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

RFP NIH-NIAID-DAIDS-BAA-08-16
"HIV Vaccine Design and Development Teams"

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:** June 8, 2007	4. **Due Date:** October 25, 2007 **Time:** 4:00 P.M., Local Time	5. **Small Bus. Set-Aside:** [ ]Yes [X] No **8(a) Set-Aside:** [ ]Yes [X] No **NAICS: 541710** (See Part IV, Section L.)
6. **Just In Time:** [ ] No [X] Yes (See Part IV, Section L.)	7. **Number of Awards:** [ ] Only 1 Award [X] Multiple Awards	8. **Technical Proposal Page Limits:** [ ] No [X] Yes (See Section J, Attachment 1, Packaging and Delivery of Proposal)
9. **Issued By:** Josh LaVine Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	10. [x] **NIAID reserves the right to make awards without discussion.** 11. **Options:** **[ ] No** **[X] Yes** (See Part IV, Section L.)	12. **Period of Performance:** Base Period: 06/27/08 – 06/26/2013 Option Periods: Option 1: 06/27/2013 – 06/26/2014 Option 2: 06/27/2014 – 06/26/2015
13. **Primary Point of Contact:** **Name :** Josh Lavine **Phone:** 1-866-410-5787 (Ext. 27149) **Fax:** 301-402-0972 E-Mail: JLaVine@niaid.nih.gov	14. **Secondary Point of Contact:** **Name:** Nancy Hershey **Phone:** 301-496-0612 **Fax:** 301-402-0972 E-Mail: NHershey@niaid.nih.gov	15. **Protest Officer:** Charles Grewe Director, OA **Address (see Block 9.)**
16. COLLECT CALLS WILL NOT BE ACCEPTED. FACSIMILE SUBMISSIONS ARE NOT ACCEPTABLE.		
17. **Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See Part III, SECTION J – Attachments)**		
18. **DELIVERY ADDRESS INFORMATION**		
19. **Hand Delivery or Overnight Service:** Josh LaVine, Contract Specialist Office of Acquisitions DEA, NIH, NIAID 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	20. **U.S. Postal Service or an Express Delivery Service** Josh LaVine, Contract Specialist 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.		

Updated thru FAC 2005-14 (11/22/2006)

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 OFFERORS PROPOSAL AND REQUIRING CONTRACTING OFFICER PRIOR APPROVAL) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. HOWEVER, THE ENCLOSED CONTRACT SCHEDULE PROVIDES ALL THE NECESSARY INFORMATION FOR THE OFFEROR TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The objective of this contract is to support the development of novel, innovative, safe and immunogenic preventive HIV/AIDS vaccine candidates with the potential for further evaluation in human trials.

ARTICLE B.2. PRICES/COSTS

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

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

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

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated ____, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

a. Technical Progress Reports

1. In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award. *(Please refer to Attachment 4, Reporting Requirements and Deliveries, of this solicitation).*

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. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. All reports shall be sent to the following address:

Contracting Officer
Office of Acquisitions
National Institute of Allergy and Infectious Diseases
National Institutes of Health
6700B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892 -7612

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

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

SECTION D - PACKAGING, MARKING AND SHIPPING

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

SECTION E - INSPECTION AND ACCEPTANCE

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

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

c. Inspection and acceptance will be performed at the National Institute of Allergy and Infectious Diseases, 6700B Rockledge Drive, Bethesda, Maryland.

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

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

or the duly authorized representative, of the items specified in the Delivery Schedule which are described in SECTION C of this contract. *(Please refer to Attachment 4, Reporting Requirements and Deliveries, of this solicitation).*

b. Deliveries required by the contractor shall be made F.o.b. destination as set forth in FAR Clause 52.247-35, F.o.b. Destination, Within consignees Premises (April 1984) [and any specifications stated in SECTION D, PACKAGING AND MARKING AND SHIPPING, of this contract] to the address/addressee listed below: *(Please refer to Attachment 4, Reporting Requirements and Deliveries, of this solicitation).*

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

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

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

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

[To be specified prior to award]

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

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

The Government may unilaterally change its Project Officer designation.

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

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

(End of Clause)

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

Name	Title

[To be specified in Contract]

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST

a. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts NIH(RC)-1 are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR 32.9, Prompt Payment.

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

One original to the following designated billing office:

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

(2) In addition to the requirements specified in FAR Subpart 32.9 for a proper invoice, the Contractor shall include the following information on all invoices/financing requests:

(a) Name of the Office of Acquisitions to which you are submitting the invoice/financing request: **NIAID**
(b) Central Point of Distribution: For the purpose of this contract, the Central Point of Distribution is **NIAIDOAInvoices**.
(c) Vendor Identification Number. This is the 7 digit number that appears after the Contractor's name in Block 7 of the Standard Form 26. **(Note: This only applies to new contracts awarded on/after June 4, 2007, and any existing contract modified to include the number).**
(d) DUNS number or DUNS+4 that identifies the Contractor's name and address exactly as stated on the face page of the contract (Standard Form 26).
(e) Identification of whether payment is to be made using a two-way or three-way match. The contract requires a **two-way** match.

b. Inquiries regarding payment of invoices should be directed to the designated billing office, (301) 496-6088.

ARTICLE G.4. INDIRECT COST RATES *(This only applies if the successful offeror is a profit making organization)*

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

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

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

ARTICLE G.5. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication, entitled, **Contractors Guide for Control of Government Property**, which can be found at:
http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) shall be submitted biannually.

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

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

b. Electronic Access to Contractor Performance Evaluations

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

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

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

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS *(This is applicable if a clinical trial is proposed as part of the Statement of Work)*

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved by NIAID, written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractors 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 *(This applies if the contract work will involve human subjects)*

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 *(This applies if a clinical trial is proposed as part of the Statement of Work)*

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

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html

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

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

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

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

ARTICLE H.4. HUMAN MATERIALS *(This applies if human materials will be acquired and/or generated under the contract)*

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

ARTICLE H.5. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE) *(This applies if the Contractor is receiving human materials from an outside source, another contract or from a subcontractor)*

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

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

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

ARTICLE H.6. RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (Including Human Gene Transfer Research) *(This applies to contracts that include research involving recombinant DNA molecules)*

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

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

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

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

ARTICLE H.7. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

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

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

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

[applicable information to be included at award]

ARTICLE H.8. NEEDLE EXCHANGE

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

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

[applicable information to be included at award]

ARTICLE H.9. 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.10. 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.11. PRIVACY ACT, HHSAR 352.270-12 (January 2006)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of

any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

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

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

(End of clause)

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

The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document is incorporated into this contract as an Attachment in SECTION J of this contract. This document is also available at: http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm.

ARTICLE H.12. ANIMAL WELFARE *(This applies when the contract will include research involving live vertebrate animals)*

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at:
http://grants1.nih.gov/grants/olaw/references/phspol.htm.

ARTICLE H.13. OMB CLEARANCE *(This applies if the contract work will involve the use of surveys or interviews of nine or more people)*

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

ARTICLE H.14. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to clause 52.217-__ set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost [plus fixed fee] of the contract will be increased as set forth in the ESTIMATED COST [PLUS FIXED FEE Article in SECTION B of this contract.

ARTICLE H.15. 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:

[Email addresses will be provided at the time of award]
[Contracting Officer/Contract Specialist]

ARTICLE H.16. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to the P.L.(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown or the applicable Executive Level for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as "indirect costs" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individuals direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individuals appointment whether that individuals time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The annual salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individuals salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

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

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

[*Applicable information to be included at award]

ARTICLE H.17. INFORMATION SECURITY

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

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

a. Information Type

[ ] Administrative, Management and Support Information:
[ ] Mission Based Information:

b. Security Categories and Levels

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

c. Position Sensitivity Designations

(1) The following position sensitivity designations and associated clearance and investigation requirements apply under this contract.

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

****** (List applicable Contractor Position Titles here if considered appropriate) ******

[ ] 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).

****** (List applicable Contractor Position Titles here if considered appropriate) ******

[ ] 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).

****** (List applicable Contractor Position Titles here if considered appropriate) ******

(2) The contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. Any revisions to the roster as a result of staffing changes shall be submitted within 15 calendar days of the change. The Contracting Officer shall notify the contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: http://ais.nci.nih.gov/forms/Suitability-roster.xls

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

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

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

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

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

d. Information Security Training

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

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

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

****** [List the required training courses here] ******

e. Rules of Behavior

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

f. Personnel Security Responsibilities

Contractor Notification of New and Departing Employees Requiring Background Investigations

(1) The contractor shall notify the Contracting Officer, the Project Officer, and the Security Investigation Reviewer within **five working days** before a new employee assumes a position that requires a suitability determination or when an employee with a security clearance stops working under the contract. The government will initiate a background investigation on new employees requiring security clearances and will stop pending background investigations for employees that no longer work under the contract.

(2) New employees: Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the government will determine the appropriate security level.

(3) Departing employees:

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

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

(1) Contractor Agreement

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

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

(2) Contractor-Employee Non-Disclosure Agreements

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

h. NIST SP 800-26 Self-Assessment Questionnaire

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

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

The annual update shall be submitted to the Project Officer, with a copy to the Contracting Officer and included with the Annual Progress Report.

i. Information System Security Plan

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

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

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

ARTICLE H.18. CONFIDENTIALITY OF INFORMATION

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

****** (NOTE: Insert as specifically as possible, the types of data which would be covered and requirements for handling the data, HERE.) ******

ARTICLE H.19. PUBLICATION AND PUBLICITY

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

"This project has been funded in whole or in part with Federal funds from the National Institute, National Institutes of Health, Department of Health and Human Services, under Contract No. _____.

ARTICLE H.20. 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.21. POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS *(This applies when contract performance will involve possession, use or transfer of selection biological agents or toxins)*

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

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

For prime or subcontract awards to ***foreign institutions*** that possess, use, and/or transfer Select Agents under this contract, before using NIH funds for any work directly involving the Select Agents, the foreign institution must provide information satisfactory to the NIAID, NIH that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at:
(http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf)
are in place and will be administered on behalf of all Select Agent work sponsored by these funds. The process for making this determination includes inspection of the foreign laboratory facility by an NIAID representative. During this inspection, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents. An NIAID-chaired committee of U.S. federal employees (including representatives of NIH grants/contracts and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will ultimately assess the results of the laboratory facility inspection, and the regulations, policies, and procedures of the foreign institution for equivalence to the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 (http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf). The committee will provide recommendations to the DEA Director, NIAID. The DEA Director will make the approval decision and notify the Contracting Officer. The Contracting Officer will inform the prime contractor of the approval status of the foreign institution. No NIH funds can be used for research involving Select Agents at a foreign institution until NIAID grants this approval.

Listings of HHS select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at http://www.cdc.gov/od/sap/ and http://www.cdc.gov/od/sap/docs/salist.pdf. Listings of USDA select agents and toxins as well as information about the registration process for domestic institutions are available on the APHIS/USDA website at:

http://www.aphis.usda.gov/programs/ag_selectagent/index.html and:

http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_forms.html.

For foreign institutions, see the NIAID Select Agent Award information:

(http://www.niaid.nih.gov/ncn/clinical/default_biodefense.htm).

ARTICLE H.22. 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.pdff 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.

Sharing of Model Organisms for Biomedical Research

[The plan for sharing model organisms submitted by the contractor is acceptable/The contractor's data sharing plan, dated_____, is hereby incorporated by reference.] The contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

ARTICLE H.23. SHARING RESEARCH DATA

[The data sharing plan submitted by the contractor is acceptable/The contractors data sharing plan, dated _____ is hereby incorporated by reference.] The contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to serve health. this contract is expected to generate research data that must be shared with the public and other researchers. NIHs 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.24. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

The Policy requests that beginning May 2, 2005, NIH-funded investigators submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at; http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html.

ARTICLE H.25. CONSTITUTION DAY *(Applies to educational institutions only)*

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

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

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

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

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

ARTICLE I.1. of this SECTION is hereby modified as follows:

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 **52.232-20, 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.]***

Alternate I (February 2002), of FAR Clause **52.232-25, Prompt Payment** (February 2002) is deleted.

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 **52.215-17, Waiver of Facilities Capital Cost of Money** (October 1997).
   (2) FAR Clause **52.216-15, Predetermined Indirect Cost Rates** (April 1998).
   (3) FAR Clause **52.217-9, Option to Extend the Term of the Contract** (March 2000).

   "(a) The Government may extend the term of this contract by written notice to the Contractor within 30 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension."

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed seven years."

