocol Timeline shall be subject to approval by the Project Officer prior to study implementation.

4. PROTOCOL IMPLEMENTATION

a. Pre-Study Initiation Requirements

Prior to study initiation, the Contractor is required to satisfy the following requirements:

1) Human Subjects Requirements

Obtain and provide to the Project Officer documentation of local Institutional Review Board (IRB) approval to conduct the clinical trial or study for all participating clinical sites;

2) Regulatory Requirements

Provide, for Project Officer approval, Essential Documentation, as defined by the International Conference on Harmonization ICH-E6-GCP, (http://www.fda.gov/cder/guidance/959fnl.pdf);

3) Study Initiation Meetings/Teleconferences

The Principal Investigator, clinical investigators and clinical study personnel who will be performing the clinical trial or study from both the VTEU and any affiliated clinical sites, shall participate in a study initiation meeting and/or teleconference to be organized by the CTM contractor.

These meetings and/or teleconferences shall serve to review protocol specifications, requirements and procedures, target enrollment per clinical site, and protocol timelines.

b. Study Product Requirements

As requested by the Project Officer, provide documentation that all participating clinical sites have received the appropriate supply of the investigational product from the DMID repository or other entity. This shall encompass investigational product accountability, including:

- accurate records documenting receipt of test article;
- date and amount of test article dispensed to each subject;
- amount of test article used and verified during a monthly physical inventory;
- date and quantity of test article returned to DMID repository, if applicable;
- preservation and validation of cold chain for investigational and licensed products including records to verify cold chain for all materials stored at other than room temperature;
- packaging and labeling of test article in compliance with applicable labeling regulations;
- transport of investigational products to clinical area; and
- return of unused product to the DMID repository or other entity.

c. Interactions with Food and Drug Administration (FDA)

The Principal Investigator shall be available for up to six (6) teleconferences and one (1) meeting with the FDA to discuss protocols, preclinical and clinical packages, studies, and/or data resulting from studies as needed.

d. Clinical Trial Conduct

Conduct clinical trials and studies in accordance with all Federal regulations and requirements, NIAID Clinical Terms of Award (http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf), the ICH-E6-GCP guidelines (http://www.fda.gov/cder/guidance/959fnl.pdf), the clinical protocol and the Manual of Operations or standard operating procedures.

e. Protocol Amendments and Other Clinical Trial Modifications

1) Recommend to the Project Officer amendments to the clinical protocol, the Manual of Operations and the informed consent documents, including a written description of the proposed amendments/modifications and their rationale.

2) All amendments and modifications shall require approval by the Project Officer prior to implementation.

3) Obtain and provide documentation of IRB approval for protocol amendments for the Contractor and all affiliated clinical sites prior to implementation.

f. Data Management and Quality Control

1) Develop and implement standards and procedures for the entry and quality control of study data for all clinical trials and studies conducted under the contract, including those conducted at any affiliated clinical site.

2) Ensure that clinical data are accurate, complete and entered in a timely fashion.

3) The Contractor and all affiliated clinical sites shall transfer study data to the data management system, operated by the DMID Data Coordinating Center contractor, within seventy-two (72) hours of study activity to maintain up-to-date information of all clinical and laboratory data.

4) Training in the use of the data management system for clinical site personnel will be provided by the DMID Data Coordinating Center contractor prior to study implementation.

5) Perform data management activities in collaboration with the DMID Data Coordinating Center contractor or the data coordinating center of an industry collaborator.

6) Manage data and address queries in accordance with DMID source document guidelines in collaboration with the DMID Data Coordinating Center contractor (www.niaid.nih.gov/dmid/clinresearch/sourcedocumentationstandards.pdf), or the data management center of an industry collaborator.

7) Upon approval of the Project Officer, provide clinical study data to the Investigational New Drug (IND) sponsor for use in the Annual IND Report to the FDA. This data shall also be used in the Final Clinical Study Report prepared by DMID which shall follow the International Conference on Harmonization (ICH) Guidelines on Structure and Content of Clinical Study Reports E3 to be submitted to the FDA by DMID within one (1) year of closure of activity on study (link for annual report: http://a257.g.akamaitech.net/7/257/2422/01apr20051500/edocket.access.gpo.gov/cfr_2005/aprqtr/21cfr312.23.htm and link for final report: http://a257.g.akamaitech.net/7/257/2422/01apr20051500/edocket.access.gpo.gov/cfr_2005/aprqtr/21cfr312.64.htm).

g. Study Analysis

The Principal Investigator shall collaborate and coordinate with the DMID Protocol Team and DMID Data Coordinating Center contractor or the data management center of an industry collaborator in the analysis of final study data including submission, receipt, collation and interpretation of study data.

5. **PROTOCOL OVERSIGHT**

a. Oversee the safety of all clinical trials and studies conducted, including those conducted at affiliated clinical sites. Oversee adherence to all Federal regulations and to the DMID, NIAID, NIH policies and guidelines, including the NIAID Clinical Terms of Award governing research involving human subjects (http://www.niaid.nih.gov/dmid/clinresearch).

b. The specific protocol safety oversight responsibilities of the Principal Investigator include coordination of oversight functions in collaboration with the existing DMID Clinical Trials Management (CTM) contractor and with the Safety Oversight Structure, as delineated below.

1) Safety Oversight Structure

a) For each clinical trial and study, DMID will establish a Safety Oversight Structure, independent of the Principal Investigator and coordinated by the CTM contractor. All Safety Oversight Structures shall operate in a manner consistent with DMID Safety Oversight Guidances (http://www.niaid.nih.gov/dmid/clinresearch/). The Contractor shall be responsible for presenting the study and study data to the Safety Oversight Structure.

b) The Safety Oversight Structure will accommodate the risk and complexity of the clinical trial or study. For clinical trials and other trials for which the risks and complexities justify it, the Safety Oversight Structure shall be a Data and Safety Monitoring Board (DSMB); for most Phase 1 and Phase 2 clinical trials, the Safety Oversight Structure shall be a Safety Monitoring Committee (SMC). In all cases, the DSMB or the SMC shall be established by DMID and coordinated by the CTM contractor. Some small early phase studies of low risk may be overseen by an Independent Safety Monitor and designated back–up monitor.

c) The Independent Safety Monitor and back-up monitor shall be identified by the Contractor for all affiliated clinical sites and must be approved by the Project Officer.

d) At the Project Officer's request, nominate individuals to serve on Safety Oversight Structures, and all such nominations shall require approval by the Project Officer based on DMID Safety Oversight Guidances.

e) Collaborate with the Data Coordinating Center contractor or industry data coordinating center to provide both interim and final analyses when appropriate.

2) Clinical Site Monitoring

a) Accommodate clinical site monitoring/auditing, at the request of the Project Officer, to verify that the rights and well-being of the study participants are protected, the study data are accurate, complete and verifiable, and the conduct of the study is in compliance with Good Clinical Practices (GCP), the clinical protocol and applicable regulatory requirements.

b) Make available for clinical site monitoring purposes, all necessary facilities, personnel and records to support monitoring requirements during the active recruitment, dosing, follow-up and close-out phases of all clinical trials and studies.

c) When NIAID is the IND sponsor, clinical site monitoring for all clinical trials and studies conducted by the Contractor and affiliated clinical sites shall be carried out by the CTM contractor. In those limited cases when DMID is not the IND sponsor, appropriate monitoring staff designated by the IND sponsor shall carry out this function.

d) The Principal Investigator shall be responsible for developing and implementing remedial actions to address site performance problems and issues identified through the clinical site monitoring process.

3) System of Records

Design, implement and maintain a system of records for each clinical trial and study undertaken. This system of records shall be in accordance with the Privacy Act and the Confidentiality of Information Clauses contained within the contract.

6. ADDITIONAL EVALUATIONS AND ANALYSES

a. Design and conduct additional evaluations and analyses. Such additional studies may be requested by the Project Officer or proposed by the Contractor. These include:

- pharmacogenomic studies;
- targeted surveillance for pathogens of interest in study populations as background information in the context of protocol development;
- evaluations of novel investigational product delivery systems; and
- evaluations of current vaccine formulations, schedules and modes of delivery.

b. For each of these additional evaluations and analyses, develop and submit, for Project Officer approval, a proposed plan covering the following:

1) a description of the scope and design of the proposed research;
2) the rationale for the additional work based on need, opportunity and public health importance;
3) a description of potential risks and problems and proposed approaches to reducing risk and overcoming problems;
4) a timeline for study implementation, reporting of interim data, study completion and analysis of final study data;
5) any proposed affiliated clinical sites and personnel and a brief description of the qualifications and experience of all proposed personnel;
6) a proposed budget to include a breakdown of proposed study specific personnel by:
   - function,
   - position title,
   - level of effort proposed for the study;

7) total estimated costs for:
   - supplies,
   - clinical and research laboratory,
   - research pharmacy,
   - participant expenses,
   - participant incentives,
   - travel,
   - advertising costs only as they relate to recruitment from existing patient population databases, and
   - miscellaneous costs.

c. Upon written approval by the Project Officer and the Contracting Officer, conduct evaluations/analyses in accordance with the approved plan.

