SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1. Purchase Authority: Public Law 92-218 as amended			
2. **Request for Proposal (RFP) Number:** RFP-NIAID-DMID-NIHAI2008026	3. **Issue Date:** July 23, 2008	4. **Closing Date/Time:** November 6, 2008 3:00 PM, local time	5. **Set Aside:** X No [ ] Yes See Part IV Section L
6. Title : Tuberculosis Clinical Diagnostics Research Consortium (CDRC)			
7. ISSUED BY: Office of Acquisitions, DEA National Institute of Allergy and Infectious Diseases National Institutes of Health, DHHS 6700B Rockledge Drive, Room 3214 Bethesda, MD 20892-7612		8. SUBMIT OFFERS TO: **[NOTE: This solicitation has a required total page limitation of not-to-exceed 250 pages for the Technical Proposal.]** See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.	
9. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until the date and time listed in Block 4., above. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.			
10. THIS SOLICITATION REQUIRES DELIVERY OF PROPOSALS TO THE OFFICIAL POINT OF RECEIPT FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY AS STATED IN ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH HHSAR CLAUSE 352.215-70, ENTITLED, "LATE PROPOSALS, AND REVISIONS" LOCATED IN SECTION L.1. OF THIS SOLICITATION.			
11. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. http:// www.ccr.gov			
12. **PRIMARY POINT OF CONTACT**: Andrew Cherry, Contract Specialist; Phone: 301-402-2443; E-mail: cherryan@niaid.nih.gov **SECONDARY POINT OF CONTACT**: Karen M. Gamble, Contracting Officer; Phone: 301-402-2234; E-mail: gamblek@niaid.nih.gov **FAX Number:** 301-402-0972 **COLLECT CALLS WILL NOT BE ACCEPTED.**			
		Karen M. Gamble Contracting Officer and Team Lead, MIDRDB-B Office of Acquisitions, DEA National Institute of Allergy and Infectious Diseases National Institutes of Health, DHHS	

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PART I - THE SCHEDULE

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

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

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The goal of the Tuberculosis Clinical Diagnostics Research Consortium (CDRC) is to determine, early in the development process, where investigational diagnostics can be most appropriately positioned to improve speed and accuracy of TB diagnosis and/or the determination of drug resistance. The CDRC will evaluate experimental diagnostics not solely in comparison to stand alone "gold standard" diagnostics tests, but will also enable evaluation of how these diagnostics perform within a clinical algorithm.

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.

a. Review of Press Releases

The contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. In accordance with NIH Manual Chapter 1754, misrepresenting contract results or releasing information that is injurious to the integrity of NIH may be construed as improper conduct. The complete text of NIH Manual Chapter 1754 can be found at: http://www1.od.nih.gov/oma/manualchapters/management/1754/. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The contractor shall ensure that the project officer has received an advance copy of any press release related to this contract not less than four (4) working days prior to the issuance of the press release.

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 June 30, 2008, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

b. The applicable Privacy Act System of Records Number will be specified and shall be used in any design, development, or operation work to be performed under the resultant contract. Disposition of records shall be in accordance with SECTION C of the contract, and by direction of the Project Officer(s).

ARTICLE C.2. REPORTING REQUIREMENTS

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 5, Reporting Requirements and Deliverables, in SECTION J - LIST OF ATTACHMENTS. *[Note: Beginning May 25, 2008, the Contractor shall include the applicable PubMed Central or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]*

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

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

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

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

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

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

SECTION D - PACKAGING, MARKING AND SHIPPING

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

SECTION E - INSPECTION AND ACCEPTANCE

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

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

c. Inspection and acceptance will be performed at:

Division of Microbiology and Infectious Diseases
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Bethesda, Maryland, 20892-6603

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

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the STATEMENT OF WORK 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 described in SECTION C of this contract.

The items described in SECTION C, ARTICLE C.2. 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 dates specified in SECTION C, ARTICLE C.2. and any specifications stated in SECTION D, PACKAGING MARKETING AND SHIPPING, of this contract.

[NOTE: Refer to ATTACHMENT 5, Reporting Requirements and Deliverables, in SECTION J, LIST OF ATTACHMENTS, for the Delivery Schedule.]

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

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

The Government may unilaterally change its Project Officer designation.

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

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

(End of Clause)

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

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

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

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

1. Payment requests shall be submitted as follows:

   a. One original to the following designated billing office:

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

   b. One copy to the following approving official:

      Contracting Officer

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

E-Mail: NIAIDOAInvoices@niaid.nih.gov

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

2. In addition to the requirements specified in FAR Subpart 32.9 for a proper invoice, the Contractor shall include the following information on all payment requests:

   a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is 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 Standard Form 26. *[Note: This only applies to new contracts awarded on/ after June 4, 2007, and any existing contract modified to include the number.]*

   d. DUNS number or DUNS+4 that identifies the Contractor's name and address exactly as stated on the face page of the contract.

   e. Identification of whether payment is to be made using a two-way or three-way match. This contract requires a Two-Way match.

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

ARTICLE G.4. GOVERNMENT PROPERTY

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

The above link is not yet active. A paper copy is available upon request.

ARTICLE G.5. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) shall be submitted as determined by the Project Officer and Contracting Officer, but at least once during the contract period of performance.

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

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

b. Electronic Access to Contractor Performance Evaluations

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

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

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

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved by the National Institute of Allergy and Infectious Diseases (NIAID), written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, **provided** that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.

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

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

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

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

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

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

ARTICLE H.3. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

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

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

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

ARTICLE H.4. RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (Including Human Gene Transfer Research)

All research involving Recombinant DNA Molecules shall be conducted in accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html) and the September 24, 2007 Notice, "Reminder of NIH Policy for Enhancing the Science, Safety, and Ethics of Recombinant DNA Research" (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-096.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.5. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

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

of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

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

ARTICLE H.6. NEEDLE EXCHANGE

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

ARTICLE H.7. PRESS RELEASES

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

ARTICLE H.8. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING SCIENTIFIC INFORMATION

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

ARTICLE H.9. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

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

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

ARTICLE H.10. RESTRICTION ON ABORTIONS

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds for any abortion.

ARTICLE H.11. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to the current HHS annual appropriations act, the Contractor shall not use NIH Fiscal Year funds to pay the direct salary of an individual through this contract at a rate in excess of Executive Level I. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as "indirect costs" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor. The annual salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

b. Payment of direct salaries is limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred. See the following Web site for Executive Schedule rates of pay: http://www.opm.gov/oca/. *(For current year rates, click on Salaries and Wages / Executive Schedule / Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages / cursor to bottom of page and select year / Executive Schedule / Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)*

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

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

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

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

(End of clause)

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

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.13. OMB CLEARANCE or CLINICAL EXEMPTION

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

ARTICLE H.14. 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

   Completion Date of Contract

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:

[to be provided upon award]
Contract Specialist

ARTICLE H.15. INFORMATION SECURITY

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

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

a. Information Type

[X] Administrative, Management and Support Information

Scientific and Technical Research and Innovation

[ ] Mission Based Information

b. Security Categories and Levels

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

Overall Level: [X] **Low** [ ] **Moderate** [ ] **High**

c. Position Sensitivity Designations

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

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

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

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

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

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

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

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

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

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

d. Information Security Training

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

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

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

e. Rules of Behavior

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

f. Personnel Security Responsibilities

Contractor Notification of New and Departing Employees Requiring Background Investigations

1. The Contractor shall notify the Contracting Officer, the Project Officer, and the Security Investigation Reviewer **within five working days** before a new employee assumes a position that requires a suitability determination or when an employee with a security clearance stops working under the contract. The Government will initiate a background investigation on new employees requiring security clearances and will stop pending background investigations for employees that no longer work under the contract.
2. New employees: Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the Government will determine the appropriate security level.
3. Departing employees:
   - Provide the name, position title, and security clearance level held by or pending for the individual.
   - Perform and document the actions identified in the "Employee Separation Checklist", attached in Section J, ATTACHMENTS of this contract, when a Contractor/Subcontractor employee terminates work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request.

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

1. Contractor Agreement

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

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

2. Contractor-Employee Non-Disclosure Agreements

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

h. NIST SP 800-53 Self-Assessment

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

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

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

i. Information System Security Plan

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

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

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

j. Common Security Configurations

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

ARTICLE H.16. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY (January 2008)

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

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

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

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

Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding increment funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Annual Report to the Contracting Officer and Contracting Officer's Technical Representative (also known as Project Officer or Contracting Officer's Representative). Unless otherwise directed by the Contracting

Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available at: http://508.hhs.gov/ under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding incremental funding, as applicable.

Schedule for Contractor Submission of Section 508 Annual Report:

[End of HHSAR 352.270-19(c)]

ARTICLE H.17. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS

The Contractor shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that investigators (defined as the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded under NIH contracts) will not be biased by any conflicting financial interest. 45 CFR Part 94 is available at the following Web site: http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=cc7504e541bc62939c52389e9afc27d5&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45

As required by 45 CFR Part 94, the Contractor shall, at a minimum:

a. Maintain a written, enforceable policy on conflict of interest that complies with 45 CFR Part 94 and inform each investigator of the policy, the investigator's reporting responsibilities, and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.

b. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in NIH-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such conflict. 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. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 CFR Part 94, under Management of Conflicting Interests.

c. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

d. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

If a conflict of interest is identified, the Contractor shall report to the Contracting Officer, the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the NIH-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research.

The Contracting Officer may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in NIH-funded research, including a review of all records pertinent to compliance with 45 CFR Part 94.

The Contracting Officer may require submission of the records or review them on site. On the basis of this review, the Contracting Officer may decide that a particular conflict of interest will bias the objectivity of the NIH-funded research to such an extent that further corrective action is needed or that the Contractor has not managed, reduced, or eliminated the conflict of interest. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that NIH-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an investigator with a conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

ARTICLE H.18. PUBLICATION AND PUBLICITY

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

> "This project has been funded in whole or in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN2722009XXXXXC"

ARTICLE H.19. 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.20. POSSESSION, USE OR TRANSFER OF A HIGHLY PATHOGENIC AGENT

The work being conducted under this contract may involve the possession, use, or transfer of a *Highly Pathogenic Infectious Agent (HPA).* The NIAID defines an HPA as a pathogen that, under any circumstances, warrants a biocontainment safety level of BSL3 or higher according to either:

1. The current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)(http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm);
2. The Contractor's Institutional Biosafety Committee (IBC) or equivalent body; or
3. The Contractor's appropriate designated institutional biosafety official.