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

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

(5) FAR Clause 52.219-25, **Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting** (October 1999).
(6) FAR Clause 52.224-1, P**rivacy Act Notification** (April 1984).
(7) FAR Clause **52.224-2, Privacy Act** (April 1984).
(8) FAR Clause 52.227-14, **Rights in Data - General** (June 1987).
(9) **Alternate IV** (June 1987), FAR Clause **52.227-14, Rights in Data - General** (June 1987).
(10) **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:

(11) FAR Clause 52.227-16, **Additional Data Requirements** (June 1987).
(12) FAR Clause **52.230-2, Cost Accounting Standards** (April 1998).
(13) FAR Clause **52.230-3, Disclosure and Consistency of Cost Accounting Practices** (April 1998).
(14) FAR Clause **52.230-4, Consistency in Cost Accounting Practices** (August 1992).
(15) FAR Clause **52.230-5, Cost Accounting Standards - Educational Institution** (April 1998).
(16) FAR Clause 52.230-6, **Administration of Cost Accounting Standards** (April 2005).
(17) FAR Clause 52.242-3, **Penalties for Unallowable Costs** (May 2001).
(18) FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984).

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

(1) HHSAR Clause **352.223-70, Safety and Health** (January 2006).
(2) HHSAR Clause **352.224-70, Confidentiality of Information** (January 2006).
(3) HHSAR Clause **352.270-7, Paperwork Reduction Act** (January 2006).
(4) HHSAR Clause **352.270-8(b), Protection of Human Subjects** (January 2006).
(5) HHSAR Clause **352.270-9(b), Care of Live Vertebrate Animals** (January 2006).

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

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

(1) **NIH (RC)-7, Procurement of Certain Equipment** (April 1984).
(2) **NIH(RC)-11, Research Patient Care Costs** (4/1/84).

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

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

This contract incorporates the following clauses in full text.

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

1. 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 the end of this RFP
Attachment 2:	Proposal Intent Response Sheet	See Attachment Section at the end of this RFP
Attachment 3:	Statement of Work	See Attachment Section at the end of this RFP
Attachment 4:	Reporting Requirements and Deliverables	See Attachment Section at the end of this RFP
Attachment 5:	Additional Technical Proposal Instructions	See Attachment Section at the end of this RFP
Attachment 6:	Additional Business Proposal Instructions	See Attachment Section at the end of this RFP
Attachment 7:	DAIDS Enterprise System	See Attachment Section at the end of this RFP
Attachment 8:	List of Current HVDDT Contractors	See Attachment Section at the end of this RFP

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

Attachment No.	Title	Location
Attachment 9:	Targeted/Planned Enrollment Table	http://rcb.cancer.gov/rcb-internet/forms/enroll-table.pdf
Attachment 10:	Annual Technical Progress Report Format for Each Study	http://rcb.cancer.gov/rcb-internet/forms/atpr.pdf
Attachment 11:	Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Attachment 12:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Attachment 13:	Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
Attachment 14:	Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (formerly Optional Form 310	http://rcb.cancer.gov/rcb-internet/forms/of310.pdf
Attachment 15:	Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf

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

Attachment No.	Title	Location
Attachment 16:	Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Attachment 17:	Small Business Subcontracting Plan	http://rcb.cancer.gov/rcb-internet/forms/SBA Plan Nov 2005.pdf
Attachment 18:	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
Attachment 19:	Offerors Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Attachment 20:	Certificate of Current Cost or Pricing Data	http://rcb.cancer.gov/rcb-internet/forms/cert-current-cost.pdf
Attachment 21:	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.)

Attachment No.	Title	Location
Attachment 22:	Invoice/Financing Request Instructions--Cost-Reimbursement, NIH(RC)-1	http://rcb.cancer.gov/rcb-internet/forms/rc1.pdf
Attachment 23:	Privacy Act System of Records *System of Records No. 09-20-005 is applicable to this RFP.*	http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm
Attachment 24:	Safety and Health, HHSAR Clause 352.223-70	http://rcb.cancer.gov/rcb-internet/forms/safety&health-1-06.pdf
Attachment 25:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Attachment 26:	Research Patient Care Costs, NIH(RC)-11	http://www.niaid.nih.gov/contract/forms/nih-rc-11.pdf
Attachment 27:	Inclusion Enrollment Report	http://rcb.cancer.gov/rcb-internet/forms/inclusion-enrollment.pdf
Attachment 28:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf
Attachment 29:	Commitment To Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Attachment 30:	Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Attachment 31:	Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

1. Go to the Online Representations and Certifications Application (ORCA) at: https://orca.bpn.gov/and complete the Representations and Certifications; and

2. Complete, and include as part of your BUSINESS PROPOSAL, SECTION K which can be accessed electronically from the INTERNET at the following address:
   http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

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

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

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

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

"Discussions" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officers 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 solicitations 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 offerors 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 agents 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 Governments control prior to the time set for receipt of offers; or
(*3*) It is the only proposal received.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(2) The Government may reject any or all proposals if such action is in the Governments 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 offerors initial proposal should contain the offerors 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 Governments 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 agencys evaluation of the significant weak or deficient factors in the debriefed offerors offer.
(ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.
(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iv) A summary of the rationale for award.
(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.
(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

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

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

b. "JUST IN TIME"

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information needed during the initial evaluation of proposals. Certain documents will no longer be required to be submitted with initial proposals, but will be requested at a later stage in the competitive process. Specifically, the travel policy, the annual financial statement, the total compensation plan, the subcontracting plan, and certain types of cost/pricing information will only be required to be submitted from those offerors included in the competitive range, or the apparent successful offeror. The special procedures for submission of this documentation are set forth in detail below:

Travel Policy. The offerors (and any proposed subcontractors) written travel policy shall not be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a travel policy as a part of their final proposal revision.

Annual Report. The offerors most recent annual report shall not be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a copy of their most recent annual report as a part of their final proposal revision.

Total Compensation Plan. The offerors total compensation plan shall not be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a total compensation plan as a part of their final proposal revision.

Subcontracting Plan. The offerors Small Business Subcontracting Plan shall not be submitted with the initial business proposal. Only those offerors included in the competitive range will be required to submit an acceptable subcontracting plan.

c. 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 System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

d. 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 June 27, 2008.

It is anticipated that the award(s) from this solicitation will be a multiple-year cost reimbursement type, completion contract with a period of performance of 5 years with options for 2 one year extensions of the period of performance. Incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. ESTIMATE OF EFFORT

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government estimates the average total annual cost to be a maximum of $4 million (including direct and indirect costs) during the base period and the average total annual cost to be a maximum of $1 million (including direct and indirect costs) during the option periods. This information is furnished for the offerors information only and is not to be considered restrictive for proposal purposes.

f. COMMITMENT OF PUBLIC FUNDS

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

g. COMMUNICATIONS PRIOR TO CONTRACT AWARD

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

h. RELEASE OF INFORMATION

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

i. COMPARATIVE IMPORTANCE OF PROPOSALS

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

j. PREPARATION COSTS

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

k. SERVICE OF PROTEST (SEPTEMBER 2006) - FAR 52.233-2

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

Charles Grewe
Director, Office of Acquisitions
National Institute of Allergy and Infectious Diseases, NIH
6700B Rockledge Drive, Room 3214, MSC 7612
BETHESDA MD 20892-7612

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

(End of Provision)

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

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

(End of provision)

2. **INSTRUCTIONS TO OFFERORS**

a. **GENERAL INSTRUCTIONS**

INTRODUCTION

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

(1) Contract Type and General Clauses

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

(2) Authorized Official and Submission of Proposal

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

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

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

III. BUSINESS PROPOSAL

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

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

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

(4) Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offerors 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 procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

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

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

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

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

(9) Standards for Privacy of Individually Identifiable Health Information

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

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

(10) Privacy Act - Treatment of Proposal Information

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

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

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

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

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

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

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

- to the cognizant audit agency and the 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 and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offerors 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) Based on the written recommendations of the technical review committee/peer review group/source evaluation panel, the Contracting Officer will, in concert with Program Staff, establish an Order of Merit Ranking. This ranking will be based upon the scientific/technical merit, scientific priority, programmatic balance, and the availability of funds.

Communications will be held with offerors whose proposals are the most highly rated. All aspects of the proposal are subject to discussion, including cost, technical approach, and contractual terms and conditions. At the conclusion of discussion, each offeror still being considered for award shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct limited negotiations to finalize details of the award with the selected source(s) in accordance with HHSAR 315.70.

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 Government reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet the Government's 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 Institutions policy, the Investigators 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 Institutions 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 Institutions 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 *(This applies to educational institutions only)*

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

1. Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).
2. Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
3. Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).
4. Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997). *(This applies to commercial organizations only)*
5. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
6. Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. **TECHNICAL PROPOSAL INSTRUCTIONS** *(NOTE TO OFFEROR: Offerors are advised to refer Attachment 5 , Additional Technical Proposal Instructions)*

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

(1) Technical Discussions

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

a) Project Objectives, NIH-1688-1

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

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

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

b) 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 offerors best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

c) Personnel

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

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

(1) Single Principal Investigator/Project Director

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

(2) Other Investigators

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

(3) Additional Personnel

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

-The specific items or expertise they will provide.

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

-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) Resumes

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

(2) Technical Evaluation

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

(3) Additional Technical Proposal Information

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Governments 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 offerors 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.
) Recommendations for changing reporting requirements if such changes would be more compatible with the offerors proposed schedules.

IMPORTANT NOTE TO OFFERORS: The following paragraphs [(5) through (15)] shall be addressed, as applicable, in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

(5) Human Subjects

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

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

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

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

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

(e) In accordance with 45 CFR Part 46, prospective Contractors being considered for award shall be required to file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects

involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. HHS regulations for the protection of human subjects (45 CFR Part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information can be accessed at the OHRP Web site:

http://www.hhs.gov/ohrp/

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

(End of provision)

(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 offerors plans for inclusion of women and minorities in the research proposed; or (2) the offerors justification(s) for exclusion of one or both groups from the research proposed.

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

The proposal must include the following information:

- A description of the subject selection criteria
- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group
- The proposed sample composition using the "Targeted/Planned Enrollment Table"(see Section J, Attachments)

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

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

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

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

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm Definitions - Significant Difference).
*The definition of an "NIH-Defined Phase III clinical trial" can also be found at this website.)

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

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

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

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

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

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

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

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

(9) Inclusion of Children in Research Involving Human Subjects

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

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

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

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

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

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

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

Justifications for Exclusion of Children

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

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

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

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

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

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

Definition of a Child

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

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

(10) Research Involving Prisoners as Subjects

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

b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

On June 20, 2003 the Secretary of HHS waived the applicability of certain provisions of Subpart C of 45 CFR Part 46, (Additional DHHS Protections Pertaining to Biomedical and Behavioral Research

Involving Prisoners as Subjects) to specific types of epidemiological research involving prisoners as subjects.

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

1. The sole purposes are:

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

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

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

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

(11) Research Involving Human Fetal Tissue

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

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

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

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

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

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

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

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

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

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

(13) Human Embryonic Germ Cell (HEGC) Research

1. Guidelines

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

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

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

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

If, in response to the solicitation, the offeror proposes to use human embryonic germ cells, it must submit, as a separate attachment to its proposal, an original and two copies of the documentation and assurances that address the areas covered in the "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" at:
(http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html).
Prior to any award made under this solicitation, the documentation and assurances will be subject to review by the HPSCRG, which meets in a public meeting. No research involving the use of human embryonic germ cells may begin prior to HPSCRG approval.

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

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

(14) Human Embryonic Stem Cell (HESC) Research

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

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

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

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

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

(15) Data and Safety Monitoring in Clinical Trials

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

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

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

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

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

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

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

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

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

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

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

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

(16) Care of Live Vertebrate Animals

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

Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, HHSAR 352.270-9(a) (January 2006)

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

(End of Provision)

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

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

c. If an Animal Assurance is already in place, the offerors proposal shall include:

-The Animal Welfare Assurance number.
-The date last certified by OLAW. (i.e. assurance letter from OLAW)
-Evidence of recent AAALAC Accreditation, if required by the SOW contained in this solicitation.

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

Notice to Offerors of Requirements of: 42 CFR Part 73, Possession , Use, and Transfer of Select Agents and Toxins (relating to public health and safety):
(http://www.cdc.gov/od/sap/42_cfr_73_final_rule.pdf;
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 or 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.

(18) Obtaining and Disseminating Biomedical Research Resources

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

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

research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

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

http://ott.od.nih.gov/NewPages/64FR72090.pdf

(a) Sharing Research Data

[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. NIHs 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://www.autm.net/aboutTT/ then search "Implementing Letter")

- How will inappropriate “reach-through” requirements (as discussed in the NIH Research Tools Policy) on materials transferred be discussed?

- How will technologies remain widely available and accessible to the research community, for example, if any intellectual property rights arise for which a patent application may be filed?