7. STORAGE, SHIPPING AND TRACKING OF CLINICAL SAMPLES

a. Ship clinical specimens for further testing to laboratories or repositories designated by the Project Officer.

b. Ensure that blood and other body fluids and tissue samples are classified, labeled, documented, packaged, shipped, and tracked according to Federal regulations and the International Air Transport Association (IATA) requirements for the shipment of dangerous goods (http://www.iata.org/ps/publications/9065.htm).

c. Samples shall be shipped under temperature monitored conditions and within the time frame specified in the clinical protocols or other documents.

d. Confirm receipt of specimens in the appropriate condition for further testing by the DMID-designated laboratory or repository to which the specimens are shipped.

8. QUALITY ASSURANCE/QUALITY CONTROL (QA/QC)

a. Quality Assurance/Quality Control Plan

1) Develop and implement a Quality Assurance/Quality Control plan to standardize contract research processes to ensure that the conduct of any clinical trial and all data generated meet all regulatory standards and other standards (see http://www.niaid.nih.gov/dmid/clinresearch/OP_QM001Rev0.pdf for guidance). This plan shall include standard operating procedures for establishing and maintaining the QA/QC process. It shall also include a description of the process for internal quality audits of site protocols and a description of remediation procedures for addressing issues when identified.

2) Submit a draft of this plan within ninety (90) calendar days of contract award.

3) The Project Officer will provide comments to the Contractor within two (2) weeks of receipt of the draft plan.

4) Submit a final plan that incorporates the Project Officer's comments within two (2) weeks after comments are received.

b. Independent Audits

1) Arrange for independent audits, as needed or as requested by the Project Officer with concurrence by the Contracting Officer. Audits may be requested to assure that Contractor and/or affiliated clinical site facilities and all planned procedures meet FDA regulations and guidance for GCP standards.

2) Ensure that all Contractor and/or affiliated clinical site records and staff are available for independent audits.

3) Provide interim and final audit reports to the Project Officer and the Contracting Officer within thirty (30) calendar days after audit completion.

9. SCIENTIFIC AND TECHNICAL PERSONNEL

a. Principal Investigator

1) The Contractor's Principal Investigator shall be licensed as a physician and shall ensure that active licensure is maintained for the entire period of contract performance.

2) The Principal Investigator shall possess experience in the design and conduct of clinical trials and studies for infectious diseases.

b. Other Scientific/Technical Personnel

1) Provide and maintain appropriately trained personnel to carry out the clinical research requirements of the contract. This shall include:

a) Physician investigators as required per protocol. Physician investigators conducting clinical trials shall be licensed physicians and shall ensure that active licensure is maintained for the entire period of contract performance. In addition, all such protocol-specific physician investigators shall be experienced in the design and conduct of studies of infectious diseases and in the assessment of participants for study eligibility and safety post enrollment.

b) Clinical Research Study Staff as required per protocol, including: nurse managers, study coordinators, clinical support staff, laboratory personnel, personnel with regulatory expertise, and data managers. All clinical research study staff shall be trained and experienced in Good Clinical Practices.

c) A Research Pharmacist proficient in all aspects of investigational product management as needed to meet the requirements of each protocol.

d) Collaborating clinical investigators in other medical specialties when necessary to meet protocol-specific requirements.

e) Qualified personnel necessary to package, label, and transport under appropriate conditions clinical specimens to DMID-designated laboratories or DMID-supported repositories in cases where laboratory tests are not to be performed at the Contractor's facility.

f) Qualified personnel, such as microbiologists with specialized expertise, necessary for the processing of investigational products in accordance with protocol-specific requirements.

g) Qualified personnel necessary to meet emerging, high priority public health needs.

h) Protocol-related training opportunities for designated scientists to learn techniques and methods relevant to the conduct of studies or clinical trials under this contract.

10. CLINICAL RESEARCH FACILITIES AND RESOURCES

a. Outpatient Clinical Research Facilities

The Contractor, as well as all affiliated clinical sites participating as subcontractors, shall provide outpatient clinical facilities to accommodate enrollment, administration of investigational products, and follow-up of subjects in accordance with the specific requirements of the clinical protocols approved for implementation. These facilities shall include the following:

1) Areas which allow for temporary subject waiting, check-in and discharge.

2) Examination rooms which allow for full physical examinations and privacy for discussions with subjects, including counseling, obtaining medical histories and informed consent, and administration of investigational products.

3) Outpatient laboratory facilities for the collection, processing and temporary storage of clinical specimens.

4) Computers with broadband secure internet access for randomization, remote data entry and transmission of digitalized test results including electrocardiograms and other diagnostic test results and digital photographs.

5) Emergency care and accommodations in the event a study subject requires such services.

b. Inpatient Clinical Research Facilities

Provide inpatient facilities for the implementation of protocols requiring inpatient care, utilizing affiliated clinical sites as necessary. These inpatient clinical research facilities shall meet the requirements of the Joint Commission on Accreditation of Healthcare Organizations (www.jcaho.org). Facilities shall include:

1) Clinical research facilities to accommodate overnight clinical care of subjects as specified in protocols approved for implementation.

2) Availability of standard clinical support services for inpatient care, twenty four (24) hours/day, seven (7) days/week, to include nursing, emergency, respiratory, dietary, laboratory, radiology and laundry services for active inpatient protocols.

3) Computers with broadband secure internet access for randomization, remote data entry and transmission of digitalized test results including electrocardiograms and other diagnostic test results and digital photographs.

4) Emergency care and accommodations in the event a study subject requires such services.

c. Clinical Laboratory Facilities

Provide the following clinical laboratory facilities and services, utilizing affiliated clinical sites as necessary:

1) Process and store clinical specimens and conduct protocol-required tests to determine participant eligibility and safety evaluations.

2) Qualified personnel and other resources necessary to maintain current Clinical Laboratory Improvement Amendment certification (www.cms.hhs.gov/clia) and Joint Commission on Accreditation of Healthcare Organizations approval (www.jcaho.org).

3) Clinical laboratory support services which are available twenty four (24) hours/day, seven (7) days/week.

d. Research Laboratory Facilities

Provide research laboratory facilities and resources as follows, utilizing affiliated clinical sites as necessary:

1) Process and store specimens and conduct protocol relevant cultures and/or immunologic assays (humoral and cellular) to determine participant eligibility, baseline levels on entry into a study, and response to the candidate vaccines.

2) Ensure that work conforms to standards acceptable for IND and/or Biological Licensing Application (BLA) submission (see http://www.niaid.nih.gov/dmid/clinresearch/#resources for guidance).

3) Prepare and submit a Semiannual Research Laboratory Report that includes all laboratory work performed to support clinical protocols, laboratory work performed at the request of the Project Officer and a discussion of technical and administrative problems encountered, their resolutions or proposed corrective action, and an explanation of differences between planned and actual progress.

e. Research Pharmacy Facilities

The Contractor, as well as all affiliated clinical sites, shall provide research pharmacy facilities and resources for the management of investigational products according to protocol-specific requirements. This includes:

1) The development and implementation of Standard Operating Procedures (SOPs) for research pharmacy functions.

2) The development and implementation of appropriate procedures and policies to provide for, store appropriately, and monitor controlled access to investigational products.

3) The receipt of investigational products from the DMID Regulatory Support contractor repository or other supplier, and the returning of investigational products to this repository or disposing of investigational products as specified in the protocol or Manual of Operations

f. General Clinical Research Facilities

The Contractor and all affiliated clinical sites shall provide general clinical research facilities and other resources for the conduct of clinical trials and studies approved for implementation. This includes:

1) Non-clinical space for contract management, data management and study coordination.

2) Computers with broadband secure internet access.

3) Dedicated space for clinical site monitoring staff to include access to site computers with broadband secure internet access and access to regulatory and subject records.

4) Areas for secure storage of confidential study documents with controlled access.

11. **PROJECT MANAGEMENT**

a. Overall Project Management

1) Provide for the overall management, integration and coordination of all contract activities, including the management and coordination of activities carried out under subcontracts.