If there is ambiguity in the BMBL guidelines and/or there is disagreement among the BMBL, an IBC or equivalent body, or institutional biosafety official, the highest recommended containment level must be used.

ARTICLE H.21. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

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

guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

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

ARTICLE H.22. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

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

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

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

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

ARTICLE H.24. CONSTITUTION DAY

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

ARTICLE H.25. GUIDELINES FOR INCLUSION OF WOMEN, MINORITIES, AND PERSONS WITH DISABILITIES IN NIH-SUPPORTED CONFERENCES

Pursuant to the NIH Revitalization Act (P.L. 103-43, Section 206), which adds Section 402(b) to the Public Health Service Act, it is required that NIH, "in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research." In addition, Section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act of 1990 require reasonable accommodations to be provided to individuals with disabilities.

It is NIH policy that organizers of scientific meetings should make a concerted effort to achieve appropriate representation of women, racial/ethnic minorities, and persons with disabilities, and other individuals who have been traditionally underrepresented in science, in all NIH sponsored and/or supported scientific meetings.

Therefore, it is the contractor's responsibility to ensure the inclusion of women, minorities, and persons with disabilities in all events when recruiting speakers and/or participants for meetings or conferences funded by this contract.

See the policy announcement for additional details and definitions at:
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-066.html

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

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

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

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

a. FAR 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.

b. **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.

c. **Alternate II** (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (April 2008) is added.

d. 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.]**

e. FAR Clause **52.216-11, Cost Contract--No Fee** (April 1984) is deleted in its entirety and FAR Clause **52.216-8 Fixed Fee** (March1997) is substituted therefor.

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

   FAR Clause **52.249-5, Termination For Convenience Of the Government (Educational And Other Non-Profit Institutions)** (April 1984) is deleted in its entirety and FAR Clause **52.249-6, Termination (Cost-Reimbursement)** (May 1986) is substituted therefor.

   HHSAR Clause **352.249-14, Excusable Delays** (January 2006) is deleted in its entirety and FAR Clause **52.249-14, Excusable Delays** (April 1984) is substituted therefor.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (December 2007).

2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (December 2007).

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

Poster(s)	Obtain From"
HHS Contractor Code of Ethics and Business Conduct Poster	http://www.oig.hhs.gov/hotline/OIG_Hotline_Poster.pdf

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

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

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

5. FAR Clause **52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting** (April 2008).

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

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

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

9. FAR Clause **52.227-13, Patent Rights--Ownership by the Government** (December 2007).

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

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

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

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

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

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

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

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

15. FAR Clause **52.227-15, Representation of Limited Rights Data and Restricted Computer Software** (December 2007).

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

17. FAR Clause **52.227-17, Rights in Data--Special Works** (December 2007).

18. FAR Clause **52.229-8, Taxes-Foreign Cost-Reimbursement Contracts** (March 1990).

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

20. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (March 2008).

21. FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).

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

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

24. FAR Clause **52.247-63, Preference for U.S. Flag Air Carriers** (June 2003).

25. FAR Clause **52.251-1, Government Supply Sources** (April 1984).

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

1. *HHSAR Clause **352.223-70, Safety and Health** (January 2006).*

2. *HHSAR Clause **352.224-70, Confidentiality of Information** (January 2006).*

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

4. *HHSAR Clause **352.270-7, Paperwork Reduction Act** (January 2006).*

5. *HHSAR Clause **352.270-8(b), Protection of Human Subjects** (January 2006).*

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

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

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

1. ***NIH (RC)-7, Procurement of Certain Equipment** (April 1984).*

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

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

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

This contract incorporates the following clauses in full text.

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

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

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

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

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

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

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

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

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and
(ii) Within 60 to 120 days prior to the exercise date specified in the contract for any option thereafter.

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

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

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

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

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

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

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

(End of clause)

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

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

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

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

Notice to Employees

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

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

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

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

To locate the nearest NLRB office, see NLRB's website at http://www.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 2021, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

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

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

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c).
For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint

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

(End of Clause)

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

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

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

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

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

[To be filled in by the Contracting Officer]

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal (R & D)	[Attached to RFP]
Attachment 2:	Proposal Intent Response Sheet	[Attached to RFP]
Attachment 3:	Statement of Work	[Attached to RFP]
Attachment 4:	Points to Consider in The Drafting of Consortium Meetings	[Attached to RFP]
Attachment 5:	Reporting Requirements and Deliverables	[Attached to RFP]
Attachment 6:	Additional Technical Proposal Instructions, Format for Technical Proposal, and Table of Contents	[Attached to RFP]
Attachment 7:	Uniform Cost Assumptions	[Attached to RFP]

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 8:	Targeted/Planned Enrollment Table	http://rcb.cancer.gov/rcb-internet/forms/enroll-table.pdf
Attachment 9:	Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Attachment 10:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Attachment 11:	Protection of Human Subject 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 12:	Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 13:	Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Attachment 14:	Small Business Subcontracting Plan	http://www.hhs.gov/osdbu/read/SampleSubcontractingPlan.doc
Attachment 15:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	http://oamp.od.nih.gov/contracts/BUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls
Attachment 16:	Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Attachment 17:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 18:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 19:	Financial Report of Individual Project/ Contract NIH 2706	http://www.niaid.nih.gov/contract/forms/nih-2706.pdf
Attachment 20:	Instructions for Completing Form NIH 2706	http://www.niaid.nih.gov/contract/forms/instructions2706.pdf
Attachment 21:	Privacy Act System of Records	http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm
Attachment 22:	Safety and Health, HHSAR Clause 352.223-70	http://rcb.cancer.gov/rcb-internet/forms/safety&health-1-06.pdf
Attachment 23:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Attachment 24:	Research Patient Care Costs, NIH(RC)-11	http://www.niaid.nih.gov/contract/forms/nih-rc-11.pdf
Attachment 25:	Inclusion Enrollment Report	http://rcb.cancer.gov/rcb-internet/forms/inclusion-enrollment.pdf
Attachment 26:	Commitment to Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Attachment 27:	Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Attachment 28:	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 2006)]*

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

"Discussions" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

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

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

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

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

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

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

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

(2) The first page of the proposal must show--

(i) The solicitation number;

(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);

(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) Submission, modification, revision, and withdrawal of proposals.

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

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

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

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

(3) It is the only proposal received.

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

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

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

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

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

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

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

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

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

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

(e) Restriction on disclosure and use of data.

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

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

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

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

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

(f) Contract award.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(End of Provision)

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

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

b. **NAICS CODE AND SIZE STANDARD**

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

1. The North American Industry Classification System (NAICS) code for this acquisition is 541711.
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.

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

It is anticipated that one award will be made from this solicitation and that the award will be made on/about June 30, 2009.

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

d. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 21 FTEs (full-time equivalents) per year. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

e. **COMMITMENT OF PUBLIC FUNDS**

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

f. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

g. **RELEASE OF INFORMATION**

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

h. **PREPARATION COSTS**

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

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

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

Contracting Officer
Office of Acquisitions, DEA
National Institute of Allergy and Infectious Diseases, NIH, DHHS
6700-B 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)

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

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

(End of provision)

2. **INSTRUCTIONS TO OFFERORS**

a. **GENERAL INSTRUCTIONS**

INTRODUCTION

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

1. **Contract Type and General Clauses**

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

2. **Authorized Official and Submission of Proposal**

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

   I. COVER PAGE

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

   II. TECHNICAL PROPOSAL

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

   III. BUSINESS PROPOSAL

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

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

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

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

   The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates,

materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See SECTION J, Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY.) However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

5. **Alternate Proposals**

   You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

6. **Uniform Resource Locators (URLs) in Contract Proposals**

   All proposals must be self-contained within the specific page limitations cited in Attachment 1 in this solicitation. Unless otherwise specified, URLs/Internet addresses shall not be used to provide information necessary to the review because reviewers are under no obligation to review the Internet sites.

7. **Evaluation of Proposals**

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

8. **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.

9. **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.

10. **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.

11. **Privacy Act - Treatment of Proposal Information**

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

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

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

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

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

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

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

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

12. **Selection of Offerors**

a. The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques.

The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b. The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

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

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

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

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

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

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

e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror.

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

13. **Institutional Responsibility Regarding Conflicting Interests of Investigators**

45 CFR Part 94 promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research to be performed under NIH contracts will be biased by any conflicting financial interest of an Investigator. The Institution shall comply with all requirements of 45 CFR Part 94 at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=cc7504e541bc62939c52389e9afc27d5&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45.

14. **ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless

of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

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

15. **Past Performance Information**

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

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

Include the following information for each contract or subcontract listed:

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

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

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

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

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

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

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

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

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

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

(End of provision)

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

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

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

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

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

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

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

b. **TECHNICAL PROPOSAL INSTRUCTIONS**

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

Note to Offerors: Beginning May 25, 2008, the offeror shall include the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.

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

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

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

3. Methods

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

4. Schedule

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

c. **Personnel**

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

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

1. Single Principal Investigator/Project Director

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

2. Other Investigators

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

3. Additional Personnel

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

   - The specific items or expertise they will provide.
   - Their availability to the project and the amount of time anticipated.
   - Willingness to act as a consultant.
   - How rights to publications and patents will be handled.

4. Resumes

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

2. **Other Considerations**

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

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

3. **Technical Evaluation**

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

<u>IMPORTANT NOTE TO OFFERORS</u>: The following 10 paragraphs [4. through 13.] shall be addressed, as applicable, in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

4. ***Human Subjects***

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

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

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

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

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

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

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

(End of provision)

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

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

a. Risks to the subjects

- Human Subjects Involvement and Characteristics:
    - Describe the proposed involvement of human subjects in response to the solicitation.