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

(19) Information Security is applicable to this solicitation and the following information is provided to assist in proposal preparation.

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

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

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

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

(a) Information Type

[X] Administrative, Management and Support Information:
[ ] Mission Based Information:

(b) Security Categories and Levels

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

(c) Position Sensitivity Designations

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

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

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

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

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

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

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

(d) Information Security Training

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

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

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

(e) Offerors Official Responsible for Information Security

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

(f) NIST SP 800-26 Self-Assessment Questionnaire

The offeror must include in the "Information Security" part of its Technical Proposal, a completed Self-Assessment Questionnaire required by NIST Draft SP 800-26, Revision 1, Guide for Information Security Program Assessments and System Reporting Form at:
(http://csrc.nist.gov/publications/drafts/Draft-sp800-26Rev1.pdf See Appendix B for submission format). NIST 800-26 assesses information security assurance of the offerors internal systems security. This assessment is based on the Federal IT Security Assessment Framework and Draft NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems, at:
(http://www.csrc.nist.gov/publications/drafts/800-53-rev1-clean-sz.pdf).

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

(g) Draft Information System Security Plan

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

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

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

(i) References

(1) Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); http://csrc.nist.gov/policies/FISMA-final.pdf
(2) DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf
(3) NIH Computer Security Awareness Training Course: http://irtsectraining.nih.gov/

The following NIST publications may be found at the following site: http://csrc.nist.gov/publications/
[Note: The search tool on the left side of this page provides easy access to the documents.]

(4) NIST Special Publication 800-16, Information Technology Security Training Requirements; and Appendix A-D
(5) NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems
(6) NIST SP 800-26, Revision 1, Computer Security
(7) NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems
(8) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I; and
Volume II, Appendices to Guide For Mapping Types of Information and Information Systems To Security Categories, Appendix C, and Appendix D
(9) NIST SP 800-64, Security Considerations in the Information System Development Life Cycle
(10) FIPS PUB 199, Standards for Security Categorization of Federal Information and Information Systems
(11) FIPS PUB 200, Minimum Security Requirements for Federal Information and Information Systems

c. **BUSINESS PROPOSAL INSTRUCTIONS *(NOTE TO OFFEROR: Offerors are advised to refer to Attachment 6, Additional Business Proposal Instructions)***

(1) Basic Cost/Price Information

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

(2) Proposal Cover Sheet

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

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;

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

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

(3) Information Other than Cost or Pricing Data

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

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

Unless otherwise stated in this solicitation, the information may be submitted in the offerors 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 offerors design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $650,000, 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 offerors 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) Salary Rate Limitation in Fiscal Year 2007

Offerors are advised that pursuant to P.L. 110-005**, no NIH Fiscal Year 2007 (October 1, 2006 - September 30, 2007) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individuals direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individuals appointment whether that individuals 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 employees annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 110-005** applies only to Fiscal Year 2007 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individuals annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limitation also applies to individuals proposed under subcontracts; however, it does not apply to consultants. P.L. 110-005** states in pertinent part:

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

LINK TO FY 07 EXECUTIVE SCHEDULE SALARIES: http://www.opm.gov/oca/07tables/html/ex.asp

**Note to Offerors: The current Fiscal Year Executive Level I Salary Rate should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year 2007 Executive Level I Salary rates.*

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

(5) Small Business Subcontracting Plan

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

If the proposed contract exceeds a total estimated cost of $550,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

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

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

c) The offeror understands that:

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

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

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

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

(5) It is the offerors 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 offerors 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 Governments Contracting Officer or as otherwise directed, with a copy to the prime Contractors 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 offerors subcontracting program and a description of his/her duties.

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

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $550,000 adopt a plan similar to the plan agreed upon by the offeror.

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

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

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

(6) HUBZone Small Business Concerns

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

(7) Extent of Small Disadvantaged Business Participation

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $550,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

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

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

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

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

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

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

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

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

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

(8) Qualifications of the Offeror

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

a) General Experience

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

b) Organizational Experience Related to the RFP

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

c) Performance History

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

d) Pertinent Contracts

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

e) Pertinent Grants

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

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

(9) Other Administrative Data

a) Property

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

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

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

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

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

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

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

(1) The solicitation number (or other procurement identification number).
(2) The offerors name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offerors official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offerors financial agent.
(5) The offerors account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offerors 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 offerors financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

d) Financial Capacity

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

e) Incremental Funding

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

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

(a) It is the Governments intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds as specified in FAR 52.232-22. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. The Government intends to allot additional funds up to and including the full estimated cost of the contract for the remaining years of performance by contract modifications. However, the Government is not obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor is the Contractor obligated to perform in excess of the amount allotted.

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

(End of provision)

f) Facilities Capital Cost of Money, FAR 52.215-16, (June 2003)
(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.
(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

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

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

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

(10) Subcontractors

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

a) Willingness to perform as a subcontractor for specific duties (list duties).
b) What priority the work will be given and how it will relate to other work.
c) The amount of time and facilities available to this project.
d) Information on their cognizant field audit offices.
e) How rights to publications and patents are to be handled.
f) A complete cost proposal in the same format as the offerors cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:
http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

(11) Proposers Annual Financial Report

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

(12) Representations and Certifications - SECTION K

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

(13) Travel Costs/Travel Policy

a) Travel Costs - Commercial

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) Travel Policy

One copy of the offerors (and any proposed subcontractors) 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.

SECTION M - EVALUATION FACTORS FOR AWARD

(1) GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against three factors. The factors in the order of importance are: technical, cost, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, cost/price, and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. 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.

In addition, because of the uncertainty in candidate HIV/AIDS vaccine efficacy, the need to maintain a balanced portfolio of different vaccine modalities in order to meet NIAID's commitment to HIV/AIDS vaccine development is critical and will be considered in making awards. Overlap with funding made through other DAIDS funding mechanisms will also be considered as a factor in achieving programmatic balance. Thus, the Government reserves the right to make awards to cover significantly different novel vaccine concepts as a mechanism to achieve programmatic balance.

All technical proposals will undergo evaluation by a peer review group also known as a Scientific Review Group (SRG).

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

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

Offerors must demonstrate in their proposals that they have the necessary expertise and capabilities for conducting the research as requested by this solicitation. Each proposal must document the feasibility of successful implementation of the requirements of the BAA.

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

(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 NCI that a designated exemption is appropriate.

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

The reviewers will evaluate the proposal with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to

be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated “unacceptable” (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or “acceptable.” If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

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

(b) Women and Minorities

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(c) Children

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

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

Based on the reviewers' evaluation of the offeror's response, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in

accordance 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 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 address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion of children is still found to be unacceptable, then your proposal may not be considered further for award.

(d) Data and Safety Monitoring

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

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

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

(3) EVALUATION OF OPTIONS

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s). In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Governments best interests. Evaluation of options will not obligate the Government to exercise the option(s).

(4) EVALUATION OF DATA SHARING PLAN

The offerors plan for the sharing of final research data shall be assessed for appropriateness and adequacy. If your proposal does not include a plan or if the plan in your proposal is considered “unacceptable,” and the Government includes your proposal in the 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 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.

(5) 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.

(6) TECHNICAL EVALUATION CRITERIA

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

CRITERIA	**WEIGHT**
CRITERION 1: Scientific Rationale	**35**

a) Soundness of the scientific rationale for the development of the proposed vaccine concept including proof of concept studies in an appropriate animal model and innovativeness of the proposed vaccine concept as a preventive vaccine.
b) Soundness and feasibility of the rationale and criteria proposed to advance the candidate vaccine concept through the product development/production process and into Phase I and/or Phase I/II clinical trials.
c) Soundness and feasibility of the rationale for the suitability and applicability of the envisioned product for worldwide use, including potential for large-scale manufacture and widespread acceptance of the proposed product.
d) Suitability and uniqueness of the approach for surmounting scientific obstacles to HIV/AIDS vaccine development (e.g., the difficulty of inducing strong durable antibody or cell-mediated immunity to divergent HIV antigens).

CRITERION 2: Technical Approach **35**

A. Comprehensive Strategic Product Development and Clinical Testing Plan:

1) The suitability and feasibility of the proposed key objectives and milestones for optimizing the vaccine concept and proposed methods and procedures for implementing the scientific plans and achieving the proposed key objectives and milestones.
2) The appropriateness and feasibility of the proposed time schedule for achieving contract objectives and milestones.
3) The appropriateness and feasibility of the proposed qualitative and quantitative criteria for deciding whether and when to proceed to the next phase of development toward a candidate vaccine product.
4) The suitability and feasibility of the plans for modifying key objectives and milestones based on adverse experimental or production results, or on new scientific findings along the development path.

B. Preclinical Research and Development

The soundness, adequacy and feasibility of the proposed experimental approaches and methodologies, including assays to detect immune responses, for preclinical research and development *in vitro* and in animal models, and capacity to adhere to Good Laboratory (GLP) standards and practices.

C. Production of Vaccine Product

The soundness and suitability of proposed plans for the production of vaccine product under Good Manufacturing Practices (GMP), including: development of working cell banks; conduct of process

development; manufacture of non-cGMP and cGMP pilot lots; formulation of final product; and conduct of long-term stability studies of cGMP bulk and final product.

D. Clinical Trials

The soundness, adequacy and feasibility of proposed plans for clinical trial(s), including: statistical design, data and safety monitoring and reporting, and analysis and interpretation of final study data; management of clinical trials to ensure adherence to regulatory requirements and guidelines governing research involving human subjects; and representation of appropriate genders, racial/ethnic and age groups

E. Offeror's Proposed Statement of Work

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

CRITERION 3: Qualifications/Availability of Proposed Scientific and Technical Personnel **15**

a) Principal Investigator (PI): Adequacy and appropriateness of the education, training, experience, expertise, qualifications and level of effort of the proposed PI with respect to planning, coordinating and directing a vaccine product development project encompassing preclinical research, product manufacturing, and clinical trials.

b) Other Scientific and Technical Personnel: Adequacy and appropriateness of the education, training, experience, expertise, qualifications and level of effort of other proposed scientific and technical personnel of the Offeror and all proposed subcontractors with respect to the following: design, conduct and analysis of preclinincal studies to evaluate vaccine products; production of vaccine products under GMP; and design, conduct and analysis of clinical trials of vaccine products, including statistical design, safety monitoring, regulatory compliance, and data management and quality control for clinical trials proposed to be conducted independently of an existing DAIDS-supported Clinical Trials Network.

CRITERION 4: Facilities, Equipment and Other Resources **15**

Documented availability and adequacy of facilities, equipment, and other resources necessary to safely and successfully perform all phases of the proposed project, including:

a) detailed laboratory layouts, including location of major equipment.
b) information regarding ownership/lease of facilities, including demonstrated availability for the duration of the contract.
c) plans for compliance with all safety guidelines and regulations, including training and monitoring of personnel for exposure to infectious and other hazardous materials.
d) production of the vaccine product under GMP conditions.
e) documentation of the availability and adequacy of facilities and resources to perform FDA-required safety, immunogenicity, and other preclinical studies.
f) a plan demonstrating capacity to perform regulatory- and human subjects protection-compliant clinical trials, or describing intent to collaborate with a NIAID/DAIDS-sponsored clinical trial network to perform clinical trials with the Offeror's proposed vaccine product.

g) a plan for obtaining, adding or deleting facilities as necessary due to progress during the course of product development.
h) other research support resources (including Information Technology systems) which will be required to effectively complete the Offeror's proposed Statement of Work.

CRITERION 5: Project Management **10**

a) Adequacy of the Project Management Plan in terms of staffing, organization, responsibilities, leadership and lines of authority.
b) Suitability of systems proposed for tracking project activities and monitoring progress, timelines and budgets.
c) Suitability of plan for how the PI will communicate with the Project Officer and the Contracting Officer, as well as establish lines of communication among all performance sites and activities.
d) Suitability of plan for soliciting, evaluating, negotiating, awarding and managing any proposed subcontracts in accordance with Federal regulations.
e) Adequacy of plan to identify and remediate problems in subcontractor performance.
f) Adequacy of plan to protect and share confidential information with the Independent External Advisory Group members.
g) Suitability of plan to organize the Annual Site Visit Review Meetings and provide for a thorough assessment of contract status, problems and approaches to their resolution, and future plans.

TOTAL POSSIBLE POINTS FOR BASE PERIOD: **110**

OPTION **10**

Adequacy, appropriateness, feasibility, and soundness of proposed plans for the design and implementation of the option for further optimization and/or preclinical testing of the vaccine product, including: (i) the rationale for conducting further optimization and/or preclinical testing; (ii) the anticipated additional studies required; (iii) proposed approaches/methodologies to scale-up process development and/or improve vaccine formulations; (iv) facilities, equipment and other resources to be made available; and (v) projected timeline for the completion of proposed work to be carried out under the option.