2) Provide a technical and administrative infrastructure to ensure the planning, initiation, implementation, management and timely completion of all projects carried out under this contract and effective communications with the Project Officer and the Contracting Officer.

3) Include a Principal Investigator with responsibility for overall project management and communications, tracking, monitoring and reporting on project status and progress, and recommending modifications to project requirements and timelines, including projects undertaken by subcontractors.

4) Include personnel to coordinate contract and study specific activities conducted and administrative staff with responsibility for financial management and financial reporting on all activities conducted by the Contractor and subcontractors.

b. Affiliated Clinical Site Subcontract Management and Reporting

The Contractor shall carry out the following for each project to be conducted under a subcontract:

1) Solicit, evaluate, award and manage subcontracts, including overseeing the technical, administrative and operational activities of subcontractors; auditing subcontractor facilities, services, and financial expenditures; and tracking deliverables and reporting requirements.

2) Assess and provide quarterly technical reports on subcontractor performance and progress toward achievement of defined milestones; and identify and resolve problems with subcontractor performance.

3) Ensure that subcontractor personnel, equipment and facilities are compliant with regulatory requirements in effect throughout the contract period.

4) Ensure the complete and effective transfer of technology by the subcontractors to the Contractor, the United States Government, or a third party as designated by the Project Officer.

5) Perform all necessary transition and closeout functions on each subcontract as specified in each protocol.

c. Coordination with DMID Clinical Research Support Services Contracts

Ensure the effective and efficient coordination of specified functions in collaboration with the DMID clinical research support services contractors identified in the Statement of Work. These functions include:

- clinical site monitoring;
- clinical trial/study statistical design and analysis;
- preparation of case report forms;
- data collection, management, quality assurance and entry;
- safety monitoring;

- auditing; and
- clinical agent repository functions for distribution and tracking of IND products.

d. Technology Transfer

1) The Contractor and any subcontractor(s) may be required to transfer assays or other techniques developed or improved under the contract to specified DMID/NIAID contracts. These contract-generated resources shall include complete protocols and critical reagents for products developed and/or improved with contract funding and must be submitted at the request of the Project Officer.

2) The Contractor shall also have the capability to transfer in assays or other technologies needed to support clinical trials.

e. Meetings

1) Contract Initiation Meeting

Within three (3) months of contract award, participate in a one-day contract initiation meeting with the Project Officer, the Contracting Officer, other key NIAID staff and key contract scientific, technical and administrative personnel, to be held in Bethesda, Maryland. The purpose of this initiation meeting is to orient the Contractor to NIAID contract procedures.

2) Annual VTEU Meetings

Key personnel shall participate in one (1) meeting per year for two (2) days, to be held in the Bethesda, Maryland area.

The purpose of this meeting is to:

- organize, facilitate and plan clinical trial and study coordination;
- address regulatory issues related to clinical trials and studies proposed and approved for implementation.
- review:
  - status of ongoing clinical trials and studies,
  - risks and obstacles,
  - proposed approaches to reducing risk and overcoming obstacles, and
  - interim and final clinical trial/study results.

3) Annual Site Visits

a) Host an annual site visit for NIAID contract and program staff. These site visits shall be attended by the Principal Investigator, the Contractor's business representative, all key personnel and investigators and coordinators of active projects from the previous twelve months, including affiliated clinical site key personnel.

b) The Contractor shall be responsible for:

- agenda planning,
- development of written and oral presentation materials, and
- logistical arrangements for all non-Government site visit participants.

c) Presentations and discussions shall focus on:

- summaries of all goals and milestones reached during the review period;
- all problems encountered that impact the completion of approved clinical trials and studies;
- the submission of contract deliverables;
- proposed modifications to established milestones and timelines; and
- the rationale for proposed future plans for effectively and efficiently carrying out the requirements of the contract.

d) A report of each annual site visit shall be prepared by the Contractor and submitted to the Project Officer and the Contracting Officer within thirty (30) calendar days of completion of each site visit.

4) Protocol Specific Meetings

Participate in study initiation meetings, Protocol Team meetings, scientific planning meetings, as needed. These meetings may be conducted in person at the Contractor's site or another designated site, web-based or via teleconference.

f. Publications and Presentations of Contract-Generated Data and Findings

1) Develop and implement policies and procedures for authorship, preparation, review, and final approval of publications, abstracts and oral presentations resulting from contract-sponsored studies, and for submission of manuscripts for publication in peer reviewed journals. During the publication review and approval process, the respective roles and responsibilities of pharmaceutical/biotechnology companies providing experimental products for evaluation in clinical trials and studies shall be addressed in specific Clinical Trial Agreements (CTA) between DMID and the company.

2) The Contractor shall not publish, present or disseminate any information from work performed under this contract without submission of the materials to the Project Officer for review.

3) The Project Officer shall have seven (7) calendar days from receipt of materials to review and provide comments on an abstract and thirty (30) calendar days from receipt of materials to review and provide comments on other publications and presentations. If the Project Officer does not respond within these time frames, the Contractor may proceed with such publications or presentations.

12. **TRANSITION**

a. Transition Plan

Three (3) months prior to the completion date of this contract, the Contractor shall provide a plan for an orderly transition of data and materials, including stored participant specimens and records, to the Government. This plan will be subject to the approval of the Project Officer and the Contracting Officer.

b. Transition of Data and Materials

On or before the completion date of the contract, the Contractor shall deliver data and materials, including participant specimens and records, to locations specified by the Project Officer and in accordance with the approved transition plan.

Vaccine and Treatment Evaluation Units (VTEUs): Evaluation of Control Measures Against Infectious Diseases Other than AIDS
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REPORTING REQUIREMENTS AND DELIVERABLES

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with ARTICLE F.1. DELIVERIES of this contract.

All reports shall be submitted in an electronic format approved by the Project Officer . Electronic files shall be sent by e-mail or on computer discs (CD) by U.S. mail or courier service.

All reports shall include a cover page containing:

- Contract title and number;
- Title of report
- Protocol identifier (if applicable)
- Period of performance being reported;
- Contractor's name, and address
- Date of submission

A. Monthly Technical Progress Report

The Contractor shall submit a Monthly Technical Progress Report. The first report shall cover the period consisting of the first full calendar month following the effective date of the contract and any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month. Reports shall be due on or before the 30th calendar day following each reporting period. The Monthly Technical Progress Report shall not be due the month that the Annual Technical Progress Report and Final Report are due. It shall:

1. Summarize progress to date in each protocol;

2. List each protocol and for each protocol, include discussion of activities which include screening, recruitment, retention, dosing, adverse events, follow-up, early terminations, IRB status, personnel assigned to projects. Also include any problems encountered and how they were resolved.

B. Monthly Expenditure Report by Protocol

The Contractor shall submit a Monthly Expenditure Report. The first report shall cover the period consisting of the first full calendar month following the effective date of the contract and any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month. Reports shall be due on or before the 30th calendar day following each reporting period. This report shall include:

1. Original protocol budget as submitted with the Concept Proposal;

2. Cumulative spending for each protocol;

3. Current month expenditures for each protocol;

4. Expenses to be reported include: personnel (% effort, salary amount), fringe benefits, consultants (identify role on protocol), materials and supplies (identify materials and supplies), equipment (identify equipment), staff travel (identify travel), other direct costs (identify);

5. Variances from the original budget shall be justified.

C. Quality Assurance (QA)/Quality Control (QC) Plan

The Contractor shall submit a Quality Assurance/Quality Control Plan. A draft of this plan is due within ninety (90) calendar days of contract award. The Project Officer will provide comments back to the Contractor within two (2) weeks of receipt of the draft plan. The Contractor shall submit a final plan which incorporates the Project Officer's comments two (2) weeks after Project Officer comments are received. This plan shall include:

1. Description of processes for internal quality audits of site protocols;

2. Discussion of standard operating procedures for establishing and maintaining the QA/QC process;

3. Description of remediation procedures for addressing issues when identified.

D. Quarterly Subcontractor Technical Report

The Contractor shall submit a Quarterly Subcontractor Technical Report that summarizes each subcontractor's performance and progress toward achievement of defined milestones. The report shall also identify and resolve problems with subcontractor performance. The first report shall cover the period consisting of the first full three (3) calendar months following the effective date of the contract and any fractional part of the initial month. Thereafter, the reporting period shall consist of each three (3) month period. Reports shall be due on or before the 30th calendar day following each reporting period.