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

- Sources of Materials:
  - Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.
- Potential Risks:
  - Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.
  - Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

b. Adequacy of Protection Against Risks

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

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

- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.
- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

d. Importance of the Knowledge to be Gained

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

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

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

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

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

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

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at http://ohsr.od.nih.gov/cbt/. You may download the information at this site at no cost and modify it, if desired. The University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at
http://www.centerwatch.com/order/pubs_profs_protect.html.
In addition, the NCI sponsors an online training course at:
http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp
If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

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

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

It is NIH policy that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an Institute/Center Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43), **and applies to research subjects of all ages.**
All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

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

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

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

Information Required for ALL Clinical Research Proposals

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

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

The proposal must include the following information:

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

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

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

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

In addition to the above requirements, solicitations for **NIH defined Phase III clinical trials *** 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.

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

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

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

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

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

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

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

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

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

- The objective of the solicitation is not relevant to children.
    - There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.
    - The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.
    - A separate, age-specific study in children is warranted and preferable. Examples include:

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

Definition of a Child

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

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

9. **Research Involving Prisoners as Subjects**

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

b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

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

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

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

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

10. **Research Involving Human Fetal Tissue**

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

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

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

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

11. **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).

12. **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 Required Review by Human Pluripotent Stem Cell Review Group (HPSCRG)

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

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

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

to the Contracting Officer. This documentation will be forwarded for review and approval to the HPSCRG.

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

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

13. **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.

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

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

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

to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

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

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

a. **Sharing Research Data**

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

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

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

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

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

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

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

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

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

a. Information Type

[X] Administrative, Management and Support Information:

Scientific and Technical Research and Innovation

[ ] Mission Based Information:

b. Security Categories and Levels

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

c. Position Sensitivity Designations

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

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

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

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

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

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

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

d. Information Security Training

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

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

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

e. Offeror's Official Responsible for Information Security

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

f. NIST SP 800 53 Self Assessment

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

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

g. Draft Information System Security Plan

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

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

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

h. Common Security Configurations

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

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/drivers/documents/FISMA-final.pdf
2. DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf
3. NIH Computer Security Awareness Training Course: http://irtsectraining.nih.gov/

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

c. **BUSINESS PROPOSAL INSTRUCTIONS**

1. **Basic Cost/Price Information**

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

2. **Proposal Cover Sheet**

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

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

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

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

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

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

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

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

1. **Direct Labor**

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

2. **Materials**

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

3. **Subcontracted Items**

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

4. **Raw Materials**

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

5. **Purchased Parts**

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

6. **Fringe Benefits**

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

7. **Indirect Costs**

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

8. **Special Equipment**

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

9. **Travel**

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

10. **Other Costs**

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

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

(a) Exceptions from cost or pricing data.

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

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.
(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;
(B) For market priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;
(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

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

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

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15 2 of FAR 15.408.
(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406 2.

(End of provision)

5. **Salary Rate Limitation in Fiscal Year 2008**

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

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 110-161 applies only to Fiscal Year 2008 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limitation also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 110-161 states in pertinent part:

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

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

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

6. **Small Business Subcontracting Plan**

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

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

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

c. The offeror understands that:

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

    2. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses,

Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

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

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

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

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

d. Each plan must contain the following:

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

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

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

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

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

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

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

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

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

10. Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (Individual Subcontract Reports (ISRs) and Summary Subcontract Reports (SSRs) to the Government.

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

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

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

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

12. **NOTE** : A subcontracting plan with zero percent goals in any of the above categories may not be considered acceptable by the NIH.

7. **HUBZone Small Business Concerns**

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

8. **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS 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.

9. **Other Administrative Data**

a. **Property**

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

below , the proposal must include a comprehensive justification addressing the following items:

a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.

b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

2. Government Property

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

a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);

b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;

c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and

d. The voluntary consensus standard or industry leading practices and standards to be used in the management of Government property, or existing property management plans, methods, practices, or procedures for accounting for property.

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

3. Government-Furnished Property

No Government Furnished Property is offered for this acquisition

4. The management and control of any Government property shall be in accordance with 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

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

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

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

(End of Provision)

c. **Financial Capacity**

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

d. **Incremental Funding**

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

Incremental Funding, HHSAR 352.232-75 (January 2006)

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

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

(End of provision)

10. **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.

11. **Subcontractors**

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

a. Willingness to perform as a subcontractor for specific duties (list duties).

b. What priority the work will be given and how it will relate to other work.

c. The amount of time and facilities available to this project.

d. Information on their cognizant field audit offices.

e. How rights to publications and patents are to be handled.

f. A complete cost proposal in the same format as the offeror's cost proposal.

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

12. **Proposer's Annual Financial Report**

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

13. **Representations and Certifications - SECTION K**

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

14. **Travel Costs/Travel Policy**

a. **Travel Policy**

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

15. **Certification of Visas for Non-U.S. Citizens**

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its outlying areas, then the offeror must indicate in the proposal that these individuals have the required visas.

SECTION M - EVALUATION FACTORS FOR AWARD

1. **GENERAL**

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

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

2. **HUMAN SUBJECT EVALUATION**

This research project involves human subjects. NIH Policy requires:

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

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

3. **EVALUATION OF DATA SHARING PLAN**

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

If your proposal does not include a plan or if the plan in your proposal is considered "unacceptable," and the Government 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.

4. **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. All sub-criteria are considered to be of equal importance.

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

CRITERIA **WEIGHT**

CRITERION 1: TECHNICAL PLAN/APPROACH **55**

1. Establishment and Maintenance of the TB Clinical Diagnostics Research Consortium (CDRC)

A. Clinical Study Sites

1) Adequacy and appropriateness of the proposed clinical study sites as evidenced by the following:

a. Experience in the diagnosis and treatment of TB.
b. Established relationships with local TB control programs.
c. Experience in conducting clinical studies of human TB relevant to the scope of the CDRC, including obtaining clearances from in-country human subject review boards and adherence to Good Clinical Practice (GCP) guidelines.
d. Access to sufficient numbers of appropriate adult and pediatric study populations, including individuals with co-infections and co-morbid conditions, individuals with exposure to other mycobacterial diseases, and individuals who have received childhood vaccination with BCG.
e. Plan for the recruitment and retention of study participants, including collaborative arrangements with local clinicians/institutions to serve as referral sources.

2) Adequacy and appropriateness of proposed plans for determining the need for additional clinical study sites and identifying and assessing such study sites.

3) Plans to serve as a resource to the TB research community to provide advice and support for moving TB diagnostics forward in the clinical setting.

B. CDRC Data Management Center

Adequacy and appropriateness of the proposed CDRC Data Management Center as evidenced by the following:

1) Clinical Database System:

a. The features of the proposed clinical database system.
b. Proposed plans and procedures for data collection, management, quality control and reporting, training of clinical study site personnel, and required

interactions with clinical study site personnel.

c. Experience in providing database management services, particularly for projects involving multi-national collaborations and foreign sites in resource-limited countries.

2) Statistical Design and Analysis:

a. Plans for providing statistical design and analysis assistance for CDRC clinical protocols.
b. Experience in providing statistical design and analysis assistance for studies of human TB, including TB diagnostics, and for multi-national collaborative studies involving foreign sites in resource-limited countries.
c. Understanding of methodological considerations, challenges and potential limitations in statistical design and analysis of investigational TB diagnostics in TB-endemic countries; recommendations for overcoming/minimizing such challenges and limitations; and understanding of the level of data quality required to improve further diagnostic development for use in TB-endemic countries.

C. Clinical Study Protocols

1) Protocol Development:

a. Proposed process to provide for substantial involvement of clinical study site investigators and clinicians from TB-endemic countries in protocol development and to address current health care practices in the context of protocol design.
b. Understanding of potential problems/obstacles related to use of a collaborative, multi-national protocol development process, and recommended approaches for resolving/minimizing such problems and obstacles.
c. Experience in designing and developing protocols for clinical studies of human TB, particularly for multi-national studies of TB diagnostics in TB-endemic countries.

2) Clinical Study Protocols for Initial Diagnostics

a. The appropriateness of the 2 proposed investigational diagnostics for evaluation by the CDRC, including the soundness and completeness of data on (1) use of the proposed devices/assays in a diagnostic setting, (2) preliminary specificity and sensitivity against target organism(s), and (3) appropriate quality assurance of the prototype.
b. The scientific basis/rationale for testing the specific diagnostic modalities, and how these modalities are expected to improve TB diagnosis in the host countries.
c. The scientific and technical soundness and feasibility of the proposed clinical study designs.
d. Documentation of availability of and access to proposed study populations by the participating clinical study sites.
e. Soundness of the rationale for how the proposed studies will yield novel data, contribute to direct improvements in further design and testing of the investigational diagnostics, and/or improve feasibility of implementation in the host countries.
f. Appropriateness and feasibility of proposed timelines for all clinical study activities.
g. Appropriateness and adequacy of any proposed collaborations with academia and/or industry for the conduct of the clinical studies.
h. Transactional agreements with both 3rd party suppliers and in-country collaborators.

D. Protocol Implementation, Management, Oversight, Reporting and Analysis

The appropriateness and adequacy of the following:

1) Plan for the oversight of CDRC clinical studies.

2) Proposed policies and procedures to ensure timely initiation and completion of CDRC clinical studies; how real and potential problems in study progress will be identified and corrected; and potential circumstances under which requests for timeline modifications may be justified.
3) Completeness of Letters of Understanding between collaborating parties to address intellectual property, facilitate development of commercialization, and resolve disputes.

E. Solicitation, Review and Prioritization of Proposals for CDRC Diagnostic Studies

Adequacy and appropriateness of the proposed plan to solicit, review and prioritize proposals, including:

1) Descriptive materials, frequency and target audiences for soliciting proposals.
2) Documentation required for proposal submissions.
3) Timelines and evaluation criteria to be used to assess and prioritize proposals.

F. Publications, Presentations and Data Dissemination

1) Appropriateness and feasibility of proposed approaches and methods for disseminating data and major findings to the research community.
2) Appropriateness and feasibility of proposed approaches and avenues for interacting with scientific groups to maximize resources and provide advice to aid in development and clinical implementation of new TB diagnostics.

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

1. Principal Investigator

Documentation of appropriate experience, qualifications and knowledge with respect to: planning, managing and directing multi-national collaborative clinical research projects involving multiple clinical sites and centralized data management services; designing, implementing and overseeing multi-national collaborative clinical studies of TB diagnostics conducted in TB-endemic countries and within local health care practices and clinical diagnostic algorithms; diagnostic development and requirements for moving investigational diagnostics into the clinical setting; and serving as a resource to the TB research community.