TOTAL POSSIBLE POINTS (Base Period plus Option) **120**

(7) EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

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

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

Offers will be evaluated on the following sub-factors:

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

SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP

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

ATTACHMENT 1
PACKAGING AND DELIVERY OF THE PROPOSAL
HIV Vaccine Design and Development Teams
NIH-NIAID-DAIDS-BAA-08-16

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-DAIDS-BAA-08-16**
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**
Josh LaVine Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20817	Josh LaVine Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612

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

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

C. NUMBER OF COPIES:

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

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

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

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

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

alternate sources of information.

CREATING AND NAMING ELECTRONIC FILES:

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

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

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

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

3. CDs should be named using the following format:

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

THE NUMBER OF COPIES AND APPLICABLE PAGE LIMITATIONS REQUIRED OF EACH PART OF YOUR PROPOSAL ARE AS SPECIFIED BELOW.
PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE PROVIDED TO THE REVIEWERS TO BE READ OR EVALUATED.
OFFERORS MUST CERTIFY THAT THE INFORMATION IN THE PAPER AND ELECTRONIC COPIES IS EXACTLY THE SAME.

Document	Number of Copies	Page Limits
Technical Proposal and all Appendices	**PAPER** One (1) unbound SIGNED ORIGINAL. Six (6) unbound COPIES **ELECTRONIC FILES ON CD** Three (3) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices)	Not to Exceed 200 pages (inclusive of all Attachments and Appendices)
Business Proposal	PAPER **One (1) unbound SIGNED ORIGINAL.** **Five (5) unbound COPIES** **ELECTRONIC FILES ON CD** **Three (3) 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

ATTACHMENT 2
PROPOSAL INTENT RESPONSE SHEET
HIV Vaccine Design and Development Teams
NIH-NIAID-DAIDS-BAA-08-16

RFP No.: NIH-NIAID-DAIDS-BAA-08-16
RFP Title: "HIV Vaccine Design and Development Teams"

Please review the attached Request for Proposal. Furnish the information requested below and return this page by September 25, 2007. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

[ ] DO INTEND TO SUBMIT A PROPOSAL
[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____
Address (print): _____
_____
_____
_____

Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (print clearly):
_____
_____

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____
Title: _____
E-Mail Address: _____
Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):

_____
_____
_____
_____
(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
OA, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

Attn: Josh LaVine
RFP-NIH-NIAID-DAIDS-BAA-08-16
FAX# (301) 402-0972
Email: JLaVine@niaid.nih.gov

ATTACHMENT 3
RESEARCH and TECHNICAL OBJECTIVES
HIV Vaccine Design and Development Teams
NIH-NIAID-DAIDS-BAA-08-16

BROAD AGENCY ANNOUNCEMENT INFORMATION

You are invited to submit a proposal in accordance with the requirements of this BROAD AGENCY ANNOUNCEMENT (BAA) solicitation, NIH-NIAID-DAIDS-BAA-08-16, entitled "HIV Vaccine Design and Development Teams." The Broad Agency Announcement is authorized by Federal Acquisition Regulation (FAR) 6.102 and further described in FAR 35.016 as well as the NIH Manual Issuance 6035, Broad Agency Announcements. A BAA is a general announcement of an agency's research interest. The intent of a BAA is to encourage the submission of creative and innovative approaches to specific research areas identified by the Government.

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

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

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

An Order of Merit Ranking is established by the Contracting Officer in lieu of a Competitive Range. All competing proposals are ranked on the basis of scientific merit, programmatic balance and the availability of funds. The scores assigned by the SRG are considered the final scores. Negotiations are conducted with Offerors selected from the Order of Merit Ranking based on their scientific merit and those specific considerations set forth in this solicitation under Section M, Evaluation Factors. During negotiations, there is an opportunity to refine the proposed Statement of Work in consultation with the Project Officer including comments of the SRG, as appropriate. At the conclusion of negotiations with the Offerors selected from the Order of Merit Ranking, those Offerors are allowed the opportunity to submit a Final Proposal Revision (FPR), to address weaknesses in the proposal and questions identified by the SRG.

It is anticipated that multiple awards will result from this announcement, and these awards will be multi-year, cost reimbursement, completion type contracts. The length of time for which funding is requested should be consistent with the nature and complexity of the proposed research. The maximum period of performance is 7 years. Contracts will be awarded for a base period of 5 years with an option to extend the contract for up to two additional years to support further optimization and/or preclinical testing of the vaccine product. The National Institute of Allergy and Infectious Diseases (NIAID) anticipates awarding 1-2 contracts. Awards are expected to be made on or about June 20, 2008. The NIAID estimates the average total annual cost (direct and indirect cost combined) for these contracts to be a maximum of $4M per base year of the contract and $1 million for each of the two option years. However, it is anticipated that the total cost for each award may vary depending on the scope and capacity of the technical objectives of the award.

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

BACKGROUND and INTRODUCTION

The Division of Acquired Immune Deficiency Syndrome (DAIDS) of the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), is committed to the development of efficacious preventive vaccines against HIV and AIDS for worldwide use in stemming the AIDS epidemic and supporting the scientific strategic plan of the Global HIV/AIDS Vaccine Enterprise (PLoS Medicine, February 2005, 2 (2)). While industry, government, and academia have all targeted considerable resources to this end over the past 20 years, identification of an efficacious vaccine against HIV/AIDS has yet to be accomplished. A wide assortment of candidate HIV-1 vaccines has already been pursued and many have reached the stage of safety and immunogenicity testing in humans. However, efficacy trials of only two candidate HIV/AIDS preventive vaccines have been initiated. At this time, the highest priority of DAIDS is the discovery, development, and evaluation of preventive HIV/AIDS vaccines. To augment the vaccine product pipeline, DAIDS is seeking opportunities to advance vaccine concepts toward the product stage via a focused, development-based approach. Specifically, the goal of this solicitation is to support the development of novel, innovative, safe, and immunogenic preventive HIV/AIDS vaccine candidates with the potential for further evaluation in human trials.

The HIV Vaccine Design and Development Team (HVDDT) awards were first made in FY 2000 to establish consortia of scientists from industry and academia with novel concepts, as well as product development experience, to advance vaccine concepts along a well-defined development path to a vaccine product and into clinical testing. The first competition was limited to the development of preventive HIV/AIDS vaccines. That competition attracted a high level of both interest and quality of Offerors, and four awards were made for five years in June 2000. Each of the Contractors advanced vaccine candidates into clinical trials by the fourth year of the award period. The initiative was re-competed for award in FY 2002 and FY 2003. These solicitations resulted in five additional five-year awards. The competition in 2005 and 2006 for HIV Vaccine Design and Development Teams also included development of therapeutic AIDS vaccines, and led to the award of a total of three preventive HIV Vaccine Design and Development Teams and three therapeutic HIV Vaccine Design and Development Teams. The purpose of the present solicitation is to reissue this research and development program and award multiple contracts for a maximum term of seven years to continue the development of innovative preventive HIV vaccine concepts into products suitable for testing in humans. Teams shall be required to enter vaccine products into clinical trials by the beginning of the fifth year of funding. If the results from preclinical non-human primate challenge and immunogenicity studies are highly promising at that time, relative to candidates already in clinical trials, the government may exercise the option to extend the contract for up to an additional two years to support for further product optimization and/or preclinical testing.

The NIAID reserves the right to award all or any portion of the activities proposed based on technical merit, scientific priority, programmatic balance, and the availability of funds. Furthermore, the NIAID recognizes that product development is an iterative process and that the progress of a candidate vaccine through the development pathway requires ongoing evaluation to assess and reassess the likelihood of the candidate vaccine to meet the desired prevention objectives. Furthermore, the NIAID reserves the right to determine, at any time during the contract period, that a particular candidate vaccine has not demonstrated sufficient potential to merit further investment by the NIAID in the development and evaluation of that candidate vaccine.

The NIAID, therefore, reserves the right to modify or delete milestones, decision points, research plans, schedule, or budget as need may arise. At designated milestones or decision points, the NIAID will evaluate whether work should be redirected, removed, or whether schedule or budget adjustments should be made. In any event, the NIAID reserves the right to change process, schedule, or event to add or delete part or all of these elements as need arises.

The NIAID is aware that no single organization or institution may have the expertise and facilities required to perform all parts of their Statement of Work. Therefore, it may be necessary for the Contractor to subcontract a portion of the work. In addition, the prime Contractor is not limited to a domestic institution or organization, and subcontracting to foreign organizations/institutions is permitted. The Contractor shall be responsible for ALL work performed under this contract including that performed by any subcontractor(s).

RESEARCH and TECHNICAL OBJECTIVES

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

The opening paragraph - "Independently, and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below. Specifically the Contractor shall --" should be followed by a full Statement of Work describing each step that the Contractor shall perform **after the award of the contract**, including: the tasks that will be performed to carry out the research project, how these tasks will be accomplished, and the time frame within which each task will be accomplished. Each step described in the Statement of Work will begin with the words "The Contractor shall...." Where appropriate, divide the Statement of Work into separate tasks and subtasks. An outline format should be used. Briefly describe the work related to each task and describe the tasks in the sequence in which they will be carried out. Section C, REPORTING REQUIREMENTS AND DELIVERABLES, should be completed by the Offeror. This section will provide a description of all items to be delivered to the Government during performance of the contract such as reports, work products, end products, and deliverables.

When preparing proposals in response to this BAA, Offerors must review the "Additional Technical Proposal Instructions" and Format for Technical Proposal" in Appendix A and the "Technical Evaluation Factors" included in this BAA for additional information.

This HIV Vaccine Design and Development Teams (hereinafter referred to as HIV Vaccine Teams) BAA solicitation seeks to fund consortia of scientists with product development experience from industry and/or academia who have (1) identified a promising novel, innovative preventive vaccine candidate for worldwide use, and (2) devised a comprehensive strategic product development and clinical testing plan for targeted development of the vaccine candidate into a product suitable for testing in humans. For purposes of this BAA, a vaccine product is defined to be a material and its manner of administration that could reasonably be expected to provide protection against HIV/AIDS. A vaccine concept includes both the antigens that the immune system encounters for the purpose of inducing protection against HIV or progression to AIDS and the method of delivery. Examples of antigens include virus-like particles, pseudo-virions, proteins and peptides, either delivered directly in the manner of a traditional vaccine composition or delivered as part of a vector system and expressed in the recipient and processed by the cellular machinery. These antigens may be delivered to the immune system in a number of ways, including mucosally. The delivery of these antigens to the immune system can be accomplished by DNA, vector approaches, or direct administration. In these examples, the antigen is the active part of the vaccine concept, while the DNA or vector(s) and route(s)/mechanisms of administration are the method of delivery. It is expected that the Offeror may propose to optimize the chosen delivery system(s), as well as the antigenic components of the vaccine concept. It is anticipated that optimization could include the development and methods of adjuvanting/administration of vaccine candidates to significantly enhance the breadth, intensity, persistence and/or site (e.g. mucosal vs. systemic) of the anti-HIV immune responses.

Concepts that focus on inducing broadly neutralizing antibodies are particularly encouraged. Concepts based on DNA plasmid, poxvirus-vectored, adenovirus-vectored and monomeric gp120-based vaccines are not encouraged. If one of these concepts is proposed, it must represent significant novelty compared to products that have been, are currently, or will soon be evaluated in clinical trials. On the other hand, the development of approaches for the generation of broadly reactive neutralizing antibodies remains a high priority.

It is a requirement of the contract that an HIV Vaccine Team advances the vaccine concept(s) along a well-defined development path in a timely manner to a vaccine product and into clinical testing by the beginning of the fifth year of the award period. Examples of support Offerors may request include funding for preclinical studies, manufacturing, supplies, equipment, other Investigational New Drug (IND)-enabling studies, and regulatory support. Offerors are strongly encouraged, but not required, to conduct Phase I and Phase I/II trials in collaboration with an NIAID/DAIDS-supported clinical trials network, such as the HIV/AIDS Vaccine Trials Network

(the HVTN; http://www.hvtn.org/) for preventive vaccines. In addition, after initiation of clinical trials, the Government may exercise the option to extend the contract for up to an additional two years to support further optimization and/or preclinical testing of the vaccine product.