E. Semiannual Research Laboratory Report

The Contractor shall submit a Semiannual Research Laboratory Report. The first report shall cover the period consisting of the first full six (6) months following the effective date of the contract and any fractional part of the initial month. Thereafter, the reporting period shall consist of six (6) months. This report shall be due fifteen (15) calendar days after each reporting period. The Semiannual Laboratory Report shall not be due the month that the Annual Technical Progress Reports and Final Report are due. It shall include:

1. Laboratory work performed to support clinical protocols during the preceding 6 months;

2. Laboratory work performed at the direction of the Project Officer during the preceding six (6) months;

3. Discussion of technical and administrative problems encountered, their resolution or proposed corrective action, and an explanation of differences between planned and actual progress.

F. Annual Technical Progress Report

The Contractor shall submit an Annual Technical Progress Report which summarizes the activities completed in the preceding twelve (12) month period. The report shall be due within thirty (30) calendar days after the anniversary date of the contract each year. An Annual Technical Progress Report shall not be due when the Final Report is due. Annual reports shall be composed of:

1. A Table of Contents;

2. A summary of work performed from the previous twelve (12) months divided by pending, active and completed studies;

3. Summary tables of study results from the previous twelve (12) months;

4. Publications, abstracts, and/or presentations from the previous twelve (12) months;

5. A discussion of technical and administrative problems encountered, their resolution or proposed corrective action; and, an explanation of difference between planned and actual progress;

6. Selected other additional information as may be required by the Project Officer's or as called for within individual protocols.

G. Site Visit Report

The Contractor shall summarize the annual site visit and shall include the date of site visit, the date of report submission, attendees (both Government and Contractor personnel), agenda, brief discussion of action items and any comments. A report of the site visit shall be prepared by the Contractor and submitted to the Project Officer and Contracting Officer within thirty (30) calendar days of completion of each site visit.

H. Audit Reports

Independent Audit Reports shall be submitted on an interim basis during the life of the contract. These reports shall discuss that all planned procedures meet Food and Drug Administration (FDA) regulations and Good Clinical Practices (GCP). When an audit has been conducted, the Contractor shall submit the report within thirty (30) calendar days after audit completion.

I. Transition Plan

Three (3) months prior to the completion date of the contract, the Contractor shall provide a plan for an orderly transition of data and materials, including stored participant specimens and records. In addition, as requested by the Project Officer, the Contractor shall deliver all original data and participant specimens.

J. Final Report

Draft Final Report: A draft of the Final Report is due 45 calendar days prior to the completion date of the contract. The Project Officer will provide comments back to the Contractor within two weeks of receipt of the draft Final Report. The Contractor shall submit the Final Report which incorporates the Project Officer's comments on or before the completion date of the contract.

Final Report: The Final Report shall document and summarize the results of the contract for the entire period of performance. This report shall provide comprehensive descriptions of the results achieved on each protocol, including any publications for each protocol. In addition, the Final Report shall include a Summary (not to exceed 250 words) of Salient Results achieved during the performance of the contract.

K. Technical Reports Delivery Schedule

If the Contractor is unable to deliver the reports specified hereunder by the required due date because of unforeseen difficulties notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate advance written notification of the anticipated delays with reasons therefore and a proposed revised due date. The revised due date must be acceptable to both the Project Officer and Contracting Officer. Copies of the technical reports shall be submitted as follows:

Item	Deliverable	Quantity	Delivery Schedule
1.	Monthly Technical Progress Report	3 Hard Copies plus an Electronic Version	30th calendar day following each reporting period
2.	Monthly Expenditure Report by Protocol	3 Hard Copies plus an Electronic Version	30th calendar day following each reporting period
3.	QA/QC Draft Plan	3 Hard Copies plus an Electronic Version	Ninety (90) calendar days after the effective date of the contract.
4.	QA/QC Final Plan	3 Hard Copies plus an Electronic Version	Two (2) weeks after PO comments are received.
5.	Quarterly Subcontractor Technical Report	3 Hard Copies plus an Electronic Version	30th calendar day following each reporting period
6.	Semiannual Research Laboratory Report	3 Hard Copies plus an Electronic Version	Fifteen (15) calendar days after each reporting period
7.	Annual Technical Progress Report	3 Hard Copies plus an Electronic Version	Thirty (30) calendar days after each anniversary date of the contract
8.	Annual Technical Progress Report for Clinical Research Study Populations	3 Hard Copies plus an Electronic Version	Thirty (30) calendar days after each anniversary date of the contract
9.	Annual Invention Utilization Report	3 Hard Copies plus an Electronic Version	Thirty (30) calendar days after each anniversary date of the contract
10.	Site Visit Report	3 Hard Copies plus an Electronic Version	Thirty (30) calendar days after each site visit.
11.	Audit Reports	3 Hard Copies plus an Electronic Version	Thirty (30) calendar days after audit completion
12.	Transition Plan	3 Hard Copies plus an Electronic Version	Three (3) months prior to the completion date of the contract
13.	Draft Final Report	3 Hard Copies plus an Electronic Version	45 calendar days prior to the completion date of the contract
14.	Final Invention Report	3 Hard Copies plus an Electronic Version	On or before the completion date of the contract.
15.	Final Report and Summary of Salient Results	3 Hard Copies plus an Electronic Version	On or before the completion date of the contract.

L. The above items shall be addressed and delivered as follows:

ADDRESSEE	DELIVERABLE ITEM NUMBER	QUANTITY
Project Officer National Institutes of Health National Institute of Allergy and Infectious Diseases Division of Microbiology and Infectious Diseases Office of Clinical Research Affairs 6610 Rockledge Drive, Room 6057, MSC 6603 Bethesda, MD 20892	All	Two (2) Hard Copies, plus an electronic version
Contracting Officer National Institutes of Health National Institute of Allergy and Infectious Diseases Office of Acquisitions, DEA 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612	All	One (1) Original, plus an electronic version

Vaccine and Treatment Evaluation Units (VTEUs): Evaluation of Control Measures Against Infectious Diseases Other than AIDS
RFP NIH-NIAID-DMID-08-03

ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS AND FORMAT FOR TECHNICAL PROPOSAL

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 RFP 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; include the information requested in this appendix.

Offerors are advised to give careful consideration to the Statement of Work, all reference material, appendices and attachments, the technical evaluation criteria, and, the RFP as a whole, in the development of their Technical Proposal.

Offerors who 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.

Offerors are reminded that the total page limitation for the entire technical proposal package is 280 pages inclusive of all appendices and case studies.

Pages in excess of the limit will be removed and will not be read, evaluated, or considered for review.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1

A. PROPOSAL COVER/TITLE PAGE. Include RFP title and number, name of organization, DUNS number, proposal part, and identify if the proposal is an original or copy.
B. PROJECT OBJECTIVES, NIH FORM 1688
C. GOVERNMENT NOTICE FOR HANDLING PROPOSALS
D. TABLE OF CONTENTS
E. PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)

SECTION 2: TECHNICAL PROPOSAL OVERVIEW

Provide a brief description of the proposed VTEU program, including:

A. A description of the activities to be performed by the offeror and those that shall be provided by all 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. This section should identify the specific types of clinical research to be carried out by the offeror and all proposed subcontractors, as well as both the general and additional study populations that the offeror and all proposed subcontractors will provide access to for the conduct of Phase 1, 2, 3 and 4 clinical trials, as well as other analyses and evaluations.

B. A brief description of the facilities, equipment and other resources to be made available by the offeror and all proposed subcontractors, including: outpatient and inpatient clinical research facilities, clinical laboratory, research laboratory and research pharmacy facilities, and general clinical research facilities.

SECTION 3: TECHNICAL PLAN/APPROACH

A. Study Populations and Enrollment Requirements (SOW Item 1)

1. General Population: Describe capability and experience of the offeror and all proposed subcontractors in the recruitment and retention of the number and type of subjects required to serve as study participants. Identify anticipated problems and difficulties that may arise in recruiting and retaining these study participants and discuss proposed approaches to overcome or minimize such problems and difficulties.
2. Provide a plan for the rapid expansion of enrollment of study participants directly through the offeror's institution and/or through proposed affiliated clinical sites.
3. Additional Populations: Describe capability and experience of the offeror and all proposed subcontractors in the recruitment and retention of additional populations, including women of reproductive age, pregnant women, immunocompromised populations, non-U.S. populations, and populations with underlying medical conditions. Identify anticipated problems and difficulties that may arise in recruiting and retaining these study participants and discuss proposed approaches to overcome or minimize such problems and difficulties.

B. Protocol Development (SOW Item 3)

Provide a scientific, technical and operational plan for the following two (2) clinical trial case studies.