2. Other Scientific and Technical Personnel

The appropriateness and adequacy of the training, qualifications, experience and knowledge of the following other scientific and technical personnel relevant to the scope of CDRC clinical research activities, including documentation of physician licensure, current GCP training, and biosafety training:

A. Clinical Study Site Personnel, including: Lead Clinical Investigators, other clinical site investigators, nurse coordinators, laboratory technicians and data entry personnel.
B. CDRC Data Management Center Personnel, including: statisticians, database management personnel for data quality assurance/quality control, and Information Technology (IT) personnel.
C. Other Scientific and Technical Personnel of the offeror for evaluation of proposed investigational diagnostics, protocol design and development, management, oversight and reporting for CDRC clinical studies, conduct of assays and analyses, and IT support.

CRITERION 3: FACILITIES, EQUIPMENT, SAFETY REQUIREMENTS, SAFETY TRAINING AND OTHER RESOURCES **10**

1. The adequacy and suitability of all proposed facilities, equipment, and other resources to be made available under the contract, including documentation of lease or ownership, for the following:

A. Clinical study site research facilities and equipment for: (1) patient screening, enrollment, administration of investigational diagnostics, and safety monitoring; (2) access-controlled storage for confidential clinical records; (3) performance of protocol-required laboratory tests; and (4) storage and shipping of clinical specimens.
B. Laboratory facilities of the offeror for conducting assays and analyses.
C. Central data management facility and off-site back-up facility.
D. Other support resources, including IT systems.

2. Documentation of the safety of all proposed facilities and equipment in accordance with current Biosafety in Microbiology and Biomedical Laboratories (BMLB) guidelines, and adequacy of safety training and safety practices to be used to ensure a safe working environment for all personnel handling or in contact with pathogenic mycobacteria.

CRITERION 4: PROJECT MANAGEMENT **10**

Adequacy, appropriateness and feasibility of plans and capabilities in the following areas:

1. Proposed plans for project organization, staffing, communications, direction and oversight, with clear lines of authority, responsibility and accountability; proposed plans and timelines for coordinating, managing and assessing study progress and performance of clinical study sites and the CDRC Data Management Center to ensure a cooperative, integrated and focused scientific effort, including the coordination of studies involving the collaboration among multiple TB-endemic countries, and implementing remedial actions when necessary.

2. Prioritizing important project elements and adjusting priorities to accommodate unanticipated developments or problems.

3. Systems proposed for tracking project activities and monitoring progress, timelines and budgets.

TOTAL POSSIBLE WEIGHT: **100**

5. **PAST PERFORMANCE FACTOR**

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

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

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

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

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

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

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

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

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

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the 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 of commitment to use SDB concerns

b. Complexity and variety of the work SDB concerns are to perform

c. Extent of participation of SDB concerns in terms of the value of the total acquisition.

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

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

PACKAGING AND DELIVERY OF THE PROPOSAL

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

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

A. EXTERNAL PACKAGE MARKING:

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

"**RFP-NIAID-DMID-NIHAI2008026"**
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
Andrew Cherry Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20817	Andrew Cherry 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).
- Offerors shall NOT use 8.5 x 14 legal size paper.

- 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. Ten (10) unbound COPIES **ELECTRONIC FILES ON CD** Three (3) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices)	**Not to Exceed 250 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

PROPOSAL INTENT RESPONSE SHEET

RFP-NIAID-DMID-NIHAI2008026
RFP Title: Tuberculosis Clinical Diagnostics Research Consortium (CDRC)

Please review the attached Request for Proposal. Furnish the information requested below and return this page by **_September 23, 2008_**. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

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

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

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

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

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

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):
_____
_____
_____
_____
(Continue list on a separate page if necessary)

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

Attn: Andrew Cherry
RFP--NIAID-DMID-NIHAI2008026
FAX# (301) 402-0972
Email: cherryan@niaid.nih.gov

ATTACHMENT 3: STATEMENT OF WORK

Tuberculosis Clinical Diagnostics Research Consortium (CDRC)
RFP NIAID-DMID-NIHAI2008026

1. BACKGROUND AND INTRODUCTION:

The National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), conducts and supports basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases. For more than 50 years, NIAID research has led to new therapies, vaccines, diagnostic tests, and other technologies that have improved the health of millions of people in the United States and around the world.

M. tuberculosis (Mtb) is a high priority pathogen at NIAID for the development of new therapies, vaccines, and diagnostic tests. One-third of the world's population is thought to be infected with Mtb, and 5 to 10 percent of infected people are likely to develop active Tuberculosis (TB) at some point in their lives; for people infected with HIV, the likelihood of developing and dying from TB is much higher. In 2005, an estimated 1.6 million people died of TB, 195,000 of who were co-infected with HIV. Today, increasingly fueled by the HIV epidemic, TB disproportionately affects young adults in their most productive years, and the deadly synergy between HIV/AIDS and TB has led to an increase in the number of new TB cases throughout the world. Increased rates of TB have also resulted from the development of multidrug resistant strains of Mtb. These higher rates of TB increase the need not only for the development of interventions, such as new drugs and more effective vaccines, but also the need for improved diagnostic technologies.

Improved diagnostic tools and the application of appropriate technologies to develop effective treatment plans in the clinic are an important component of addressing the challenges of TB. Current technologies are antiquated and labor intensive. Development of new, more effective diagnostics for TB depends not only on the identification of new technologies and improved engineering of diagnostic devices, but also on the integration of these diagnostic technologies into the existing clinical algorithms to simplify and/or expedite the clinical diagnosis or exclusion of TB in TB-endemic countries (www.who.int/tb/publications/global_report/2007/pdf/full.pdf, as updated yearly).

The goal of the Tuberculosis Clinical Diagnostics Research Consortium (CDRC) is to determine, early in the development process, where investigational diagnostics can be most appropriately positioned to improve speed and accuracy of TB diagnosis and/or the determination of drug resistance. The CDRC will evaluate experimental diagnostics not solely in comparison to stand alone "gold standard" diagnostics tests, but will also enable evaluation of how these diagnostics perform within a clinical algorithm. This is particularly important since the "gold standard" currently used for TB diagnosis (the acid fast stain) is an antiquated test with limited specificity and sensitivity. Through evaluation of new diagnostic tests in combination with a clinical algorithm, it is expected that the CDRC will demonstrate that even diagnostic tests with limited sensitivity and specificity may nevertheless show great utility when evaluated in the context of a diagnostic process.

It is anticipated that advanced preclinical development of diagnostic tests initially evaluated by the CDRC will be carried out by commercial sponsors, non-governmental organizations, and other government agencies, such as the World Health Organization (WHO), the Centers for Disease Control and Prevention (CDC), other NIH funding sources, and other components of the Department of Health and Human Services (DHHS).

NOTE: *The CDRC is not intended to replace or compete with existing programs for clinical evaluation and implementation of new diagnostic tests but rather to assure,* ***early in the development process,*** *that new diagnostics indeed have the potential to contribute in a positive manner to existing diagnostic strategies. This approach is built on the premise of bringing together clinicians in the U.S. and TB-endemic countries with diagnostic developers at the earliest possible stage in the creation of new and improved tests.*

2. SCOPE:

A. This contract shall establish the Tuberculosis Clinical Diagnostics Research Consortium (CDRC), a consortium of clinical study sites in TB-endemic countries to assess the performance of novel, early stage TB diagnostics in the context of existing clinical diagnostic algorithms. Diagnostic devices, technologies and assays eligible for evaluation under this contract must have demonstrated preliminary specificity and sensitivity against the target organism(s) and must be available as at least a quality assured prototype diagnostic device, assay or test. CDRC clinical studies shall be designed to determine how new diagnostics can most effectively contribute to diagnostic fidelity and/or speed in comparison to, or in concert with, currently utilized diagnostics, and to ready diagnostic tests for further development by commercial and/or other non-governmental sponsors. The CDRC shall also serve as a resource to the research community to provide support and advice for the early stage development of TB diagnostics in the clinical setting and contribute to the overall scheme for moving diagnostics into clinical validation.

B. Initially, the Contractor shall include up to two diagnostic tests ready for assessment by the CDRC; additional diagnostics may be identified by either the Contractor or by the research community. Sources for additional diagnostic tests include NIAID-funded cooperative partnerships, Small Business Innovation Research (SBIR) grants, Small Business Technology Transfer (STTR) grants, Research Grants, pharmaceutical/biotechnology companies and foundations, academic institutions, and other governmental and non-governmental agencies.

C. The CDRC shall provide data of sufficient practical nature to aid in the selection and development of diagnostic tests for the identification of active or latent TB in immune-competent or immune-suppressed persons infected with Mtb and not compromised by standard Bacille Calmette Guerin (BCG) vaccination or the presence of other mycobacterium.

D. The CDRC must provide access to adequate numbers of relevant patient populations to ensure the timely screening, enrollment and completion of clinical studies.

E. It is expected that this contract will coordinate activities with other NIAID or U.S. Government, and privately funded diagnostic and relevant clinical research projects to maximize contribution to global diagnostic development.

NOTE: **This contract will NOT support:**

- The development of **new** clinical research facilities and laboratories for testing new diagnostics.
- The development of new diagnostics and new assays.
- Interventional clinical trials.
- Studies to collect data to support a 510(k) application, or equivalent, with the FDA or regulatory agencies outside the United States.
- The establishment or maintenance of a publicly accessible specimen repository.
- Any development and testing of investigational drugs and vaccines for the treatment or prevention of TB.

3. TECHNICAL REQUIREMENTS:

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the work described below.

A. ESTABLISHMENT AND MAINTENANCE OF THE TUBERCULOSIS CLINICAL DIAGNOSTICS RESEARCH CONSORTIUM (CDRC)

1. Establish and direct the CDRC, a consortium of scientific and clinical investigators and institutions with expertise and experience in the conduct of multi-disciplinary, multi-national TB research and in the design and conduct of early stage clinical evaluations of novel TB diagnostics in TB-endemic countries by:

   - utilizing established collaborations with qualified, experienced institutions in TB-endemic countries for conducting clinical studies;
   - providing substantial input into study design, development and analysis to ensure that the development of new diagnostic tools and methods will be relevant to TB health care practices in these endemic countries; and
   - establishing, directing, and coordinating the activities of the CDRC Data Management Center.