Each HIV Vaccine Team shall be required to perform the following activities and provide the following resources:

A. Implement a Comprehensive Strategic Product Development and Clinical Testing Plan, with clearly defined goals and milestones, to advance the vaccine concept along a well-defined development path to a vaccine product suitable for testing in humans by the beginning of the fifth year of the contract award.
B. Develop a specific novel preventive vaccine concept into a product capable of being tested in a clinical trial.
C. Provide for the production of vaccine products under Good Manufacturing Practices (GMP).
D. Host a cGMP compliance audit within first two years of the base period of performance.
E. Design and implement one or more Phase I or Phase I/II clinical protocols, independently or in collaboration with a DAIDS-funded clinical trials network, by the beginning of the fifth year of the contract award period.
F. Provide a research, production and administrative team with the requisite expertise to perform the research and management activities of the contract.
G. Provide the requisite infrastructure, facilities, equipment, and other resources necessary for performing all phases of the contract.
H. Establish, in collaboration with NIAID/DAIDS, an Independent External Advisory Group to assist in the review of progress toward achieving defined goals and milestones.
I. Conduct annual site visit reviews for NIAID contract and program staff and the Independent External Advisory Group.
J. Provide a research plan for further optimization and/or preclinical testing of the candidate vaccine after clinical trials have been initiated.
K. Conduct further optimization and/or nonclinical testing of the candidate vaccine for a period of up to two years if the Government elects to exercise this option for continued research.

Additional information relevant to the Technical and Research Objectives of NIAID and the requirements of the contracts to be awarded under this solicitation is provided below.

A. COMPREHENSIVE STRATEGIC PRODUCT DEVELOPMENT AND CLINICAL TESTING PLAN

The Comprehensive Strategic Product Development and Clinical Testing Plan shall include:

1. key development objectives and milestones for vaccine product development;
2. a detailed work plan describing proposed time schedules for achieving contract objectives and milestones;
3. for each milestone, a description of the process for making decisions to proceed or not proceed (go/no-go), i.e., specific qualitative and quantitative criteria for advancement of vaccine molecules or constructs through each stage of preclinical product development, including decisions to proceed or not proceed vis a vis immunogenicity, safety, and manufacturability;
4. a detailed product development plan for advancing the proposed vaccine product into Phase I and/or Phase I/II clinical studies, including a conceptual framework, design, iterative evaluations, the experimental approach and methodology proposed, and proposed assays to detect immune responses;
5. a detailed advanced development plan for further optimization and/or preclinical testing of the vaccine product, including process development plans;
6. plans for quality control over the implementation and operation of the contract;
7. procedures to handle adverse experimental or production results, and integrate new scientific findings into the proposed goals and milestones;
8. a plan for sharing data developed under the contract with the scientific community.

B. PRECLINICAL RESEARCH AND DEVELOPMENT

Product development activities in this area include:

1. select and develop vaccine candidate
2. evaluate dose, route, and immunization schedule of the vaccine candidate in animal models
3. optimize the vaccine candidate for stability, antigen expression, and immunogenicity
4. develop, characterize, and qualify reagents and assays required for the clinical and nonclinical evaluation of the vaccine candidate.

C. PRODUCTION OF VACCINE PRODUCTS UNDER cGMP

The Contractor shall produce vaccine products under current Good Manufacturing Practices (cGMP, as defined in the U.S. Code of Federal Regulations – 21 CFR §211) and provide all the necessary support for obtaining the U.S. Government and ethics-related approvals to proceed.

GMP production of the vaccine candidate includes the following: (1) develop master and working cell banks under current GMP guidelines; (2) conduct process develop for the manufacture of cGMP product; (3) manufacture of non-cGMP and cGMP pilot lots of product in amounts sufficient to carry out required nonclinical and Phase I and Phase I/II clinical trials; (4) formulate final product; (5) prepare final product; and (6) conduct long-term stability studies of cGMP bulk and final product.

Prior to GMP manufacture, the Contractor shall provide to DAIDS aliquots of selected plasma/cell samples from preclinical animal immunogenicity studies for testing in DAIDS-sponsored laboratories, and aliquots of the candidate vaccine/vaccine product. The Contractor shall also provide up to 50 doses of the GMP-manufactured vaccine, as requested, for confirmatory testing in a laboratory designated by DAIDS.

D. DESIGN AND IMPLEMENTATION OF CLINICAL TRIALS

Conduct of Phase I and/or I/II Clinical Trials Requirement: As an essential element of vaccine development and refinement, the design and conduct of Phase I or I/II human clinical trials is required under this BAA. It is expected that vaccine product design and development are sufficiently advanced to plan for initiation of at least one Phase I or Phase I/II clinical trial of the newly developed candidate vaccine product by the beginning of project year five. Candidate vaccines shall not advance to GMP production for clinical trials until they meet the negotiated decision criteria as to when the vaccine concept is sufficiently advanced for human studies. NEITHER PHASE III CLINICAL TRIALS NOR PRODUCTION OF VACCINE PRODUCT FOR PHASE III CLINICAL TRIALS WILL BE FUNDED UNDER THIS SOLICITATION.

Clinical Trials Conducted Within DAIDS-Supported Clinical Trial Networks: The Contractor shall develop clinical protocols in conjunction with the appropriate DAIDS-sponsored clinical trial network and all such protocols shall be submitted by the Network for DAIDS review. In addition to the clinical protocol, the Contractor shall develop, in conjunction with the appropriate DAIDS-sponsored clinical trial network, a schedule for protocol finalization, implementation, completion and analysis of final study data.

Clinical Trials Conducted Independently: Contractors who elect to perform clinical trials independently, rather than through a DAIDS-supported clinical trials network, shall be required to:

1. Submit a protocol for each clinical trial for approval by the NIAID Prevention Science Review Committee (PSRC). Protocols must include: (1) a description of the vaccine product; (2) results of preclinical (IND-enabling) toxicology studies; (3) a description of the trial design, including definition of objectives, approaches and procedures for implementation; (4) the plan for participant recruitment, retention and follow-up; (5) the plan for data collection, quality control and management; (6) the data and safety monitoring plan; (7) the proposed plan for the analysis and interpretation of final study data; (9) a sample Informed Consent; and (10) plans for publication of results.

2. Obtain final NIAID and local Institutional Review Board (IRB) approval of the protocol prior to submission of an IND to the U.S. Food and Drug Administration (FDA) and other non-U.S. regulatory authorities and prior to participant enrollment.

3. Comply with NIAID Clinical Terms of Award (http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf).

4. Provide selected clinical trial data through the DAIDS Enterprise System (DAIDS-ES) which includes separate systems for adverse event reporting and protocol management. Reporting of adverse event shall be done through the DAIDS Expedited Adverse Event Reporting System (DAERS), and reporting on protocol development, registration, conduct, accrual, oversight and site monitoring, tracking and clinical trial closeout shall be done through the DAIDS Protocol management System. Contractors shall be required to interface, integrate, or adapt their information system(s) to interact with these and future components of the DAIDS-ES as necessary. To achieve compatibility, DAIDS and its contractors will implement applications or data exchange mechanisms using platform technology standards such as: Web Services, eXtensible Markup Language (XML), XML Schema Definitions (XSD), RDBMS, .NET Framework, UDDI, IIS, Internet Explorer, Service Oriented Architecture (SOA), Design Patterns, Frameworks and Templates as defined by the DAIDS-ES. DAIDS Contractors shall adhere to these guidelines and standards on a continual basis.

5. Provide plasma/sera and frozen peripheral blood mononuclear cell specimens, collected 2 weeks after the final immunization and one later time point to be determined, to an independent immune assessment laboratory designated by NIAID that supports the Global HIV/AIDS Vaccine Enterprise.

E. REGULATORY COMPLIANCE AND DATA MANAGEMENT

As required for the implementation of the Comprehensive Strategic Product Development and Clinical Testing Plan, the Contractor shall:

1. be responsible for the development and implementation of data management and quality control systems/procedures, including the transmission, storage, confidentiality and retrieval of all study data.
2. provide for the statistical design and analysis of data resulting from the research undertaken.
3. provide raw data or specific analyses of data generated with contract funding to the Project Officer.
4. ensure strict adherence to FDA regulations and guidance, including requirements for the conduct of animal studies and assays under GLP, the manufacturing of the vaccine candidate under cGMP, and the conduct of clinical trials under GCP standards. The Contractor shall maintain quality assurance documentation to support adherence in these areas.
5. arrange for independent audits, as needed or as requested by the Project Officer and as concurred by the Contracting Officer. Audits may be requested to ensure that Contractor and/or subcontractor facilities and all planned procedures comply with FDA regulations and guidance that are required to meet GLP, cGMP and GCP standards. In addition, the Contractor shall ensure that all Contractor and/or subcontractor records and staff are available for audits. The NIAID reserves the right to conduct independent audits of the Contractor and its subcontractors as needed to evaluate compliance with FDA regulations and guidance.

F. RESEARCH, PRODUCTION AND ADMINISTRATIVE TEAM

The Contractor shall provide all expertise needed for the development, optimization, preclinical and clinical testing, and production of an HIV/AIDS vaccine based on the vaccine concept selected. An HIV Vaccine Team must include strong scientific leadership, as well as significant experience in the management, design, and execution of large multi-faceted research and development programs focused on product development, manufacture, and testing.

G. FACILITIES, EQUIPMENT AND OTHER RESOURCES FOR PERFORMING ALL PHASES OF THE

CONTRACT

The Contractor shall provide the facilities, equipment and other resources for production of the awarded optimized vaccine concept under GMP conditions, performance of IND-enabling preclinical animal studies under Good Laboratory Practices (GLP; as defined in 21 CFR §58), and performance of clinical trials in humans under Good Clinical Practices (GCP; 21 CFR §312 and ICH Guidelines document E6) if clinical trials will be performed by the Contractor rather than by a DAIDS-supported clinical trials network.

H. INDEPENDENT EXTERNAL ADVISORY GROUP

Within 3 months of the effective date of the contract, the Contractor shall establish an Independent External Advisory Group to periodically review performance and progress based on negotiated objectives, product development activities and milestones. The membership of the Independent External Advisory Group shall be proposed by the Contractor and agreed to by the Project Officer.

I. ANNUAL SITE VISIT REVIEWS

At the middle (6-month mark) of each contract year, the Contractor shall plan and conduct a one full day site visit review for NIAID contract and program staff and the Independent External Advisory Group. The Principal Investigator (P.I.) and all senior Contractor and subcontractor staff shall attend these annual meetings. An update and summary of progress shall be presented, including: (1) summaries of all goals or milestones reached during the review period and interim and final results generated on each component of the product development activities; (2) a description of all problems encountered that will impact the achievement of particular goals and milestones as outlined in the Contractor's Comprehensive Strategic Research Plan, and proposed approaches to overcoming problems encountered; (3) goals, milestones and development objectives for the coming year, including any proposed modifications in project activities, objectives and milestones. Additionally, application of the policies and procedures for monitoring the direction of specific projects shall be presented. For Contractors with foreign subcontracts, this annual site visit shall also report details on approvals for manufacturing, preclinical or clinical testing that have been obtained from both the U.S. and foreign governments.

J. PROJECT MANAGEMENT

The Contractor shall provide for:

1. Overall Project Management
    a. The overall management, integration and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, direction and completion of all contract activities.
    b. Effective communication with the Project Officer and the Contracting Officer.
    c. A PI with responsibility for overall project management and reporting on project status and progress, and for recommending modification to project requirements and timelines, including projects undertaken by subcontractors.
    d. A Project Manager with responsibility for monitoring and tracking day-to-day progress and timelines, coordinating communication, project activities and costs incurred.
    e. The implementation of plans to protect and share confidential information with the Independent External Advisory Group.

2. Intellectual Property
    a. The Contractor shall be solely responsible for the timely acquisition of all appropriate proprietary rights, including intellectual property rights, and all materials needed to perform the project. Before, during and subsequent to the award, the U.S. Government is not required to obtain for the Contractor any proprietary rights, including intellectual property rights or any materials needed by the Contractor to perform the project. The Contractor is required to report to the U.S. Government all inventions made in the performance of the project, as specified in FAR 52.227.11 (Bayh-Dole Act).

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

3. Reports and Deliverables
The Contractor shall prepare and provide all reports and deliverables listed in the "Reporting Requirements and Deliverables" section of this BAA as they relate to the Contractor's specific Statement of Work. The reports and deliverables will be agreed upon by the Government and the Contractor during negotiations.

[END OF RESEARCH AND TECHNICAL OBJECTIVES FOR BASE PERIOD]

K. OPTION

In cases where the results from preclinical non-human primate challenge and immunogenicity studies are highly promising for significantly unique/improved vaccine candidates, the Government reserves the right to exercise the option to extend the contract for a period of up to two years to support continued optimization and/or preclinical testing of the vaccine product after clinical trials have been initiated. If this option is exercised, the Contractor shall:

1. Not later than 6 months prior to the expiration date of the contract, provide to the Project Officer a detailed Advanced Product Development Plan for further optimization and/or preclinical testing of the vaccine product. This Plan shall include: (i) proposed approaches/methodologies to scale-up process development and/or improve vaccine formulations (e.g., stability, storage, lypholization, etc.); (ii) milestones for each stage of advanced product development; (iii) a timeline for the initiation, conduct and completion of each milestone; and (iv) a proposed budget by milestone. Revise the Plan as necessary based on Project Officer comments.