Case studies are suggested to be a total of 20 single-sided pages.

Case Study 1: Phase 1 Clinical Trial of West Nile Virus Vaccine

Design a Phase 1 clinical trial to test a live, attenuated West Nile Virus vaccine candidate. The supporting efficacy data derived from animal models is very promising; however, the pre-clinical information detected some EKG changes and some mild laboratory abnormalities (elevated fibrinogen, decreased hemoglobin, increased INR and an increase in calcium concentration). The vaccine is supplied as two components which are mixed in exact volumetric amount in order to achieve the different dosages and must be administered within thirty (30) minutes of mixing.

Provide the following documents and plans for protocol development:

-- Study design and justification
-- Sample size
-- Sample informed consent
-- Target population
-- Safety Oversight Structure
-- Inclusion/exclusion criteria
-- Schedule of events and timeline
-- Safety assessments (elements and time points) and complete safety plan (including reactogenicity and other adverse events and how the Safety Oversight Structure will review such information)
-- Data analysis plan
-- Recruitment plans and feasibility of recruitment of an ethnically diverse population in the appropriate age range, with the appropriate health status in a timely fashion
-- Plans for IRB approval, including historical timelines and any local IRB factors that need to be taken into consideration
-- Feasibility of conducting the study as it impacts staffing, infrastructure and equipment
-- Feasibility of using remote data entry system with data entry turn around time of seventy-two (72) hours
-- Plans for Independent Safety Monitor (ISM) and a backup, as well communication plans for adverse events with the proposed safety oversight structure and DMID
-- Plans for pharmacy support, cold chain maintaining, mixing and supply to the clinic, and specimen storage
-- Plans for mixing of vaccine prior to administration
-- Plans for laboratory support for screening labs and tests and antibody processing
-- Plans for shipment of sera to a central laboratory
-- Plans for QA/QC of the conduct of the study to ensure compliance with Federal regulations and protocol-specific requirements
-- Plans for specific processes and actions implemented to insure that all obligations described in FDA form 1572 are met (see: http://www.fda.gov/cder/forms/1571-1572-help.html)
Plans for monitoring access to data, physical space and availability of study personnel
-- Approaches to the evaluation of safety data based on results obtained
-- Case Study Technical Cost Summary: a breakdown of direct costs for proposed study-specific personnel by function, position title, and level of effort, and proposed direct costs for supplies, clinical and research laboratory services, research pharmacy services, study participant expenses, study participant incentives, advertising and miscellaneous costs, for the offeror and any proposed subcontractors.

Case Study 2: Phase 3 Clinical Trial of an Inactivated Influenza Vaccine

Design a Phase 3 clinical trial pivotal for the licensure of an inactivated influenza vaccine with a novel adjuvant in a healthy adult population ages 18 to 64. The clinical trial requires 2,500 subjects and must be enrolled within a month. The study has an immunogenic endpoint. In the Phase 2 clinical trial, one case of an "ill defined" neurologic weakness occurred that resolved after twelve (12) weeks.

Provide the following documents and plans for protocol development:

-- Study design and justification
-- ample informed consent
-- Target population
-- Number of clinical trial sites and enrollment plans per site
-- Inclusion/exclusion criteria
-- Safety Oversight Structure
-- Schedule of events and timeline
-- Safety assessments (elements and time points) and complete safety plan (including reactogenicity and other adverse events and how the Safety Oversight Structure will review such information)
-- Halting Rules
-- Informed Consent
-- The risk/benefit section of the protocol and discuss the relevance of the previous but limited clinical information
-- Randomization scheme that allows equal enrollment of two age groups within the adult cohort and at all sites
-- Data analysis plan
-- Recruitment plans and feasibility of recruitment of ethnically diverse population in the age ranges and timeframes stated above, including requirements for subcontracts
-- Plans for IRB approval, including historical timelines and any local IRB factors that need to be taken into consideration
-- Feasibility of conducting the study as it impacts staffing, infrastructure and equipment
-- Feasibility of using remote data entry system, with data entry turn around time of seventy-two (72) hours
-- Plans for pharmacy support, cold chain maintaining, and specimens storage
-- Plans for laboratory support for screening labs and antibodies processing
-- Plans for shipment of sera to a central laboratory
-- Plans for QA/QC of the conduct of the study to ensure compliance with Federal regulations and protocol-specific requirements
-- Plans for specific processes and actions implemented to insure that all obligations described in FDA form 1572 are met (see: http://www.fda.gov/cder/forms/1571-1572-help.html)
-- Plans for monitoring access to data, physical space and availability of study personal
-- A description of the evaluation for Pharmacovigilance if deaths occur on study
-- Approaches to the evaluation of safety data based on results obtained
-- Case Study Technical Cost Summary: a breakdown of direct costs for proposed study-specific personnel by function, position title, and level of effort, and proposed direct costs for supplies, clinical and research laboratory services, research pharmacy services, study participant expenses, study participant incentives, advertising and miscellaneous costs, for the offeror and any proposed subcontractors.

C. Additional VTEU Evaluations and Analyses (SOW Item 6)

This Case Study is suggested to be a total of 20 single-sided pages.

Case Study 3: Phase 1Clinical Trial of a Meningitis Vaccine

Design a study to evaluate a new, live attenuated vaccine (MENA) against meningitis. Animal studies have shown the vaccine to be highly effective, but only when administrated intra-nasally in sufficient concentration. Those studies showed that if the vaccine is administered in such a way that most of the fluid form is delivered into the pharynx, the vaccine is rendered ineffective.

In a Phase 1 study performed on a similar vaccine, MENB, two of the participants developed a mild, self limiting encephalitis which resolved within a week. No further work has been carried out on that vaccine.

Pre-clinical studies of both vaccines had not detected any neuralgic symptoms.

Provide the clinical protocol and informed consent for this study and in particular address:

-- Study design and justification
-- Sample size
-- Target population
-- Sample informed consent
-- Safety Oversight Structure
-- Inclusion/exclusion criteria
-- Schedule of events and timeline
-- Risk/Benefit assessment, including risk mitigation
-- Safety assessments (elements and time points) and complete safety plan (including reactogenicity and other adverse events and how the Safety Oversight Structure will review such information)
-- Plans for specific processes and actions implemented to insure that all obligations described in FDA form 1572 are met (see: http://www.fda.gov/cder/forms/1571-1572-help.html)
-- Data analysis plan
-- Product administration
-- Case Study Technical Cost Summary: a breakdown of direct costs for proposed study-specific personnel by function, position title, and level of effort, and proposed direct costs for supplies, clinical and research laboratory services, research pharmacy services, study participant expenses, study participant incentives, advertising and miscellaneous costs, for the offeror and any proposed subcontractors.

D. Protocol Implementation and Oversight (SOW Items 4 and 5)

1. Describe procedures for receiving, storing and tracking study products.
2. Describe the proposed reporting system to provide data and information from the safety and efficacy testing of candidate vaccines and therapeutics to the Project Officer and product supplier.
3. Describe your internal procedures for assuring safety oversight for participants in clinical trials.

4. Describe your capability to accommodate clinical site monitors. Please include a description of the physical site for monitors and relevant experience in participating in monitored studies.
5. Describe your current system of records for all documentation required for the conduct of clinical trials.

SECTION 4: STORAGE, SHIPPING AND TRACKING OF CLINICAL SAMPLES (SOW Item 7)

A. Describe procedures and capabilities for the labeling, tracking and appropriate storage of clinical samples, and for monitoring of storage conditions.
B. Provide a plan to demonstrate ability to meet the requirements of the International Transport Association for the shipping of dangerous goods.
C. Provide one sample Standard Operating Procedure for an inventory control system to track store and ship clinical specimens to be used for microbiological evaluation.

SECTION 5: QUALITY ASSURANCE/QUALITY CONTROL PLAN (SOW Item 8)

A. 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 back-up, transmission of data, data reporting and exporting system, access control and confidentiality, and data retrieval and disaster recovery.
B. Describe your capability to accommodate independent auditors and relevant experience in participating in independent audits.

SECTION 6: SCIENTIFIC AND TECHNICAL PERSONNEL (SOW Item 9)

The Technical Proposal should include all information relevant to document individual training, experience, qualifications and expertise necessary for the successful completion of all contract requirements. Proposals should include a Staffing Plan for the conduct of the Statement of Work with role descriptions and level of effort of key scientific and technical personnel, including scientific and technical personnel of all proposed subcontractors. Limit CVs to 2-3 pages and provide selected references for publications relevant to the scope of the RFP.