2. *Within six months after the effective date of the contract*, the Contractor is required to enter into a consortium agreement outlining the terms guiding the CDRC. A final copy of the agreement should be provided to the Project Officer and Contracting Officer. *[Refer to the Attachment entitled "Points to Consider in Drafting of Consortium Agreements" for points to consider when drafting such an agreement.]*

The CDRC shall consist of the following components:

1. Clinical Study Sites

   a. The CDRC shall include at least one foreign clinical study site located in a TB-endemic country (as identified by the WHO annual Global Report, www.who.int/tb/publications/global_report/2007/pdf/full.pdf, updated yearly) to conduct clinical studies. Countries considered to be TB-endemic will also include countries that may be newly identified as TB-endemic during the contract period of performance.

   b. Clinical study site(s) shall have established clinical facilities and laboratories capable of conducting clinical studies to evaluate and aid in the development of new TB diagnostics, as well as established, collaborative relationships with local clinicians familiar with the current clinical algorithms for the diagnosis of TB.

   c. The clinical study sites in TB-endemic countries shall provide, at a minimum, the following:

      1) A Lead Clinical Investigator with experience and expertise in the design and conduct of clinical studies of human TB, including new diagnostics, to direct the assessments of diagnostic devices, technologies and assays.

2) Clinical investigators, nurse coordinators and other clinical and technical personnel experienced in the conduct of clinical studies of human TB, including: patient screening, recruitment and retention; adherence to Good Clinical Practices (GCP) and host country requirements and regulations governing the safe and ethical conduct of research involving human subjects; assessment and reporting of adverse events; management of study products; collection and quality control of study data; and maintenance and storage of research records. Clinical and technical personnel must also have experience in human TB diagnosis, TB studies in TB-endemic countries, and relevant TB patient populations.

3) Facilities and personnel to carry out study-specific laboratory testing in accordance with Good Laboratory Practice (GLP) guidelines and for the storage of patient samples under appropriate conditions.

4) Access to adequate numbers of relevant patient populations to ensure the timely screening, enrollment and completion of clinical studies. The following adult and pediatric patient populations shall be available in at least one of the clinical sites and all patient populations shall be represented in the overall consortium:

- ♦ TB patients with drug sensitive and/or drug resistant disease;
- ♦ adult and pediatric subjects presenting with TB related co-infections and co-morbid conditions, such as HIV/AIDS;
- ♦ volunteers with exposure to mycobacteria other than Mtb, such as *Myocbacterium leprae*; and
- ♦ volunteers who have received childhood vaccination with BCG, when appropriate for the diagnostic being tested.

5) Clinical study sites not active at the time of contract award may be added as necessary during the period of performance to conduct specific clinical studies and/or ensure access to adequate numbers of relevant patient populations. These sites must receive prior approval by the Project Officer and must meet the same requirements as sites originally included in the contract.

2. CDRC Data Management Center

The CDRC Data Management Center shall include experts in statistics and database management to carry out the following functions:

a. Operation and maintenance of a state-of-the-art database system at a central facility for the receipt, quality control, tracking, storage and retrieval of all clinical study data, including the following system features:

1) compliance with all current Federal regulations (§21 CFR 11 and/or similar statutes, http://www.fda.gov/cber/guidelines.htm) and current globally-accepted standards, including International Conference on Harmonization (ICH) E-2, Clinical Safety Data Management and ICH M-5, Data Elements and Standards for Drug Dictionaries (http://www.ich.org/cache/compo/475-272-1.html and http://www.ich.org/cache/compo/2196-272-1.html, respectively);

2) computerized registration and randomization of the majority of subjects, and non-computerized methods as needed on a limited basis for selected study sites;

3) computerized study forms and systems for remote data entry and transmission, generally via the internet, of subject data from study sites and laboratories to the central data management facility;

4) non-computerized methods when necessary, for example paper Case Report Forms (CRFs); and

5) security against anticipated risks, including loss of confidentiality of subject electronic records and data summaries, and catastrophic loss of study data or important software, including an off-site secured storage facility for system back-ups.

b. Development and implementation of procedures for the collection, management, quality control and reporting of all clinical study data, and training of clinical study site personnel on appropriate procedures.

c. Provision of expertise and assistance to CDRC Protocol Teams in the statistical design of study protocols, the development of statistical analysis plans, and the analysis of study data.

d. Preparation of interim and final analyses of study data.

B. OBJECTIVES AND REQUIREMENTS FOR CDRC CLINICAL STUDIES

Experimental TB diagnostics may be evaluated either independently or in conjunction with other diagnostic tests and within the clinical algorithms of TB-endemic countries to determine how these experimental diagnostics can contribute to improved speed or accuracy of diagnosis of TB and/or determination of drug resistance by clinicians in TB-endemic countries.

1. Clinical studies shall be designed to provide novel data and shall not needlessly duplicate studies conducted by other investigators.

2. Evaluation of diagnostic tests for other mycobacteria may be included in comparison to inform studies of experimental TB diagnostics.

3. Clinical studies may be designed to incorporate new protocols for evaluating experimental diagnostics within ongoing clinical trials or studies, or may be designed specifically as an independent protocol to evaluate an experimental diagnostic.

4. Clinical studies shall incorporate methods to evaluate how best to utilize particular diagnostics as part of an overall diagnostic and control plan in TB-endemic countries, including consideration for suitable settings and populations most likely to benefit from a particular device or strategy.

5. Clinical studies shall maximize utilization of local expertise to conduct assays and analyses with human-derived specimens and consider local health care practices in the development of Clinical Study Plans.

6. Clinical study data shall be of a suitable quality to provide researchers with information to improve the development of new diagnostics and inform researchers of the suitability of a diagnostic for use within the local TB care practices.

7. Clinical studies shall be conducted in one or more TB-endemic countries that routinely use BCG vaccination as part of their control strategies when that background is appropriate for the diagnostic being tested.

8. Patient population shall include:

    - TB patients with drug sensitive and/or drug resistant disease;
    - adult and pediatric subjects presenting with TB related co-infections and co-morbid conditions, such as HIV/AIDS;
    - volunteers with exposure to mycobacteria other than Mtb, such as *Myocbacterium leprae*; and
    - volunteers who have received childhood vaccination with BCG, when appropriate for the diagnostic being tested.

9. Clinical studies shall provide for substantial involvement of clinical study site investigators and clinicians in study design, development and analysis to ensure that development of new diagnostic methods will be relevant to TB health care practices in these endemic countries and contribute to improved speed or accuracy of diagnosis of TB and/or identification of drug resistance.

10. Clinical studies shall be coordinated with other NIAID contractors and grantees, to be identified by the Project Officer, throughout the contract period of performance via face-to-face meetings, teleconferences and/or through inclusion in Annual Contract Review meetings to ensure that planned CDRC studies have relevance to other TB research efforts.

C. SOLICITATION, REVIEW, PRIORITIZATION AND APPROVAL OF PROPOSALS FOR CDRC DIAGNOSTIC STUDIES

In addition to diagnostic studies submitted and approved as part of the original contract, the Contractor shall solicit additional diagnostic candidates from the community for evaluation under this contract.

1. Solicitation, Review and Prioritization Plan

    a. *Within 30 calendar days after the effective date of the contract*, prepare and submit, for Project Officer review and approval, the Solicitation, Review and Prioritization Plan for proposals from the community for testing of diagnostic candidates under this contract. This Plan must include:

        1) The process to be used for soliciting proposals, including descriptive materials, frequency of solicitations, and target audiences.

        2) The proposal submission process to be used by the community to request approval for the conduct of clinical studies by the CDRC, including all documentation required in order to provide for a thorough and meaningful evaluation of scientific/technical/clinical merit.

3) The review process, including timelines, to be used to evaluate the technical/scientific/clinical merit and feasibility of proposed clinical studies to evaluate new TB diagnostics, including the specific criteria to be applied to assess merit and feasibility of conducting clinical studies within the CDRC.

4) The process for prioritization of proposals and for recommending to the Project Officer which diagnostics should be accepted for testing, the order in which these diagnostics should be tested, and the specific geographical sites and populations required for the clinical studies recommended.

2. Agreements with Third Party Suppliers

For diagnostics accepted for assessment in the CDRC and provided by third parties, the Contractor shall enter into Material Transfer Agreements, or clinical product and confidentiality agreements, as may be necessary, to clarify rights and responsibilities regarding data release and publications, as well as training needs for CDRC clinical and laboratory staff. The Project Officer will provide a sample Material Transfer Agreement template for use by the Contractor upon contract award.

D. CLINICAL STUDY PLANS AND PROTOCOLS

Develop clinical study plans and protocols for the two initial diagnostics, and subsequently for any additional diagnostics identified in the Solicitation, Review and Prioritization Plan and approved for implementation by the Project Officer, as outlined below.

1. General Protocol Development Process

a. Coordinate all protocol development activities with the Project Officer and his/her designees. Develop protocols in accordance with NIAID/DMID clinical research policies, templates and requirements as specified at http://www3.niaid.nih.gov/research/resources/DMIDClinRsrch/policies.htm.

b. Establish a Protocol Team consisting of scientific, clinical and technical staff of the Contractor, the clinical study sites, the CDRC Data Management Center, the Project Officer and his/her designees to refine study designs, as necessary, and develop draft and final protocols and protocol-related documents.

c. In collaboration with the Protocol Team, prepare initial and, as necessary, subsequent drafts of clinical protocols and protocol-related documents, including informed consent forms to include permission to store and use clinical specimens for future studies, CRFs, and Manuals of Operation (MOOs). Submit Final Protocols and protocol-related documents for Project Officer approval. Protocols for clinical studies shall proceed to the implementation stage only after receipt of written Project Officer approval of the Final Protocol and protocol-related documents.

d. Prior to study implementation, acquire appropriate approvals from local and/or national government ethics committees and/or other human subject protection review boards and submit to the Project Officer along with other required documentation.

e. Where applicable, adhere to the current Federal Guidelines for Research Involving Recombinant DNA molecules (www4.od.nih.gov/oba/rac/guidelines/guidelines.html).