2. Implement the approved Advanced Product Development Plan and provide the Contracting Officer and Project Officer a final report detailing study results.

ATTACHMENT 4
REPORTING REQUIREMENTS AND DELIVERABLES
HIV Vaccine Design and Development Teams
NIH-NIAID-DAIDS-BAA-08-16

A. Technical Reports

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

1. A cover page identifying the contract, Contractor, addressee, and date of submission
2. Section A – an introduction covering the purpose and scope of the contract

1. Semiannual Progress Report

The Semiannual Progress Report shall include:

Section B - A description of overall progress plus a separate description of each task or other logical segment of work on which effort was expended during the reporting period. The description shall include pertinent data and/or figures in sufficient detail to explain any significant results from analysis and scientific evaluation of data accumulated to date under the project. Special emphasis shall be placed on goals or milestones that were reached, or problems that were encountered that prevented reaching a scheduled goal or milestone, and how those problems were/will be addressed. In addition, requests and approvals to conduct human trials, and Inclusion Enrollment Report, when appropriate, shall be included.

Section C – A summary of the proposed goals and milestones for the duration of the contract, including any proposed revisions based on results generated to date. For the goals and milestones expected to be completed during the next 12 months, provide a detailed description of the criteria to be used to define their accomplishment.

The initial report will be submitted for the first full six months of the contract performance period, including any fractional part of the initial month. Thereafter, the reporting period shall consist of six full calendar months. Semiannual Progress Reports shall not be submitted when an Annual Report is due.

2. Annual Progress Report

The Annual Progress Report shall include:

Section B - A description of overall progress plus a separate description of each task or other logical segment of work on which effort was expended during the reporting period. The description shall include pertinent data and/or figures in sufficient detail to explain any significant results from analysis and scientific evaluation of data accumulated to date under the project. Special emphasis shall be placed on goals or milestones that were reached, or problems that were encountered that prevented reaching a scheduled goal or milestone, and how those problems were/will be addressed. In addition, requests and approvals to conduct human trials, and Inclusion Enrollment Report, when appropriate, shall be included.

Section C – A summary of the proposed goals and milestones for the duration of the contract, including any proposed revisions based on results generated to date. For the goals and milestones expected to be completed during the next 12 months, provide a detailed description of the criteria to be used to define their accomplishment.

An Annual Report will not be required for the period when the Final Report is due.

3. Annual Technical Progress Report for Clinical Research Study Populations

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. The Contractor shall submit this information in the format indicated in the attachment entitled, "Inclusion Enrollment Report," which is set forth in Section J of the contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the Final Report. The Contractor shall submit the report in accordance with ARTICLE F.1. DELIVERIES of the contract. In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October 2001 applies. 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.

Human Subject Enrollment Reports for non-NIAID network clinical trials. To aid NIAID in fulfilling reporting requirements, the Contractor must complete the Inclusion Enrollment Report showing cumulative accrual information for each active clinical trial protocol. The format for the Inclusion Enrollment Report may be found at http://grants.nih.gov/grants/funding/phs398/enrollmentreport.pdf

4. Final Report

This report shall consist of the work performed and results obtained for the entire contract period of performance as stated in Section F of this contract. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted on or before the last day of the contract performance period.

Specifically, the Final Report shall include:

Section B – A detailed summary of the results of the entire contract work for the complete performance period, inclusive of the summary of the initial research plan and all of the products tested, including those that failed to meet the “Go” criteria, and a discussion of the failures. The report shall include specifications of the optimized AIDS vaccine product developed during the course of the contract. These specifications shall include: (1) the identity of the vaccine strain or strains in the final product, (2) a detailed description of the manipulations used in the vaccine design, (3) a detailed description of all processes used to expand, attenuate, inactivate, or purify the final vaccine product, (4) a detailed description of any adjuvants or other potentiating agents used in the delivery of the final optimized product, (5) a detailed description of the suggested immunization schedule to be used for optimal reactivity in humans, (6) evidence that the vaccine product can be manufactured under GMP conditions for use in human vaccine trials, (7) a list of all patent filings that have resulted from this contract, and (8) data from clinical trials using the vaccine. In addition, the Contractor shall indicate whether INDs were filed in relation to vaccine products developed during the course of the contract, and provide a description of the IND and the results of the filings. For Contractors requiring any foreign approvals for manufacturing and testing, this report shall include details concerning approvals for manufacturing or testing that have been obtained for or by the foreign subcontractors.

5. Summary of Salient Results

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

B. Technical Reports Delivery Schedule

Satisfactory performance of the contract is defined as satisfactorily performing the statement of work and delivering the following items.

Item	Type of Report	Initial Report Due	Recipient & Number of Hard & Electronic Copies	Subsequent Reports Due
1.	Semiannual Progress Report	6 months after Effective Date of Contract (EDOC)	1 electronic, 2 hard to PO 1 hard to CO	Semiannually after 6 full calendar months. A Semiannual Progress Report shall not be submitted when an Annual Progress Report is due.
2.	Annual Progress Report	12 months after Effective Date of Contract (EDOC)	1 electronic, 2 hard to PO 1 hard to CO	Annually; due on/before 15th day after the anniversary date. An Annual Progress Report is not due when the Final Report is due.
3.	Annual Technical Progress Report for Clinical Research Study Populations	Anniversary date of contract	1 electronic, 2 hard to PO 1 hard to CO	After commencement of clinical trial recruitment; due 30 days after the anniversary date. An Annual Technical Progress Report for Clinical Research Study Populations is not due when a Final Report is due.
4.	Final Report	Due prior to completion date of the contract	1 electronic, 2 hard to PO 1 hard to CO	Due prior to completion date of the contract.
5.	Summary of Salient Results	Due with Final Report	1 electronic, 2 hard to PO 1 hard to CO	Summary of salient results (not to exceed 200 words) achieved during the performance of the contract due with the Final Report.

C. Other Reports

In addition to the reporting, which has been described herein, the following additional reports shall be delivered to the Government during performance of the contract.

1. Goals and Milestones Achievement Reports

To facilitate the monitoring of contract progress, milestones, and their expected accomplishment dates, will be re-established annually by discussion and agreement between the Project Officer and the PI; these milestones will not be written into the Contract document. The Contractor shall submit Goals and Milestones Achievement Reports for these milestones during the contract period as specified by consultation with the Project Officer. For for-profit Contractors, since the payment of contract fee portions will be tied to the accomplishment of predetermined goals and fee-based milestones specified in the contract, the Contractor shall submit similar Goals and Milestones Achievement Reports for fee-attached milestones prior to invoicing for fee payments. Some management milestones may also be fee-based and, in that case, only one report will be required to cover both. The original hard copy of each milestone achievement report shall be submitted to the NIAID Contracting Officer, and three (3) copies (two hard copies and one electronic copy) to the DAIDS Project Officer. Each report must consist of:

1. A cover page identifying the contract, Contractor, addressee, date of submission, and milestone

2. Reports shall include at a minimum:

   Section A – An introduction describing the goal or milestone in detail

   Section B – A complete description of the results. The description shall include pertinent data and/or figures in sufficient detail to explain any significant results from analysis and scientific evaluation of data

accumulated to date under the goal or milestone. When appropriate, this report should detail specific requests and approvals for the conduct of human trials.

2. Annual Site Visit Review Report

A report of the annual site visit review shall be prepared by the Contractor within three weeks following the date of the site visit. This report shall include copies of slide presentations, as well as summaries of all discussions of modifications to goals or milestones, and discussions of approaches to overcoming problems encountered.

3. DAIDS-Enterprise System (DAIDS-ES) Reports

Contractors who elect to perform clinical studies independently, rather than through a DAIDS-supported clinical trials network, will be required to provide clinical trials data through the DAIDS-ES as the appropriate components of the system become operational. Reporting of adverse events will be done through the DAIDS Expedited Adverse Event Reporting System (DAERS). Reporting on protocol development, registration, conduct, accrual, oversight, site monitoring, tracking and clinical trial closeout will be done through the DAIDS Protocol Management System. Details on interfacing with these information management systems will be provided as the systems become operational.

D. Other Reports Delivery Schedule

Item	Type of Report	Initial Report Due	Recipient & Number of Hard & Electronic Copies	Subsequent Reports Due
1.	Goals and Milestones Achievement Reports	Specific dates will be negotiated with the PO	1 electronic, 2 hard to PO 1 hard to CO	Specific dates will be negotiated with the PO
2.	Annual Site Visit Review Report	Within 3 weeks following the date of the site visit	1 electronic, 2 hard to PO 1 hard to CO	Due within three weeks after the site visit date
3.	DAIDS-Enterprise System Reports	On an ongoing basis as directed by the PO	1 electronic, 2 hard to PO	NA

If the Contractor is unable to deliver the reports specified here within the established due dates 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 written notice of anticipated delays with reasons therefore. A new delivery date must be established.

E. ARTICLE F. 1. DELIVERIES

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

The items specified below will be required to be delivered F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of the contract.

The Contractor, at the request of the Project Officer, shall deliver to the Government or its designee the following items:

1. Aliquots of selected plasma/cell samples from preclinical animal immunogenicity studies of candidate HIV/AIDS vaccines prior to GMP manufacture for testing in DAIDS-sponsored laboratories.

2. Aliquots of HIV/AIDS candidate vaccine and vaccine products prior to commencement of GMP manufacture.
3. Up to 50 doses of each GMP-manufactured vaccine for confirmatory testing in a DAIDS designated laboratory.
4. All regulatory support for the CMC section of the IND and/or access to cross-reference the Biological Master File (BMF) in an IND application.
5. Quality assurance and quality control plans.
6. For Contractors performing clinical trials independently, the clinical trial protocol(s) and aliquots of plasma/sera and frozen peripheral blood mononuclear cell specimens collected 2 weeks after the final immunization and at one later time point to be determined.
7. All data collected and/or analyzed throughout the contract period, including computer programs supporting it.

F. Schedule for Deliverables

Offeror: Provide a description of all items to be delivered to the Government during performance of the contract, include all work product, end products, and deliverables.

Item	Type of Deliverable	Research & Technical Objectives Reference	Due	Recipient
1.	Aliquots of selected plasma/cell samples from preclinical animal immunogenicity studies of candidate HIV/AIDS vaccines	Item C	As requested, prior to GMP manufacture	PO Designee
2.	Aliquots of HIV/AIDS candidate vaccine and vaccine products	Item C	As requested, prior to GMP manufacture	PO Designee
3.	Up to 50 doses of each GMP-manufactured vaccine	Item C	As requested, after GMP manufacture	PO Designee
4.	All regulatory support for the CMC section of the IND and/or access to cross-reference the Biological Master File (BMF) in an IND application	Item C	Provide as necessary	PO
5.	Quality assurance and quality control plans	Item 1	Before GMP manufacturing	PO
6.	Clinical Trial Protocol(s)	Item D	As required by the PO	PO
7.	Aliquots of plasma/sera and frozen peripheral blood mononuclear cell specimens collected 2 weeks after the final immunization and at one later time point to be determined (requirement if testing in independent clinical trials)	Item D	Provide as requested	DAIDS-designated immunology laboratory
8.	All data collected and/or analyzed during the contract period, including supporting computer programs	All relevant items	At contract completion (upon request by the PO)	PO

G. Copies of reports shall be sent to the following addresses:

NIAID Project Officer:	National Institutes of Health, DHHS National Institute of Allergy and Infectious Diseases Division of AIDS, VRP 6700-B Rockledge Drive, Room 5136, MSC 7628 Bethesda, MD 20892-7628 (email address provided at contract award)
NIAID Contracting Officer:	National Institutes of Health, DHHS National Institute of Allergy and Infectious Diseases Division of Extramural Activities, OA 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612 (email address provided at contract award)

ATTACHMENT 5
ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS and FORMAT FOR TECHNICAL PROPOSAL
HIV Vaccine Design and Development Teams
BAA NIH-NIAID-DAIDS-BAA-08-16

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

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

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

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

Offerors are reminded that the total page limitation for the entire technical proposal is **200** page including all appendices and attachments. Any pages in excess of this limit will be expunged from the proposal and will not be considered in the technical review.
Proposals shall NOT include links to Internet Web site addresses (URLs) or otherwise direct readers to alternate sources of information.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1:

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

SECTION 2: TECHNICAL PROPOSAL OVERVIEW (maximum 3 pages)

Provide a brief description of the proposed project, including:

a) A 1-2 sentence summary describing the vaccine concept the Offeror is proposing to advance.
b) A summary describing the scope of product development activities proposed.
c) A description of the activities to be performed by the Offeror and those that shall be provided by any proposed subcontractor, including identification of the proposed subcontractors and a list of key personnel of the Offeror and the proposed subcontractor with degrees and titles.

d) A brief description of the facilities and other resources to be made available by the Offeror and any proposed subcontractors.
e) The period of contract funding requested and the proposed budget for each year in both direct and total costs.