A. Principal Investigator: Describe the experience, training, expertise, and qualifications, and percentage of effort of the proposed Principal Investigator to lead and direct the activities to be carried out under this contract. This includes scientific and technical expertise in: the design, conduct and oversight of clinical trials and clinical studies of vaccines and therapeutics for infectious diseases; the capacity to monitor progress, assess performance, identify performance problems and implement corrective actions; experience collaborating with industry and organizations providing clinical research support services; and experience in leading and directing projects of similar size and complexity.

B. Other Key Scientific and Technical Personnel: Describe the experience, training, expertise and qualifications, as well as the percentage of effort, for all proposed key scientific and technical personnel, including subcontractors. Include experience in designing and conducting clinical trials and clinical studies of infectious diseases and in carrying out projects of similar size and complexity.

SECTION 7: CLINICAL RESEARCH FACILITIES AND RESOURCES (SOW Item 10)

A. Provide a description, along with documented availability and adequacy of facilities, equipment and other resources available for performance of the contract for the offeror and all proposed subcontractors, including:

- Outpatient clinical research facilities
- Inpatient clinical research facilities
- Clinical laboratory facilities
- Clinical research laboratory facilities
- Research pharmacy facilities
- General clinical research facilities

B. Describe plans for accessing the facilities, services and other resources of affiliated clinical sites when necessary and appropriate to meet contract requirements.

C. Describe plans for and procedures to be utilized to insure compliance with all safety guidelines and regulations, including training and monitoring of personnel.

D. Describe plans for any change in facilities as necessary due to progress or performance issues that arise during the course of the clinical protocol.

SECTION 8: PROJECT MANAGEMENT (SOW Item 11)

A. <u>Overall Project Management</u>

1. Describe how the project will be staffed, organized and managed. Describe in detail the responsibilities and level of effort for all proposed personnel who will be assigned to the contract, and provide an administrative framework indicating clear lines of authority and responsibility for the personnel. Include a diagram of the proposed organizational/management structure for the project.

2. Describe project management systems that will be used to track activities and to keep multiple activities on time and within budget. The plan should include a description of quality control methods that will be used to ensure the effective initiation, implementation, management and oversight of contract activities.

3. Outline how the Principal Investigator will communicate and interact with the Contracting Officer and Project Officer and how the Principal Investigator will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).

4. Provide a plan for how the Contractor and any subcontractor(s) will safeguard confidentiality and intellectual property of data and materials provided to them by third parties or the United States Government, as well as data generated during the contract.

B. Subcontract Acquisition and Management

1. Describe experience with, and provide a plan for subcontract acquisition and management, including soliciting, evaluating, negotiating, awarding and post-award administration of subcontracts in accordance with the requirements established by Federal contracting regulations.

2. Describe qualifications and experience of proposed contract management staff in the acquisition and management of subcontracts under Federal contracts.

3. Describe proposed plans and methods to assess subcontractor performance, identify performance problems and approaches for their remediation, including noncompliance with subcontract terms and conditions, and for implementation of corrective actions when necessary.

Vaccine and Treatment Evaluation Units (VTEUs): Evaluation of Control Measures Against Infectious Diseases Other than AIDS
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ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS

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 statement of work, all reference material provided as appendices and attachments, and the technical evaluation criteria, and, the RFP as a whole, in the development of your proposal. The information requested in these instructions should be used as a guide for the development and formatting of your business proposal. Offerors should consider and include the information requested in this appendix, as well as **any other** information which will benefit the proposal.

BUSINESS PROPOSAL

SECTION 1 – PROPOSAL COVERSHEET -- Form NIH-2043 - PROPOSAL SUMMARY AND DATA RECORD

SECTION 2 – COST OR PRICE SUPPORT

Section L of the RFP specifies the minimum documentation requirements for cost data and all cost related support. All related documentation should be included in the proposal in a clearly marked section. Cost and Pricing support should be provided for all proposed subcontractors.

The following uniform cost assumptions shall be used by all offerors in preparation of their cost proposal.

1. **Clinical Trials and Study Participants**

   a. Assume that five protocols will be initiated in each year of the contract period of performance.

   - Assume that four will be Phase 1 trials and one will be a Phase 3 trial.
   - For one of the five trials to be initiated each year, assume that the Contractor shall be responsible for developing the protocol;
   - For the other four clinical trials to be initiated each year, assume that the protocol will be provided by the Project Officer.
   - Assume that for three of the clinical trials to be initiated each year, case report forms and a manual of operations shall be provided by the Project Officer and that other sources shall provide these materials for two of the clinical trials to be initiated each year.
   - Assume that the duration for each trial, Concept Proposal through closure, will be one year.

b. For these five clinical trials to be initiated annually, assume that the following total number and type of subjects will need to be recruited each year:

- 300 pediatric subjects (birth – 18 years of age)
- 1,200 adult subjects (>18 - 45 years of age)
- 300 mature adult and elderly subjects (>45 years of age and up)

c. Assume that one additional study will be conducted per year and that the study will be a targeted surveillance study that will include the collection and analysis of nasal pharyngeal swabs on 200 pediatric subjects.

2. **Clinical Specimens**

Assume that the following number of specimens will be collected each year of the contract period of performance:

- 7,200 blood specimens
- 7,200 urine specimens
- 600 stool specimens
- 600 saliva specimens
- 600 nasal specimens

3. **Assays**

Assume that 5,000 immunological (e.g., standard antibody testing) assays will be performed each year of the contract period of performance.

4. **Study Participants Costs**

Assume a total of $385,000 per year (assume a 3% annual escalation rate in years 2-7) to defray the costs incurred by subjects during participation in the clinical trial and clinical studies.

5. **Meetings and Teleconferences**

a. Contract Initiation Meeting: Assume one meeting in Bethesda, Maryland within three months after contract award to discuss contract initiation. Assume that this meeting will require a two-night stay and shall be attended by all of the Contractor's key personnel.

b. Annual VTEU Meetings: Assume one meeting per year in Bethesda, Maryland to discuss clinical trial status, progress and issues. Assume that this will require a two-night stay and shall be attended by all of the Contractor's key personnel.

c. Protocol Specific Meetings and Teleconferences: Assume five protocol specific meetings per year and 50 protocol specific teleconferences per year. Assume that these meetings will require a two-night stay in Bethesda, Maryland and shall be attended by all of the Contractor's key personnel.

d. Annual Site Visits: Assume that the Contractor shall host an annual two-day site visit at their facilities. Offerors shall assume that five (5) Government personnel and two (2) key personnel from any affiliated clinical site will attend. Travel and per diem costs for the Government personnel shall not be provided by the contract. Offerors shall assume that each Annual Site Visit Report will be ten (10) pages long.

e. General Scientific Meetings:

1) Offerors shall propose a total of $3,750 annually for the Principal Investigator (PI) and selected clinical investigators for travel to general scientific meetings for presentations of work conducted under this contract.
2) Offerors shall propose $3,750 annually for nursing staff travel to scientific meetings for presentations of work conducted under this contract or updating of clinical research knowledge/skills.
3) Assume a 3% annual escalation rate in Years 2 through 7.

f. Assume that the Principal Investigator shall be required to participate in six (6) teleconferences and one (1) meeting per year with the Food and Drug Administration (FDA) in Bethesda, Maryland.

6. **Independent Audits**

Assume one (1) independent audit per year to ensure that the Contractor and/or subcontractor facilities and all planned procedures meet FDA regulations and guidance for Good Clinical Practices (GCP) standards.

7. **Storage of Data and Materials**

Assume $750 annually (assume a 3% annual escalation rate in Years 2 through 7) for storage of data and materials.