2. Clinical Study Plan(s) and Protocol(s)

   a. Clinical Study Plan(s)

      1) A detailed description of the proposed experimental diagnostic device or assay, including a summary of how this technology has been used in a diagnostic setting for any other pathogens or diseases, any relevant laboratory data, and the type and quantity of human samples required.

      2) A description of the clinical algorithms for the diagnosis of TB in the proposed study location and population and how the diagnostic device or assay is anticipated to contribute to TB diagnosis and/or the determination of drug resistance.

      3) An assessment, based on discussions with clinicians and technicians in TB-endemic countries, of the current bottlenecks and perceived needs for improvement of speed and/or accuracy of TB diagnostics and/or determination of drug resistance and a discussion on how the proposed study design will address those needs.

      4) A description of how the local clinicians and technicians will be employed to provide input on how to best develop the diagnostic and diagnostic methods to improve diagnostic accuracy and speed.

      5) A discussion of potential scientific, clinical and technical problems or obstacles and proposed approaches to resolving such problems and obstacles.

   b. Clinical Study Protocol(s)

      1) Scientific basis/rationale for testing of the specific diagnostic modality.

      2) Proposed study population(s) and the rationale for their selection.

      3) Proposed clinical study sites and documentation of the availability of adequate numbers of study participants at the proposed clinical study sites. If new clinical study sites are proposed, documentation of appropriate and established clinical research facilities, equipment, personnel and access to adequate numbers of study participants for the clinical study.

      4) Study design, including comparator, sample size and type, inclusion and exclusion criteria, evaluation criteria and their relevance to answering the questions being addressed by the study.

      5) A detailed statistical analysis plan.

      6) A discussion of how the implementation of this diagnostic is expected to better inform clinicians in TB-endemic countries in order to improve TB diagnosis and treatment, based on a clinical needs assessment.

      7) A plan for the identification, recruitment and retention of study participants.

8) A description of any proposed collaborations with academia and/or industry to carry out the proposed study, including the conduct of any proposed clinical studies in conjunction with planned or ongoing clinical trials supported through other mechanisms and sponsored by other entities.

9) Plans for the development, negotiation and execution of agreements with third party suppliers of diagnostics to govern intellectual property and data rights.

10) Detailed timelines for protocol development, initiation, completion and analysis of final study data.

11) A breakdown of estimated costs including protocol supplies, study participant expenses, study participant incentives, advertising and miscellaneous costs, as well as costs for any proposed subcontracts.

3. Clinical Study Protocol for Initial Diagnostics

   a. *Within 30 calendar days after the effective date of the contract*, prepare and submit, for Project Officer review and approval, the Draft Clinical Study Protocol for Initial Diagnostics for the diagnostic tests originally included in the Technical Proposal.

   b. The Draft Clinical Study Protocol for Initial Diagnostics will be reviewed by the Project Officer and appropriate DMID offices according to the Clinical Terms of Award and according to the current DMID policies and timelines for the review of human subject research protocols (http://www3.niaid.nih.gov/research/resources/DMIDClinRsrch/policies.htm).

   c. The Project Officer and his/her designee will provide comments and suggested revisions to the Contractor in an iterative manner until a mutually acceptable protocol has been developed.

   d. *No later than 16 calendar days after receipt of final comments from the Project Officer*, submit the Final Clinical Study Protocol for Initial Diagnostics to the Project Officer for approval. Clinical studies for initial diagnostics shall proceed to the study development stage only after receipt of written approval by the Project Officer.

4. Clinical Study Plan(s) and Protocol(s) for Additional Diagnostics

   a. *Within 60 calendar days after receipt of Project Officer approval to accept a diagnostic submitted by the community for evaluation,* the Contractor shall submit Draft Clinical Study Plan(s) and Draft Clinical Study Protocol(s) for these diagnostics to the Project Officer and the CDRC External Scientific Advisory Group (ESAG) for review.

   b. *Within 30 calendar days after receipt of the comments from the CDRC ESAG*, the Contractor shall provide Revised Clinical Study Plan(s) for Additional Diagnostics and Revised Clinical Study Protocol(s) for Additional Diagnostics to the Project Officer that addresses the comments and concerns of the ESAG.

c. The Revised Clinical Study Plan(s) for Additional Diagnostics and Revised Clinical Study Protocol(s) for Additional Diagnostics will be reviewed by the Project Officer according to the Clinical Terms of Award and according to the current DMID policies and timelines for the review of human subject research protocols (http://www3.niaid.nih.gov/research/resources/DMIDClinRsrch/policies.htm).

d. The Project Officer will provide comments and suggested edits to the Contractor in an iterative manner until a mutually acceptable plan and protocol has been created.

e. The Final Clinical Study Plan(s) for Additional Diagnostics and Final Clinical Study Protocol(s) for Additional Diagnostics shall be *submitted no later than 16 calendar days after receipt of final comments from the Project Officer*. Clinical studies for additional diagnostics shall proceed to the evaluation stage only after receipt of written approval by the Project Officer.

E. DATA MANAGEMENT AND QUALITY CONTROL

1. *Within 60 calendar days after the effective date of the contract*, develop and submit, for Project Officer review and approval, a Draft Data Management and Quality Control Plan for all CDRC clinical studies. At a minimum, this Plan shall include:

   a. a description of the central database system to be utilized and system features;

   b. procedures for receipt, storage, quality control and retrieval of all clinical study data;

   c. plans for ensuring security against loss of data, including off-site facilities for system back-up;

   d. plans for training of clinical site personnel in the use of the central database system; and

   e. plans for transmitting data quarterly to a government-owned, secure database.

2. *Within 15 calendar days after receipt of the review of this Plan by the Project Officer*, submit the Final Data Management and Quality Control Plan incorporating all of the changes required by the Project Officer.

F. PROTOCOL IMPLEMENTATION, MANAGEMENT, OVERSIGHT, REPORTING AND ANALYSIS

Upon receipt of approval by the Project Officer of the Final Protocol(s) and protocol-related documents, the Contractor shall provide all necessary personnel, resources, and clinical research facilities to conduct approved clinical studies in accordance with the protocol and in compliance with NIAID Clinical Terms of Award (http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf). This includes the following:

1. Initial Clinical Site Assessment and Ongoing Clinical Site and Study Monitoring

   a. Clinical Site Assessment

      Each clinical study site shall undergo an initial site assessment to ensure the adequacy of clinical research facilities, equipment and operating procedures, as well

as appropriate training of clinical staff, with respect to the conduct of human subjects research. Initial clinical site assessments will be conducted by DMID staff and/or DMID-designated entities identified by the Project Officer. The Contractor shall make all relevant study personnel, documentation, facilities and equipment, available for such assessments and shall implement any Project Officer-approved corrective actions resulting from such assessments.

b. Clinical Site and Study Monitoring

Clinical site and study monitoring visits during the conduct of CDRC clinical studies will also be conducted by DMID staff and/or DMID-designated entities identified by the Project Officer. The Contractor shall make all relevant study personnel, documentation, facilities and equipment, available for such site visits and shall implement any Project Officer-approved corrective actions resulting from such monitoring.

2. Monthly Clinical Progress Reports

Within 30 calendar days after the effective date of the contract, and on/before the 30th of each month thereafter, prepare and submit to the Project Officer Monthly Clinical Progress Reports addressing the following:

a. progress in accrual of study participants, including problems encountered in recruitment and retention and proposed approaches to resolving any such problems;

b. proposed revisions to the established timelines for protocol implementation, completion and analysis, including the rationale/justification for the proposed revisions;

c. proposed modifications to the approved clinical study protocol and their rationale; and

d. any recommendations for curtailing or discontinuing approved clinical studies based on scientific rationale, feasibility and other factors.

3. Annual Institutional Review Board (IRB) Approval

Submit, to the Project Officer, documentation of the Annual IRB review and approval for each protocol as soon as such documentation is available.

4. Safety Monitoring and Oversight

Conduct safety monitoring and oversight for all clinical studies in collaboration with the DMID Office of Clinical Research Affairs and the Project Officer. Submit safety monitoring reports as outlined in each protocol.

5. Final Clinical Study Reports

Within 60 calendar days after the completion of each clinical study, prepare and submit to the Project Officer a Final Clinical Study Report containing:

a. the study protocol;

b. final study demographics;

c. final analysis and interpretation of study results;

d. an assessment of the impact of study findings on the state of the science, the enhancement and/or improvement of approaches to evaluating the safety and efficacy of new diagnostics, recommendations for specific steps to be taken to improve that diagnostic being tested or rationale for how to best implement the diagnostic, and the contributions of study findings to informing local TB care practices; and

e. a listing of scientific articles and manuscripts published, submitted and in preparation resulting from each study.

6. Audits

a. Arrange for independent audits of CDRC facilities and operations to be conducted by qualified organizations not affiliated with the Contractor, and make available for such audits all necessary personnel, facilities, equipment and records. A copy of each audit report shall be provided to the Project Officer within 15 calendar days following the completion of each audit.

b. Comply with all Project Officer-approved corrective and remedial actions resulting from audits and provide written reports on the implementation of corrective and remedial actions and the resolution of all issues identified through the auditing process.

c. NIAID reserves the right to conduct independent audits of the Contractor and its subcontractors, as needed, to evaluate compliance with FDA required GCP standards and expect that all records and staff shall be available for site visits or study specific audits by NIAID or its designees.

G. EXTERNAL SCIENTIFIC ADVISORY GROUP

1. *Within 60 calendar days after the effective date of the contact*, and with the concurrence of the Project Officer, establish an External Scientific Advisory Group (ESAG) to provide recommendations on:

a. the overall scientific direction and priorities of the CDRC;
b. specific scientific issues;
c. experimental diagnostics proposed for assessment; and
d. Clinical Study Plans for approved clinical studies.

2. ESAG members shall be selected on the basis of the types of expertise the Contractor and Project Officer deem necessary to complement the expertise of Contractor and subcontractor staff.

3. ESAG members shall be appointed for an initial term of two years; membership may be renewed with concurrence by the Project Officer and the Contractor.

4. Specifically, the Contractor shall:

   a. *Within 30 calendar days after the effective date of the contract*, submit a brief description of the key areas of expertise to be represented on the ESAG, and provide the names and CVs for proposed members. Project Officer concurrence will be provided *within 15 calendar days after receipt of proposed ESAG members*.

   b. *Within 15 calendar days after receipt of Project Officer concurrence*, confirm ESAG members.

   c. Provide all Clinical Study Plans, Clinical Study Protocols and protocol-related documents to the ESAG and obtain comments and recommendations from ESAG members prior to submission to the Project Officer.

   d. Obtain advice from ESAG members through teleconferences and attendance at Annual Contract Review Meetings.