SECTION 3: SCIENTIFIC RATIONALE AND TECHNICAL APPROACH

A. SCIENTIFIC RATIONALE FOR THE DEVELOPMENT OF THE VACCINE CONCEPT

The Technical Proposal shall provide the following with respect to the vaccine concept proposed for development:

1. Justification to warrant the extensive effort of optimization, production and testing of the proposed vaccine concept(s), including the scientific rationale for: why the vaccine concept is particularly suited for use as a preventive vaccine; the selection of specific antigens [sequences or epitopes] and novel delivery vehicles relative to the proposed clinical trial population; the rationale and criteria proposed to advance the candidate vaccine concept through the product development/product production process and into human trials; and how the proposed vaccine concept will be developed into a product suitable for worldwide use, including large-scale manufacture and widespread acceptance of the proposed product.
2. Identification and discussion of anticipated scientific and technical obstacles and approaches surrounding them.
3. Identification and discussion of safety and regulatory issues as they relate to the testing of the proposed vaccine in relevant trial populations.
4. Relevant information from vaccines for other infectious diseases or previously tested candidate AIDS vaccines. For those concepts where there is a paucity of supporting *in vivo* or *in vitro* data, provide other justification, such as positive data from the use of the concept in vaccines for other diseases. In these cases, provision of information concerning similarity of these diseases to AIDS, or information on correlates of immunity, effectiveness, and breadth of protection induced by these vaccines, is of paramount importance.

B. COMPREHENSIVE STRATEGIC PRODUCT DEVELOPMENT AND CLINICAL TESTING PLAN (Research and Technical Objectives Item A)

The Technical Proposal shall provide a proposed Comprehensive Strategic Product Development and Clinical Testing Plan, including the following:

1. key objectives and milestones for vaccine product development and clinical testing. If the proposed vaccine concept is for a mixed modality vaccine, or if an iterative design will result in multiple Phase I and/or Phase II clinical trials, a separate set of milestones should be submitted for each component or trial. The progress of the HIV Vaccine Teams will be determined by the completion of the negotiated goals and milestones according to the negotiated schedule.
2. a detailed work plan describing proposed time schedules for achieving contract objectives and milestones
3. for each milestone, a description of the process for making decisions to proceed or not proceed (go/no-go), i.e., specific qualitative and quantitative criteria for advancement of vaccines molecules or constructs through each stage of preclinical product development, including decisions to proceed or not proceed vis a vis immunogenicity, safety and manufacturability.
4. a detailed plan for advancing the proposed vaccine product into clinical trials, including a conceptual framework, design, iterative evaluations, the experimental approach and methodology proposed, and proposed assays to detect immune responses.
5. plans for quality control over the implementation and operation of the contract and Clinical Testing Plan.
6. procedures to handle adverse experimental or production results, and integrate new scientific findings into the proposed goals and milestones.
7. a plan for sharing data developed under the contract with the scientific community.

Identify appropriate milestones and time schedules for vaccine product development, setting qualitative and quantitative criteria for determining milestone accomplishment. Examples of milestones include the following:

1) Synthesis of vaccine candidate
2) Immunogenicity testing of vaccine candidate
3) Selection of vaccine candidate/Decision to Start GMP Production Process Development
4) Preparation/Submission of CBER pre-IND meeting materials
5) Contact NIAID/DAIDS-supported Clinical Trials Network for approval of Phase I Clinical Trial Concept
6) Completion of GMP Process Development and Production of GMP Pilot Lots
7) Development of Phase I Protocol with NIAID/DAIDS-supported Clinical Trials Network
8) Pre-IND Meeting
9) Initiation of IND enabling Studies
    (a) Immunogenicity
    (b) Toxicology
    (c) Other
10) Completion of IND-enabling Studies
11) DMF/IND Filing
12) Phase I Clinical Trial Initiation
13) Phase I Clinical Trial Completion
14) Evaluation of Safety and Immunogenicity Data from Phase I Clinical Trial

The Technical Proposal shall also include a Technical Proposal Cost Information (5-year) Summary [see Section J, List of Attachments, Attachment 11]. List all subcontracts by task (e.g., GMP manufacture, IND-enabling toxicologic studies, formulation and fill, etc.). Identify within the budget the costs for the above functions if not performed by subcontract. Do not include indirect costs, G&A costs, and fee information in the Technical Proposal Cost Summary.

C. PRECLINICAL RESEARCH AND DEVELOPMENT (Research & Technical Objectives Item B)

Describe proposed plans for preclinical research and development activities, including: selection and development of vaccine candidate; evaluation of dose, route and immunization schedule of the vaccine candidate in animal models; optimization of the vaccine candidate for stability, antigen expression, and immunogenicity; and development, characterization, and qualification of reagents and assays required for the clinical and nonclinical evaluation of the vaccine candidate.

D. PRODUCTION OF VACCINE PRODUCTS UNDER GOOD MANUFACTURING PRACTICES (Research and Technical Objectives Item C)

Provide a plan for the production of vaccine products under Good Manufacturing Practices (GMP). In order to focus the description of GMP manufacture of your vaccine candidate(s) and facilitate review, consider in your Technical Proposal all of the appropriate items in the following list of generic issues to be addressed for biopharmaceutical production candidates:

1. Provide a comparison of your concept/construct with closely related concepts/constructs in use or under development (e.g. other poxvirus vectors if you are developing a poxvirus vector; other DNA vaccines if you are developing a DNA vaccine, etc.). Describe how your product expected to perform differently and/or better (immunogenicity, safety, manufacture capability).

2. Provide details of your construct including starting materials (e.g. plasmids, relevant vector maps, detailed vector construction scheme, cell substrates and their derivation history, etc.).

3. If a recombinant construct is proposed, does the construct contain an antibiotic-resistance gene or other selectable marker? If so, indicate which one. Are alternative methods of selection available? If so, these methods are to be described.

4. If the candidate is a vectored vaccine, is the vector replication-competent or replication-defective? For replication-selective vectors, describe the molecular basis of the selectivity and the conditions under which

the vector would replicate. Does your vector have an altered cell tropism? Describe. Discuss the impact of pre-existing immunity to the vector on the vaccine.

5. Do you have data evaluating the genetic stability of the recombinant vector? Have you established mutation rates and/or rates of reversion to either wild type or alternate viral genomes? If so, these data are to be provided in the Technical Proposal.

6. Do you have data evaluating the potential for genetic recombination with other organisms in the patient or in the environment? Describe.

7. Is the organism currently being grown in a qualified cGMP cell line? If not, is there a qualified cell line available for propagation of this vector? Was the cell line genetically modified to support this vector? If so, describe the details of its construction and any information you have regarding the stability of the genetic alteration in the cell line. What other expression systems have been tried for the product?

8. Delineate any issues with the cell line or viral seed with regard to BSE. Is there clear documentation of all serum exposure subsequent to 1980? If not, has a risk assessment been performed?

9. Provide details of your production method.

10. Indicate whether this material ever been produced for laboratory or clinical studies using this production system.

11. Has this material ever been produced in a related or other production system? If so, provide the details.

12. Provide details of your purification methods. Virus inactivation or elimination from products produced in mammalian cell lines may involve treatment with acid, detergent, or filtration. Provide information, if available, about the stability of your product(s) in these conditions.

13. What is the average yield of your production system before and after purification? What is the largest amount of material that you have produced in your laboratory in a single production batch? What is the largest amount that you have purified in a single batch? Provide average ratios obtained by this production method for virus particle/infectious unit and/or infectious units/cell.

14. Are there concerns about the physical properties (e.g. folding, soluble or secreted form, dimerization) and stability of your product? If so, describe.

15. Do you have reproducible assays for your product? Describe the following assays for evaluating your material, if available:

    a. Identity
    b. Purity
    c. Safety
    d. Potency (Immunologic)

16. Do you have a proposed list of release criteria for your product? If so, provide the information.

17. What is the largest single dose expected to be used in clinical trials? Indicate the doses, routes and schedules of inoculations to be used in planned clinical trials.

18. In what form (lyophilized, formulated product, etc.) and fill size will the final product be? What is the desired final product formulation?

19. Are there issues of formulation and vialing that must be resolved? If so, describe.

20. What is known about the stability of your product with respect to physical integrity and activity? Have you performed stability studies, and if so what were the results?

21. Are there any safety issues connected with the production, purification, and/or handling of your product? If so, describe.

22. Do applicable Material Transfer Agreements permit clinical trials with your product(s)?

23. Have you had or are you preparing to have any meeting with regulatory agencies, such as a pre-IND meeting with the U.S. FDA or a presentation to the NIH Recombinant DNA Advisory Committee (RAC)? If so, indicate the type of meeting, the regulatory agency, and the date or proposed date.

24. If you have had a pre-IND or RAC meeting, were any issues concerning manufacturing, safety, or stability raised by the FDA that will have an impact on producing your product? If so, describe.

E. DESIGN AND IMPLEMENTATION OF CLINICAL TRIALS (Research and Technical Objectives Item D)

Clinical Trials to be Conducted within DAIDS-supported Clinical Trial Networks:

Offerors proposing to collaborate with a DAIDS-sponsored Clinical Trials Network to perform Phase I and/or Phase I/II clinical trials with the proposed vaccine product must include a clear statement of their intent to collaborate with an appropriate DAIDS-sponsored Clinical Trials Network and a synopsis of the proposed protocol(s), including: primary and secondary objectives, trial design, immunogenic/virologic assays to be performed, requisite qualifications of the clinical trial director, and time schedule for protocol development, implementation, completion and analysis of final study data.

Clinical Trials to be Conducted Independently:

Offerors proposing to design and conduct Phase I and/or Phase I/II clinical trials independently must include in the Technical Proposal:

1. a protocol for each proposed clinical trial, including: (i) a description of the vaccine product; (ii) results of preclinical (IND-enabling) toxicology studies; (iii) a description of the trial design, including definition of objectives, approaches and procedures for implementation; (iv) the plan for participant recruitment, retention and follow-up; (v) the plan for data collection, quality control and management; (vi) the plan for data and safety monitoring and reporting; (vii) the plan for the analysis and interpretation of final study data; (viii) a sample Informed Consent; (ix) the proposed timeline for protocol development, approval, implementation, completion and analysis of final study data; and (x) plans for publication of results.
2. the name(s) of the individual(s), organization(s), and site(s) that will perform the clinical trial(s), documentation of their willingness to participate, and a description of the capabilities of all proposed participating organizations, sites, clinical investigators and other clinical staff with respect to the conduct of the proposed clinical trial(s).
3. a discussion of human subjects protection issues, including justification of potential benefits to subjects and/or society vs. risks to subjects and the adequacy of protection against risks including informed consent measures. Copies of the Department of Health and Human Services (DHHS) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protections (OHRP), Office of the Secretary (OS), DHHS – (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm).
4. representation of women, minorities and children, including justification for any exclusion. The NIH guidelines for inclusion of women and minorities, and for inclusion of children as subjects in clinical research are available at http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm and at http://grants.nih.gov/grants/guide/notice-files/not98-024.html, respectively.
5. plans for interfacing with or adapting information systems to interact with the DAIDS Enterprise System (DAIDS-ES), including the DAIDS Expedited Adverse Event Reporting System and the DAIDS Protocol Management System, as well as future components of the DAIDS-ES as they are developed and become operational.

Clinical Trials Involving Non-U.S. Clinical Trial Sites:

Clinical trials at international sites are encouraged for preventive vaccines. For international clinical trials to be performed independently of a DAIDS-supported clinical trial network, the Offeror must include a plan that details how the HIV Vaccine Team will satisfy human research subject protection concerns, as expressed by the DHHS OHRP at: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm in accordance with the norms and standards governing such studies performed using U.S. Government funds. In addition, if international sites are proposed for clinical trials, the Offeror must describe how necessary approvals from the foreign government(s) to conduct the studies will be obtained.

E. INDEPENDENT EXTERNAL ADVISORY GROUP (Research and Technical Objectives Item H)

DO NOT NAME MEMBERS OF THE EXTERNAL ADVISORY GROUP IN THE TECHNICAL PROPOSAL.