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CURRENTLY FUNDED NIAID VACCINE AND TREATMENT EVALUATION UNITS

Current VTEU contracts:

Baylor College of Medicine	N01-A1-25465
Cincinnati Children's Hospital Medical Center	N01-A1-25459
Harbor UCLA Medical Center	N01-A1-25463
Saint Louis University	N01-A1-25464
University of Maryland, Baltimore	N01-A1-25461
University of Rochester	N01-A1-25460
Vanderbilt University	N01-A1-25462

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COMPLETED AND ACTIVE VTEU STUDIES (JUNE 2002-DECEMBER 2005)

VTEU SITE ABBREVIATIONS

BCM Baylor College of Medicine
CCHMC Cincinnati Children's Hospital Medical Center
SLU Saint Louis University
UCLA University of California, Los Angeles
UMD University of Maryland, Baltimore
UR University of Rochester
VU Vanderbilt University

PROTOCOL TITLE	PHASE	STUDY POPULATION	STUDY STATUS	SITE(S)
A Phase I-II Randomized, Controlled, Dose-ranging Study of the Safety, Reactogenicity, and Immunogenicity of Intramuscular Inactivated Influenza A/H5N1 Vaccine Given Alone or with Aluminum Hydroxide to Healthy Elderly Adults	I/II	Healthy elderly adults	Pending	CCHMC UMD
A Randomized, Placebo-Controlled, Phase I/II, Dose-Ranging Study of the Safety, Reactogenicity, and Immunogenicity of Intramuscular Inactivated Influenza A/H5N1 Vaccine Given Alone or Combined with Different Adjuvants in Healthy Adults	I/II	Healthy adults	Pending	CCHMC SLU UMD
Safety and Immunogenicity of Acellular Pertussis Vaccine in Pregnant Women	II	Healthy pregnant women	Pending	BCM
A Single-site, Phase I, Double-Blind, Safety and Immunogenicity Trial of an Alphavirus Replicon Vaccine Expressing Cytomegalovirus Genes (AVX601) in Healthy Volunteers	I	Healthy adults	Pending	CCHMC
A Phase I Randomized, Observer-Blinded, Placebo Controlled Study to Evaluate the Safety, Tolerability and Immunogenicity of Chiron Corporation's HCV	I	Healthy adults	Pending	SLU

PROTOCOL TITLE	PHASE	STUDY POPULATION	STUDY STATUS	SITE(S)
E1E2/MF59 Vaccine Administered to Healthy HCV-Negative Adults				
Phase I, Double-Blinded, Placebo Controlled Dosage Escalation Study of the Safety and Immunogenicity of EBA-175 RII-NG Malaria Vaccine Administered Intramuscularly	I	Healthy adults	Pending	BCM
Immunogenicity and Safety of Pneumococcal Polysaccharide Vaccine Among Infants 12 Months of Age Following a Primary Vaccination Series with Pneumococcal Conjugate Vaccine	II	Infants	Pending	UCLA
A Randomized, Double-Blind, Placebo-Controlled, Dose-Escalation, In-Patient Phase I/II Study to Determine the Safety and Immunogenicity of Ty800 in Healthy Adult Subjects	I/II	Healthy adults	Active	CCHMC
Transfer of Herpes Simplex Virus Type 2 gD Subunit Vaccine-Induced Antibodies from Mothers to Neonates	I	Healthy mothers/neonates	Active	SLU UR
A Randomized, Double-Blind, Placebo-Controlled, Phase II Study to Assess the Safety and Efficacy of the Cytomegalovirus Infection in Healthy Adolescent Females	II	Healthy adolescent females	Active	CCHMC VU
Seroprevalence and Prospective Risk Factor Analysis of Cytomegalovirus Infection in Adolescent Males	NA	Adolescent males	Active	CCHMC VU
Immunogenicity and Safety of Live Attenuated Varicella Vaccine in 12 and 18 Month-Old Children, With and Without Concomitant Administration of Measles-Mumps-Rubella Vaccine	I/II	12 and 18 Month Old Children	Active	VU
Influenza Vaccines: Mix and Match of TIV in CAIV/T A Phase I Safety, Immunogenicity Viral Shedding Study	I	Healthy adults	Active	SLU

Evaluation Of Reactogenicity And Immunogenicity Of Different Doses Of Intramuscular Monovalent Inactivated Influenza A/H9n2 Vaccine In Ambulatory Adults	I/II	HEALTHY ADULTS	ACTIVE	BCM
A Randomized, Double-Blinded Placebo Controlled, Phase I/II Dose Ranging Study of the Safety, Reactogenicity and Immunogenicity of Intramuscular, Inactivated Influenza A/H5N1 Vaccine in Healthy Children Aged Two through Ten Years.	I, II	Healthy children	Active	CCHMC SLU UCLA UMD
Randomized, Single Blinded Study of the Safety and Immunogenicity of Pentavalent DTaP-Hep B-IPV Combination Vaccine (Pediarix™; GlaxoSmithKline (GSK) Biologicals) Administered to Healthy Neonates and Infants at Birth, 2, and 6 Months of Age with DTaP (Infanrix®; GSK) Administered at 15 Months of Age Compared to a Routine Infant Schedule at 2, 4, 6 and 15 Months of Age	II	Healthy infants	Active	UCLA
Prospective Pilot Safety Study Administering Two Doses of Inactivated Influenza Vaccine to Infants 10-22 weeks of Age	I	Healthy infants	Active	CCHMC VU
Escalation Study of the Safety and Reactogenicity of *F. tularensis* Live Vaccine Strain Administered by Scarification and Subcutaneous Routes	I	Healthy adults	Active	BCM
Evaluation of a New Challenge Pool of Norwalk Virus Inocula in Human Subjects	I	Healthy adults	Active	BCM
A Single Center, Open-label, Phase I/II Study of the Safety and Immunogenicity of Two 90	I/II	Healthy adults	Completed	UMD

mcg Doses of Intramuscular Inactivated Influenza A/H5N1 Vaccine in Healthy Adult Subjects				

A Phase I Clinical Trial To Evaluate The Safety And Immunogenicity Of The Vical Prophylactic Anthrax Dna Intramuscular Vaccine Vcl-Ab01 In Healthy Adult Subjects	I	HEALTHY ADULTS	COMPLETED	BCM UR
A Phase II Evaluation of the Reactogenicity and Immunogenicity of Different Doses of Intramuscular Trivalent Baculo-expressed Influenza HA Vaccine in Healthy Elderly Adults	II	Healthy elderly adults	Completed	BCM CCHMC UR
Evaluation of Antibodies to Type III Capsular Polysaccharide of Group B Streptococcus in Breast Milk	NA	Healthy female adults	Completed	BCM
Seroprevalence of Pertussis Toxin Antibodies in Infants of Hispanic Mothers and Relationship to Maternal Age	NA	Healthy infants	Completed	BCM
A multi-center Double-Blind, Randomized Study of the Safety and Efficacy of Aventis Pasteur's Smallpox Vaccine, USP (APSV) in Vaccinia-Naïve Adults	I	Healthy Adults	Completed	CCHMC
A Double-Blind, Randomized Dose-Response Study of Dryvax Vaccine Against Smallpox in Previously Vaccinated Adults	II	Healthy adults	Completed	BCM CCHMC SLU UCLA UR UMD VU
A Phase I Clinical Trial to Evaluate the Safety and Immunogenicity of MVA-BN in a Dose Response Regimen and in Combination with Dryvax in Healthy Adult Volunteers	I	Healthy adults	Completed	SLU
A Randomized, Double-blinded, Placebo-controlled, Phase I/II Dose Ranging study of the Safety, Reactogenicity and Immunogenicity of Intramuscular Inactivated Influenza A/H5N1 Vaccine	I/II	Healthy adults	Completed	SLU UCLA UMD UR

in Healthy Adults				

Comparisons Of The Reactogenicity And Immunogenicity In Ambulatory Elderly Subjects Of Standard Dose Fluzone And A High Dose Of A Trivalent Inactivated Influenza Virus Vaccine	I	HEALTHY ELDERLY ADULTS	COMPLETED	BCM CCHMC SLU UMD
Shigella CVD 2400: Safety and Immunogenicity of a Two Dose Regimen of CVD 1208, a Live Oral *S. flexneri* 2A Vaccine with attenuating deletions in guaBA, sen and set	I	Healthy adults	Completed	UMD
Phase I Trial of ICC-1132, a Candidate Vaccine Against *P. falciparum* Malaria Based on a Viral Like Particle Comprising Recombinant Hepatitis B Core Antigen and Circumsporozite Epitodes to Assess Vaccine Safety and Immunogenicity in Healthy Volunteers	I	Healthy adults	Completed	UMD
Phase I, Dose Escalating Study to Assess the Safety, Tolerability and Immunogenicity of Recombinant Anthrax Protective Antigen Administered Two Intramuscular Doses to Healthy Adults	I	Healthy adults	Completed	UMD
A Randomized, Double-blinded, Placebo Controlled Phase III Study to Evaluate the Immunogenicity and Safety of GSK Biologics Influenza Vaccine Administered Intramuscularly in Healthy Adults	III	Healthy adults	Completed	BCM CCHMC UMD UR
A Phase I Placebo Controlled Escalation Study of the Safety and Tolerability of Dynavax 1018ISS in Patients with Chronic Hepatitis C	I	Patients with Hepatitis C	Completed	VU