H. FACILITIES, EQUIPMENT, OTHER RESOURCES, SAFETY REQUIREMENTS AND SAFETY TRAINING

1. Provide all facilities, equipment and other resources required to carry out the functions specified in the Statement of Work, including:

   a. clinical research facilities and laboratories, equipment and other resources for patient screening, recruitment, administration of investigational diagnostics, safety monitoring, performance of protocol-specific tests, and secure maintenance of patient records;

   b. facilities and equipment for labeling and storage of clinical specimens under appropriate conditions; and

   c. central data management and back-up facility.

2. Ensure the safety of all facilities, equipment and other resources utilized in the U.S. and in non-U.S. countries, and conduct work in accordance with the most recent Guidelines for Biosafety in Microbiological and Biomedical Laboratories (BMBL, Centers for Disease Control and Prevention and the National Institutes of Health, fourth edition, HHS Publication No. [CDC 93-8395, published by the U.S. Government Printing Office, May 1999, Stock Number 017-040-0547-4)), or comparable safety standards in TB endemic countries.

3. Provide biocontainment facilities and staff with the required training, experience and expertise to operate the facilities and conduct the studies in accordance with the appropriate Biosafety Guidelines for working with pathogenic organisms (see also http://bmbl.od.nih.gov/).

4. Provide appropriate levels of training, protective garments, equipment and monitoring for all involved personnel to assure safe handling and transport of potentially hazardous microorganisms, blood products or other specimens.

I. PROJECT MANAGEMENT

1. Overall Project Management

   Provide for the overall management, integration and coordination of all contract activities, including:

   a. the efficient planning, initiation, implementation and timely completion of all projects carried out under this contract;

   b. effective communications with the Project Officer and the Contracting Officer;

   c. tracking, monitoring and reporting on project status and progress; and

   d. recommending modifications to project requirements and timelines.

2. Meetings and Teleconferences

   a. Contract Initiation Meeting

      Within 30 calendar days after the effective date of the contract, participate in a one-day Contract Initiation Meeting with the Project Officer, the Contracting Officer and other NIAID personnel designated by the Project Officer, to be held at the Contractor's site. The purpose of the Contract Initiation Meeting shall be to orient the Contractor to NIAID contract procedures, review contract requirements, procedures and timelines, discuss initial diagnostics to be evaluated by the CDRC, and additional diagnostics to be solicited, reviewed and proposed for assessment.

   b. Annual Contract Review Meetings

      1) Plan and conduct one-day Annual Contract Review Meetings to be attended by the contract Principal Investigator and key Contractor and subcontractor scientific and technical staff, members of the ESAG, the Project Officer, the Contracting Officer and other DMID staff designated by the Project Officer. Meetings shall be held in Bethesda, Maryland, at the Contractor's location or at another location. The Project Officer may request that Annual Contract Review Meetings be held in conjunction with annual meetings for other NIAID TB Program contractors and that key Contractor and subcontractor staff and ESAG members attend these joint meetings. The dates and location of Annual Contract Review Meetings shall be determined by the Project Officer in consultation with the Contractor.

      2) Meeting agendas shall be established by the Contractor's Principal Investigator in consultation with the Project Officer. Annual Contract Review Meetings shall be closed to the public and shall include status updates on all projects, a discussion of and suggested solutions to any problems that may have arisen, recommendations for any changes in timelines or projects, and plans for the coming year. The Contractor shall be responsible for:

         a) preparing and distributing to meeting participants all appropriate background materials on project status and future plans, *at least 10 calendar days prior to the meeting*;

b) preparing presentation materials, including relevant data from ongoing and completed clinical studies; and

c) preparing and submitting meeting summaries to the Project Officer and the Contracting Officer *within 30 calendar days after each meeting*.

c. Other Meetings/Teleconferences

Participate in monthly, or more frequent when required, teleconferences or face-to-face meetings with the Project Officer, the Principal Investigator and key Contractor scientific, technical and administrative staff to review the status of all projects, future plans, and issues or problems in study design, implementation or conduct that require immediate attention and resolution. As necessary, these meetings/teleconferences may include a discussion of any proposals submitted to request the evaluation of experimental diagnostics by the CDRC. The Contractor shall be responsible for:

1) preparing and distributing to meeting participants all appropriate background materials on project status and future plans, *at least 10 calendar days prior to the meeting/teleconference*;

2) preparing presentation materials, including relevant data from ongoing and completed clinical studies; and

3) preparing and submitting meeting summaries to the Project Officer and the Contracting Officer *within 30 calendar days after each meeting*.

J. INTELLECTUAL PROPERTY

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, Patent Rights--Retention by the Contractor (Short Form).

K. CDRC WEB PORTAL

1. Establish and maintain a Web Portal that may be hosted by the Contractor or outsourced.

2. The Web Portal must be designed to comply with the format to be provided to the Contractor by the Project Officer, including input from the NIAID Office of Technology and Information Systems (OTIS) as necessary.

3. *Within 30 calendar days after the effective date of the contract*, submit a Draft Web Portal Plan for the design and implementation of the Web Portal for approval by the Project Officer.

4. *Within 60 calendar days after the effective date of the contract,* submit a Final Web Portal Plan that incorporates all mutually agreed upon revisions and begin implementation of the Web Portal Plan.

L. FINAL CONTRACT TRANSITION

Plan and execute an orderly, safe and efficient transition to a successor contractor or to the Government on or before the completion date of the contract. This shall include the following:

1. *No later than six months prior to the completion date of the contract,* submit a **Draft Transition Plan** for Project Officer review and approval. The Draft Transition Plan shall include:

   a. a plan and timeline for the completion of all ongoing studies and the analysis of final study data;

   b. a plan and timeline for the transfer of contract-developed data files, software systems and CDRC Web Site with documentation and specifications – such transfer shall provide the transferee with the same rights in such materials as are possessed by the Contractor;

   c. a list of Contractor personnel to be assigned to carry out final transition activities; and

   d. an estimate of the cost to complete the transition.

2. Revise the Draft Transition Plan in accordance with comments provided by the Project Officer and submit the Final Transition Plan to the Project Officer *within 30 calendar days of the receipt of the Project Officer comments or 90 calendar days prior to the completion date of the contract (whichever is the earliest date)*. After receipt of written approval of the Final Transition Plan by the Project Officer, implement the approved Final Transition Plan to achieve a complete, timely, and orderly transition of all contract activities, resources and final deliverables.

[END OF STATEMENT OF WORK]

ATTACHMENT 4: POINTS TO CONSIDER IN THE DRAFTING OF CONSORTIUM AGREEMENTS

Tuberculosis Clinical Diagnostics Research Consortium (CDRC)
RFP NIAID-DMID-NIHAI2008026

1. Information
   - Agreement must outline the procedures and protocols for ensuring information is conveyed to all consortium members on a regular basis.
   - The Principal Investigator (PI) is responsible for ensuring regular communication with consortium members.

2. Overall Management Scheme
   - Monitoring Performance within the Consortium
   - Performance requirements of institutions must be specified, including how this will be monitored
   - PI is responsible for monitoring that participants are meeting the agreed milestones
   - Provide for coordination of TT/legal/grants/contacts/ sponsored research offices between institutions

3. Monitoring of compliance with NIH policies
   - Agreement should state that all participants agree to comply with all applicable NIH policies.

4. Equipment purchases
   - Agreements must comply with requirements for managing Assets and Equipment Purchases and the Property Management Standards as specified in U.S.C. 45, C.F.R. 74 and US OMB Circulars (as applicable).

5. Data
   - Need a mechanism for sharing data, e.g. information technology management system accessible to all (remember this may require considerable funds)
   - Ensure access and use by all participants (“Ownership” of data is not a useful concept)
   - Agreement should address how data will be shared with parties outside of the consortium

6. Confidential Information
   - Include terms in the agreement that will allow for the sharing of confidential information between all parties in the consortia.

7. Material Transfers
   - Ensure a mutually approved MTA is attached to agreement
   - How will animals, biologicals, reagents etc. be shared outside of consortium?
   - Remember NIH sharing policies

8. Publications
   - Agreement should contain publication review process, determination of first author, and address confidentiality to allow patent filing rights

9. Intellectual Property
   - Consider need to enable other participants to access institution’s relevant pre-existing IP rights to achieve goals
   - Require a philosophy of ensuring rapid utilization of inventions to benefit public health

- Agree on methods for reporting new inventions arising from the collaboration and for determining ownership, patent filing, management, licensing and royalty sharing

10. Liability
    - State legal liabilities of institutions.

11. Dispute Resolution
    - Specify how disputes will be handled.

12. Termination
    - Able to terminate institutions not in compliance after warning period/dispute resolution fails.
    - Able to give 30 days notice and withdraw.
    - Need to specify how publications, inventions and materials will be handled in case of termination.

ATTACHMENT 5: REPORTING REQUIREMENTS AND DELIVERABLES

Tuberculosis Clinical Diagnostics Research Consortium (CDRC)
RFP NIAID-DMID-NIHAI2008026

ARTICLE C.2. REPORTING REQUIREMENTS

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

a. Technical Progress Reports

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

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

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

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

1) Monthly Progress Report

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

2) Semi-Annual Progress Report

a) This report shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The initial report will be submitted for the first full six months of the contract performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of six full calendar months.

b) Monthly reports will not be submitted the month the semi-annual report is due.

3) Annual Progress Report

This report includes a summation of the results of the entire contract work for the period covered. An Annual Progress Report will not be required for the period when the Final Report is due. A Monthly Progress Report and Semi-Annual Progress Report shall not be submitted when an Annual Report is due.

4) Annual Technical Progress Report for Clinical Research Study Populations

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

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

In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October 2001, applies. If this contract is for Phase 3 clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website:

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

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.

5) Final Report

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

The Contractor shall provide the Project Officer and Contracting Officer with three copies of the Final Report in **draft** form in accordance with the DELIVERIES Article in SECTION F of this contract. The Project Officer will review the draft report and provide the Contracting Officer with comments within 15 calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary and the final version delivered as specified in the above paragraph.