F. OFFEROR'S PROPOSED STATEMENT OF WORK (not to exceed 15 single-spaced pages)

The Technical Proposal shall include the Offeror's proposed Statement of Work, written in outline format, to delineate the activities to be carried out during the contract base period of performance. Each activity described in the Statement of Work will begin with the words "The Contractor shall…" and should address all the scientific and technical requirements described in the Research and Technical Objectives section of the BAA.

The Offeror's proposed Statement of Work should begin as follows:

"Independently, and not as an agent of the U.S. Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, as needed to provide the services delineated in the negotiated Statement of Work. The Contractor shall carry out activities within the contract's Statement of Work only as requested and approved by the Project Officer, and may not conduct work on the contract without prior approval from the Project Officer. Approval to carry out specific activities will be linked to approval by the Project Officer of the Comprehensive Strategic Product Development and Clinical Testing Plan following contract award, approval of Semiannual and Annual Progress Reports, and review and approval of a Clinical Trial Protocol(s)/synopsis and supporting materials.

The Contractor acknowledges the Government's right to modify the milestones, progress, schedule, budget, or product to add or delete products, process, or schedule as need may arise. Because of the nature of this contract and complexities inherent in this and prior programs, at designated milestones the government will evaluate whether work should be redirected, removed, or whether schedule or budget adjustments should be made. Further, the Government reserves the right to change product, process, schedule, or event to add or delete part or all of these elements as need arises."

G. OPTION (Research and Technical Objectives Item K)

The Technical Proposal shall provide a discussion of how the Offeror proposes to plan for and implement the option for up to two years of additional support for further optimization and/or preclinical testing of the vaccine product. This includes: (i) a description of the rationale for conducting further optimization and/or preclinical testing; (ii) the anticipated additional studies required; (iii) proposed approaches/methodologies to scale-up process development and/or improve vaccine formulations; (iv) facilities, equipment and other resources to be made available; and (v) projected timeline for the completion of proposed work to be carried out under the option.

SECTION 4: SCIENTIFIC AND TECHNICAL PERSONNEL (Research and Technical Objectives Item F)

The Technical Proposal must describe in detail the responsibilities and level of effort of all proposed scientific and technical personnel who will be assigned to the contract, including all proposed subcontractors. The Technical Proposal shall also provide documentation of the education, training, qualifications, knowledge, experience,

competence, and availability of the PI, as well as all other proposed scientific and technical personnel. Limit CVs to 2-3 single-spaced pages, provide references to publications relevant to the scope of work to be carried out under the contract, and describe previous experience, limited to the past 5 years, with projects of similar size and complexity.

a. *Principal Investigator* (PI): Documentation of experience and qualifications with respect to the following:

(1) preclinical research for the development of vaccine products/candidates
(2) clinical trials to evaluate vaccine candidates, including compliance with regulatory requirements and guidelines
(3) manufacturing of vaccine products for evaluation in preclinical studies and in clinical trials
(4) leadership for planning and directing vaccine product development projects

If the Offeror elects to have both a scientific and a management leader, the Technical Proposal must also include documentation of the training, experience, and leadership qualifications of the management expert. In addition, the level of effort required on the part of the PI and key scientific and technical personnel will make it difficult for most Offerors to effectively manage/staff two or more concurrent HIV Vaccine Team contracts. Therefore, any current HIV Vaccine Team PI responding to this solicitation must clearly demonstrate the capacity to manage/staff more than one HIV Vaccine Team contract award.

b. *Other Scientific and Technical Personnel*: Documentation of the experience and qualifications of other scientific and technical personnel with respect to the following contract requirements:

(1) design, conduct and analysis of preclininal studies to evaluate vaccine products
(2) production of vaccine products under GMP
(3) design, conduct and analysis of clinical trials of vaccine products, including statistical design, safety monitoring, regulatory compliance, and data management and quality control for clinical trials proposed to be conducted independently of an existing DAIDS-supported Clinical Trials Network

SECTION 5: FACILITIES, EQUIPMENT AND OTHER RESOURCES (Research and Technical Objectives Item G)

The Technical Proposal must:

a. Document the availability and adequacy of facilities, equipment, and other resources necessary for performance of the contract, including:

(1) Location and features of facilities including a floor plan and a list of equipment and resources dedicated to the project for the prime contractor and any proposed subcontractors.
(2) Information regarding ownership/lease of facilities, including demonstrated availability for the duration of the contract.
(3) Plans and procedures to be utilized for compliance with all safety guidelines and regulations, including training and monitoring of personnel for exposure to infectious and other hazardous materials.
(4) Plans for obtaining, adding or deleting facilities as necessary due to progress during the course of product development.

b. Document the availability of appropriate facilities for performing assays and animal studies under GLP standards, production of vaccine material under GMP guidelines, and performance of clinical trials following GCP guidance for offerors proposing to conduct clinical trials independently.
c. Describe provisions for complying with NIH guidelines for the housing and humane care and use of laboratory animals.
d. Describe provisions for ensuring safe facilities and resources and for conducting work in accordance with biosafety guidelines.
e. Identify and describe ALL support resources (including Information Technology systems) which will be required to effectively complete the SOW.

SECTION 6: PROJECT MANAGEMENT (Research and Technical Objectives Item J)

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

a. Describe how the project will be staffed, organized and managed, including a detailed description of the responsibilities and level of effort of all proposed personnel who will be assigned to the contract, and an administrative framework indicating clear lines of authority and responsibility for all personnel including proposed subcontractors and consultants. Provide details to substantiate the feasibility and adequacy of proposed plans for managing the research activities to ensure a cooperative, integrated and focused scientific effort.
b. Describe project management systems that will be used to track activities and to keep multiple activities on time and budget.
c. Outline how the PI will communicate with the Project Officer and Contracting Officer and how the PI will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).
d. Provide a plan for soliciting, evaluating, negotiating, awarding and managing subcontracts in accordance with FAR Clause 52.244.2.
e. Describe experience and education of contract management staff in the acquisition and management of subcontracts under Federal contracts.
f. Describe experience with identification and remediation of subcontractor performance problems or noncompliance with subcontract terms and conditions.
g. Provide a plan to protect and share confidential information with the Independent External Advisory Group.
h. Provide a plan to organize the Annual Review Meetings and provide for a thorough assessment of contract status, progress, problems and approaches to their resolution, and future plans.

SECTION 7: TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

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

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

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

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

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

V) Biohazard Safety
The Technical Proposal should include a plan for biohazard safety and security requirements.

VI) Information Technology (IT) Systems Security

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

ATTACHMENT 6
ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS
HIV Vaccine Design and Development Teams
NIH-NIAID-DAIDS-BAA-08-16

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

Offerors are advised to give careful consideration to the Broad Agency Announcement Description, Background and Introduction, Research and Technical Objectives, all reference material provided as attachments, the technical evaluation criteria, and, the BAA as a whole, in the development of your proposal. The information requested in these instructions should be used as a guide for the development and formatting of your Business Proposal. Offerors should consider and include the information requested here, as well as **any other** information which will benefit the proposal.

BUSINESS PROPOSAL – TABLE OF CONTENTS

SECTION 1 – PROPOSAL COVERSHEET (use form NIH 2043 identified in Section J)

SECTION 2 – COST OR PRICE SUPPORT

Section L of the BAA specifies the minimum documentation requirements for cost data and all cost related support. All related documentation should be included in the proposal in a clearly marked section.

SECTION 3 – UNIFORM COST ASSUMPTIONS

1) Technical Cost Assumptions
The NIAID estimates the average total annual cost (direct and indirect cost combined) for these contracts to be a maximum of $4 million per base-year of the contract. For the option in years 6 and 7, Offerors must provide a budget proposal not to exceed $1 million dollars per year in total costs (including direct and indirect costs).

2) Travel

a) Offerors should include a uniform assumption of 3 trips to scientific meetings per year, for 4 days, for 3 persons.

b) Travel for activities related to Project Management is allowed.

c) The Offeror is expected to host 1 annual site visit per contract year; the budget should reflect the cost for hosting the meeting and travel for the members of the Independent External Advisory Group. Travel costs for Government employees will be reimbursed from Government funds and should not be included in Offeror's budget proposals.

3) Other

The Offeror is required to host a cGMP compliance audit within the first two years of the base period of performance.

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

1) Small Business Subcontracting Plan
Section L of the RFP specifies the minimum documentation requirements for completing a subcontracting plan. This plan should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

2) Extent of Small Disadvantaged Business Participation
Section L of the RFP specifies the minimum documentation requirements for small disadvantaged business utilization. This information should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

Attachment 7
DAIDS Enterprise System (DAIDS-ES)
HIV Vaccine Design and Development Teams
BAA NIH-NIAID-DAIDS-BAA-08-16

The DAIDS Enterprise System (DAIDS-ES) is a comprehensive system that supports the business functions, management and oversight responsibilities of the Division of AIDS. Components of the DAIDS-ES that will be functional at the time of award include:

DAIDS Protocol Management
The DAIDS Protocol Management supports end-to-end clinical trials processes, including: protocol development, registration, conduct, accrual, oversight, site monitoring, tracking and closeout.

DAIDS Master Contact
The DAIDS Master Contact is a centralized system for all address and contact information for stakeholders engaged in clinical research, such as investigators, participating institutions, laboratories, agencies, pharmaceutical sponsors, manufacturers, etc.

DAIDS Expedited Adverse Experience Reporting System (DAERS)
The DAERS is a web-based application for expedited reporting of adverse events in DAIDS sponsored clinical trials. DAERS is a 21 CFR Part 11 compliant system for use in therapeutic, vaccine and prevention trials.

DAIDS Clinical Site Monitoring System
The DAIDS Clinical Site Monitoring System provides a unified platform that will serve as the official information source for Clinical Site Monitoring activities. The system is 21 CFR Part 11 compliant and supports tracking of monitoring schedules, assignment requests, site monitoring reports and issues identified during site visits.

Successful awardees shall, as needed: 1) interface with the DAIDS-ES to provide access to data in local system(s); 2) adapt data management system(s) to receive and store data from the DAIDS-ES; 3) integrate data systems to dynamically obtain data from the DAIDS-ES. All data exchange mechanisms shall be based on DAIDS-defined platform technology standards.

To achieve compatibility, DAIDS and its collaborators (contractors, cooperative agreement holders, grantees, etc.) will implement applications or data exchange mechanisms using platform technology standards such as: Web Services, eXtensible Markup Language (XML), XML Schema Definitions (XSD), RDBMS, .NET Framework, UDDI, IIS, Internet Explorer, Service Oriented Architecture (SOA), Design Patterns, Frameworks and Templates as defined by the DAIDS-ES. Collaborators shall adhere to these guidelines and standards on a continual basis.

This requirement will include the need to utilize DAIDS-ES specified software Application Programming Interfaces (APIs) or XML and XSD, where appropriate, in all relevant applications that affect specific types of transactions, Graphical User Interfaces (GUI) and other software-based tasks that interact with or become part of the DAIDS-ES.

Depending upon the architecture and implementation of offeror data management system(s), the following activities may be required to be compatible with the DAIDS-ES.

Build Interface:
Using DAIDS-ES specified data standards, collaborators shall provide access to data in their local system(s). Standards shall either be industry data exchange standards such as those specified by NIH, CDISC, HL7 or adapted versions of these as defined by DAIDS.
System Adaptation:
Collaborators may need to adapt or modify their data management system(s) to receive and store data from the

DAIDS-ES. For example, DAIDS is establishing a standardized naming and numbering convention for its awardee institutions. The DAIDS shall provide collaborators with a single set of institution or laboratory names and identifiers for all of its research participants. Collaborators data system(s) may have to be adapted or modified to accommodate the DAIDS standard(s).

System Integration:
Collaborators may be required to dynamically obtain data from the DAIDS-ES to perform specific job functions. This will require the integration of collaborator's system(s) with the DAIDS-ES via data linkages using the appropriate latency factor or through Web Services. For example, the DAIDS-ES will serve as the central repository for investigator and protocol status information. Collaborator's whose work requires information from the DAIDS-ES must dynamically integrate it into their respective data system(s).

Attachment 8
List of Current HVDDT Contractors
HIV Vaccine Design and Development Teams
NIH-NIAID-DAIDS-BAA-08-16

Name of Organization	Principal Investigator	Contract Number
Alphavax, Inc	Jeffrey D. Chulay	N01-AI-30029
BernaBiotech, a Crucell Company	Hussein Y. Naim	N01-AI-60018
Chiron Corporation/Novartis	Susan W. Barnett	N01-AI-50007
Columbus Children's Research Institute	Philip R. Johnson	N01-AI-50008
Epimmune-Pharmexa, Inc	Mark J. Newman	N01-AI-30031
Progenics Pharmaceuticals, Inc	Paul J. Maddon	N01-AI-30030
Wyeth Pharmaceuticals, Inc	John Eldridge	N01-AI-25458