Evaluation of Immune Responses to Natural Influenza Infection in Children Six Months to Five Years of Age	NA	NA	Completed	VU
Gene Expressions Responses to IM and IN Influenza Vaccines	NA		Completed	VU
Pilot Study to Optimize and Standardize Umbilical Cord Blood Collection and the Isolation, Freezing and Transportation of Cells for Studies of Cellular Immune Responses to Immunization	NA	NA	Completed	UCLA
A Comparison of Dressing Preparations for Smallpox Vaccination Sites with a Focus Upon the Risk of Secondary Transmission of Vaccinia Virus	NA	Healthy adults	Completed	VU
Laboratory and Clinical Assessment of Coronavirus Infection in Older Adults with COPD	NA			SLU
Evaluation of a New Challenge Pool of Norwalk Virus Inocula (Lot 42399) in Human Subjects	NA	NA	Completed	BCM
Leukapheresis Procedures to Obtain White Blood Cells for Studies of TB Immunity	NA			SLU

Cholera 47000 Use In Invivo Expression Technology to Identify Virulence Factors and Protective Antigens of *V. Cholerae 01*	NA			UMD

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DMID FUNDED CLINICAL RESEARCH SUPPORT SERVICES CONTRACTS

DMID holds contracts with companies that currently provide and will continue to provide regulatory, clinical site monitoring and data management and analysis support to the VTEUs. The contractors with whom successful offerors are expected to interact in order to perform functions specified within the Statement of Work are described below. Notifications will be sent to the successful offerors of this competition when awards are made for new or recompeted contracts that provide support for these functions.

DMID Data Coordinating Center for Clinical and Epidemiologic Studies in Infectious Diseases

EMMES Corporation, located in Rockville, MD, provides several services for DMID-supported clinical research programs including the following:

1. Provides statistical leadership and clinical trial design expertise for the development of protocols and analysis of study data;
2. Establishes and administers data collection, management, quality assurance and reporting systems;
3. Provides adverse event safety reporting system and reconciles with the pharmacovigilance (SAE) system maintained by another contractor;
4. Provides detailed record maintenance and timely reporting;
5. Provides inventory and tracking system for study specimens; and
6. Collaborates with DMID, research groups, individual Principal Investigators and contractors.

DMID Clinical Trials Management Support Contract

PPD Development, LP, located in Wilmington, NC, provides clinical trials management support to DMID and DMID investigators. PPD Development specific responsibilities include, but are not limited to, the following:

1. Clinical site assessment, evaluation of clinical site for clinical research feasibility and capacity;
2. Clinical site preparation and clinical trial operations assistance; study document preparation and review;
3. Establish and assist clinical sites with internal quality control and quality assurance;
4. Provide Good Clinical Practices training;
5. External clinical site monitoring to include site initiation, interim and close-out visits and quality audit visits;
6. Centralized pharmacovigilance and safety monitoring; and
7. Information and document management through web-based systems.

DMID Clinical And Regulatory Affairs Support Contract

Fisher BioServices Corporation, located in Rockville, MD, provides regulatory support services including:

1. Preparation and maintenance of Investigational New Drug (IND) applications;
2. Consulting and audit for manufacturers of NIAID/DMID products;
3. Management and operation of a clinical agent repository for distribution and tracking of IND products.

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DATA SUBMISSION REQUIREMENTS

The EMMES Corporation serves as the Data Coordinating Center (DCC) for the Division of Microbiology and Infectious Diseases (DMID), NIAID, NIH. The Clinical and Epidemiologic Studies in Infectious Disease (CESID) contract uses a variety of technologies to collect, manage, monitor and distribute study data and information. To interface with EMMES, a computer with Internet access is required. EMMES' AdvantageEDC^{SM} is accessible via the World Wide Web using Internet Explorer 5.5 or higher. Access to the system is password restricted and passwords are issued by EMMES to individual users.

Data are submitted to EMMES from participating sites via remote data entry (RDE). The core element of EMMES' web-based data management system is Internet Data Entry System (IDES). This system includes various tools for subject enrollment, data entry, case report form management and protocol monitoring. One tool integrated with this system is GlobalTrace^{SM}, a specimen tracking system that scans a unique barcode on each specimen aliquot and tracks each aliquot from a clinical site, while in-transit and arrival at a receiving repository and/or laboratory. A second tool within AdvantageEDC^{SM} is *Integrity*. This tool examines study data for inconsistencies and completeness and generates reports of anomalies. EMMES' data management system is validated and is compliant with §21 CFR 11.

The CESID contract maintains an extensive collection of websites. Study materials, such as protocols, template consent forms, Manuals of Operations, and case report forms are posted to the website for investigators and study staff to download as needed. In addition, the websites serve to disseminate real-time study information, including overall accrual, accrual by site for multicenter studies, data queries, line listings of adverse events, deviation reports, etc. Users external to DMID, EMMES and the PPD monitoring group are restricted to only his/her site's data and only to the functions, e.g. enrollment, randomization, GlobalTrace, associated with the rights the user has been granted.

EMMES provides a training version of AdvantageEDC. The training site serves as a means to practice using system functions and utilities and is provided to familiarize new and potential users with its features. EMMES also provides AdvantageEDC and GlobalTrace training via web-cast. To access this feature, telephone, computer and high-speed internet access are required.

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PROPOSED ADVANCE UNDERSTANDINGS

1. All data and other information pertaining to therapeutic and vaccine candidates supplied by Companies serving as industry collaborators for the clinical trials and clinical studies to be undertaken by the Contractor, or supplied by the Project Officer, shall be assumed to be confidential unless specifically identified as not confidential in writing by the Project Officer. The Contractor agrees that its Principal Investigator and/or any other employees or agents of the Contractor will provide the data generated under this contract exclusively to the NIAID or, if directed by the NIAID, to the Companies and the U.S. Food and Drug Administration (FDA) or other appropriate Federal agency.

2. The Contractor understands that the NIAID must negotiate individual agreements (e.g., Clinical Trial Agreements) with various Companies to obtain vaccine and therapeutic candidates and that the terms of the agreements may vary. The NIAID intends that these agreements will provide for the Contractor's right to publish results generated by the Contractor under this contract after a reasonable period of time to allow the Companies to file patent applications and to protect their proprietary information. The Contractor agrees to abide by the terms of these agreements that the NIAID has executed unless in direct conflict with the terms of this contract.

3. The Contractor agrees to enter into confidentiality agreements with the Companies when required by the Companies. The confidentiality agreements shall reference this contract by contract number and shall be consistent with any agreement the NIAID has entered into with the Companies to obtain vaccine and therapeutic candidates. In the event the Contractor reasonably objects to the terms of the confidentiality agreement, the Contractor shall promptly bring such objection in writing to the attention of the Contracting Officer for appropriate resolution.

4. This contract is one of multiple contracts awarded as a VTEU site. Selection of a VTEU Contractor for performance of Government initiated protocols is influenced by the following factors: geographic distribution of protocols among the VTEU sites, protocol population needs (minority, age, and/or gender representation), VTEU site workload and availability. Studies may be performed at single sites, multiple sites or all VTEU sites. The Government reserves the right to select VTEU sites for protocol implementation that are in the best interest in the Government.

5. No costs for recruitment of participants outside of existing patient populations can be billed as a direct cost. These types of costs can be billed as part of indirect costs only.

SMALL DISADVANTAGED BUSINESS (SDB) PARTICIPATION PLAN

1A. OFFEROR'S NAME	2. REQUEST FOR PROPOSAL (RFP) NUMBER		
1B. OFFEROR'S ADDRESS	3. TOTAL PARTICIPATION OF SDBs IN THE CONTRACT ($)		
	4. SDB PARTICIPATION AT PRIME CONTRACT LEVEL		
	A. NAICS INDUSTRY SUBSECTOR	B. DOLLAR AMOUNT	C. PERCENTAGE

5. BREAKDOWN OF SDB PARTICIPATION AT SUBCONTRACT LEVEL BY NAICS INDUSTRY SUBSECTOR

A. NAICS INDUSTRY SUBSECTOR	B. DOLLARS	C. PERCENT

INSTRUCTIONS

Item 3. Identify total dollar amount of participation of small disadvantaged business (SDB) concerns proposed.

Item 4. Identify participation, if any, by SDB concerns at the prime contract level by NAICS Industry Subsector, dollar amount, and percentage of total contract value. All prime contract dollars must be identified under the NAICS code assigned to the acquisition (see Section L of the solicitation).

Item 5. Identify participation by SDB concerns at the subcontract level by NAICS Industry Subsector, dollar amount, and percentage of total contract value. (SDB concerns need not be identified by name.) See http://epic.od.nih.gov/naics/contents.asp for descriptions of NAICS Industry Subsectors.