6) Summary of Salient Results

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

b. Other Reports and Deliverables

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

1) Human Subjects IRB Annual Report (Form OMB No. 0990-0263 - formerly Optional Form 310)
2) Invention Report Requirement

ARTICLE F - DELIVERIES

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

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

a. Technical Progress Reports

Item	Reports	Recipients	Delivery Schedule
1.	Monthly Progress Report	1 hard copy to PO 1 original to CO 1 elec. copy to PO and CO	The first report is due on/before _____. Thereafter, each report is due on/before the 15th of each month following each reporting period.
2.	Semi-Annual Progress Report	1 hard copy to PO 1 original to CO 1 elec. copy to PO and CO	The first report is due on/before _____. Thereafter, each report is due on/before the 30th of the month following each 6-month period. Monthly reports shall not be submitted the month the semi-annual report is due.
3.	Annual Technical Progress Report for Clinical Research Study Populations	1 Paper Copy - PO 1 Original Paper - CO	First report due on/before _____, thereafter, due on/before the 30th of the month after each anniversary date of the contract.
4.	Annual Progress Report	1 hard copy to PO 1 original to CO 1 elec. copy to PO and CO	The first report is due on/before _____. Thereafter, each report is due on/before the 30th of the month following each anniversary date of the contract. Monthly and semi-annual reports shall not be submitted the

Item	Reports	Recipients	Delivery Schedule
			month the annual report is due.
5.	Annual Utilization Report	1 copy to CO	Due on/before the 30th of the month following each anniversary date of the contract.
6.	Final Invention Statement	1 copy to CO	Due on/before completion date of the contract.
7.	All reports and documentation including the invention disclosure report, the confirmatory license, and the government support certification	1 copy to Office of Policy for Extramural Research Administration (OPERA)	As required by FAR Clause 52.227-11.
8.	Draft Final and Final Report and Summary of Salient Results	1 hard copy to PO 1 original to CO 1 elec. copy to PO and CO	Draft Final Report is due 1 year prior to the completion date of contract. Final Report is due on/before the completion date of the contract.

b. Other Reports and Deliverables (Delivery Schedule)

Item	Deliverables	SOW Reference	Recipient	Delivery Schedule
1.	Solicitation, Review and Prioritization Plan	C.1.a.	1 hard copy to PO, CO 1 elec. Copy PO,CO	Within 30 calendar days after the effective date of the contract.
2.	Draft Clinical Study Protocol for Initial Diagnostics	D.3.a.	1 hard copy to PO, CO 1 elec. copy to PO, CO	Within 30 calendar days after the effective date of the contract.
3.	Monthly Clinical Progress Reports	F.2.	1 hard copy to PO, CO 1 elec. copy to PO, CO	Within 30 calendar days after the effective date of the contract and on/before the 30th of each month thereafter.
4.	Submit a brief description of the key areas of expertise to be represented on the ESAG, and provide the names and CVs for proposed members	G.4.a.	1 hard copy to PO, CO 1 elec. copy to PO, CO	Within 30 calendar days after the effective date of the contract. PO will provide concurrence within 15 calendar days
5.	Confirm EASG membership	G.4.b.	1 hard copy to PO, CO 1 elec. copy to PO, CO	Within 15 calendar days after receipt of PO concurrence.

6.	Contract Initiation Meeting	I.2.a.		Within 30 calendar days after the effective date of the contract.
7.	Draft Web Portal Plan	K.3.	1 elec. copy to PO	Within 30 calendar days after the effective date of the contract.
8.	Final Web Portal Plan	K.4.	1 elec. copy to PO	Within 60 calendar days after the effective date of the contract.
9.	Draft Data Management and Quality Control Plan	E.1	1 hard copy to PO, CO 1 elec. copy to PO, CO	Within 60 calendar days after the effective date of the contract.
10.	Establish an External Scientific Advisory Group (EASG)	G.1.	Within 60 calendar days of the effective date of the contract.	
11.	Consortium Agreement	A.2.	1 hard copy to PO, CO 1 elec. Copy PO,CO	Within 6 months after the effective date of the contract.
12.	Final Clinical Study Protocol for Initial Diagnostics	D.3.d.	1 hard copy to PO, CO 1 elec. copy to PO, CO	Within 16 calendar days after receipt of PO comments on Draft Clinical Study Protocol for Initial Diagnostics.
13.	Clinical Study Plan(s) and Protocol(s) for Additional Diagnostics	D.4.a.	1 hard copy to PO (who will provide a copy to the CDRC EASG) 1 elec. copy to PO, CO 1 hard copy to CO	Within 60 calendar days after receipt of Project Officer approval to evaluate a diagnostic submitted by the community, as identified in the Solicitation, Review and Prioritization Plan.
14.	Revised Clinical Study Plan(s) and Revised Protocol(s) for Additional Diagnostics	D.4.b.	1 hard copy to PO, CO 1 elec. copy to PO, CO	Within 30 calendar days after receipt of comments from the CDRC ESAG.
15.	Final Clinical Study Plan(s) for Additional Diagnostics and Final Clinical Study Protocol(s) for Additional Diagnostics	D.4.e.	1 hard copy to PO, CO 1 elec. copy to PO, CO	Within 16 calendar days after receipt of final comments from the Project Officer.
16.	Final Data Management and Quality Control Plan	E.2	1 hard copy to PO, CO 1 elec. copy to PO, CO	Within 15 calendar days after review of this Plan by the PO.

17.	Annual Institutional Review Board (IRB) Approval	F.3.	1 hard copy to PO, CO 1 elec. copy to PO, CO	As soon as such documentation is available for each protocol.
18.	Safety Monitoring Reports	F.4.	As outlined in each protocol.	
19.	Final Clinical Study Reports	F.5.	1 hard copy to PO, CO 1 elec. copy to PO, CO	Within 60 calendar days after the completion of each clinical study.
20.	Audit Reports	F.6.a	1 hard copy to PO 1 elec. copy to PO	Within 15 calendar days following completion of each audit.
21.	Agenda, meeting materials and summaries for Annual Contract Review Meetings	I.2.a. I.2.b	1 elec. copy to PO	Agenda and meeting items must be distributed at least 10 calendar days prior to the meeting. Summaries are due within 30 calendar days after the conclusion of each meeting.
22.	Agenda, meeting materials and summaries of Other meetings/ teleconferences	I.2.c.1 I.2.c.3	1 elec. copy to PO	Agenda and meeting items must be distributed at least 10 calendar days prior to the meeting. Summaries are due within 30 calendar days after the conclusion of each meeting or teleconference.
23.	DRAFT Transition Plan	M.1	1 hard copy to PO, CO 1 elec. copy to PO, CO	No later than 6 months prior to the completion date of the contract.
24.	FINAL Transition plan	M.2	1 hard copy to PO, CO 1 elec. copy to PO, CO	Within 30 calendar days after receipt of the Project Officer Comments on the Draft Transition Plan or 90 calendar days prior to the completion date of the contract (whichever is the earliest date).

ATTACHMENT 6: ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS, FORMAT FOR TECHNICAL PROPOSAL, and TABLE OF CONTENTS

Tuberculosis Clinical Diagnostics Research Consortium (CDRC)
RFP NIAID-DMID-NIHAI2008026

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 RFP and provide specific instructions and formatting for the Technical Proposal. While Section L.2.b. of the RFP 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 RFP. 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 Statement of Work, all reference materials, and attachments, the Technical Evaluation Criteria in Section M, and the RFP 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 250 pages including all appendices and attachments. Any pages in excess of this limit will be expunged from the proposal and will not be considered in the technical review.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1:

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

SECTION 2: TECHNICAL PROPOSAL OVERVIEW (suggested 3-page maximum – included in total page limitations)

Provide an overview of the proposed CDRC, including brief descriptions of the following:

A. Activities to be performed by the offeror and those that shall be performed by all proposed subcontractors, including the identification of the proposed subcontractors and a list of key personnel of the offeror and the proposed subcontractors with degrees and titles.

B. Proposed clinical study sites; study populations available at those sites; and any co-morbid infections, including non-tuberculosis mycobacteria and other mycobacterial pathogens, typically prevalent in the population.

C. Facilities and other resources to be made available by the offeror and all proposed subcontractors.

D. The two investigational diagnostics proposed to be tested in the initial phase of the contract.

SECTION 3: TECHNICAL PLAN/APPROACH

A. Establishment and Maintenance of the Tuberculosis Clinical Diagnostics Research Consortium

1. Clinical Study Sites

a. Describe the organizational experience and capabilities of the proposed clinical study sites to participate in CDRC clinical studies. For each proposed clinical study site, include the following:

1) *General Clinical Site Characteristics*: Length of time the organization has been in operation, length of time the organization has been diagnosing and treating adult and pediatric patients with TB, and the size and composition of the organization's clinical staff involved in TB diagnosis and treatment.

2) *Local Health Care Practices*: A description of the current technologies and methods utilized to confirm suspected TB and/or drug resistance, and local health care practices that will influence the choice of investigational diagnostics, the design of CDRC clinical studies, and the utility and applicability of the results of CDRC clinical studies with respect to treatment decisions and practices in the TB-endemic country. Also identify and describe the existing relationships between each proposed clinical study site and local TB control programs.

3) *Organizational Experience*: Documentation of organizational experience over the past 5 years relevant to the scope of clinical research to be carried out by the CRDC. Include the following:

a) a list of all relevant clinical studies completed, ongoing and in development indicating: experimental product/device/test evaluated; duration; study population and sample size; key design features; number and location of participating clinical sites and number of subjects completing the study at the proposed CDRC clinical study site; status; sponsor; and if publicly available, a brief summary of the major findings/outcomes;

b) a description of the role of the organization in protocol design, development and analysis for each clinical study identified;
c) identification of any ongoing and/or future clinical studies suitable for incorporating CDRC diagnostic protocols;
d) experience in obtaining clearances from in-country human subject review boards; and
e) adherence to GCP and local regulations governing the safe and ethical conduct of research involving human subjects, including the results of any audits conducted over the past 5 years.

4) *Access to Study Participants*: A description of the size and composition of:

a) the local adult and pediatric populations eligible for participation in CDRC clinical studies, and
b) the adult and pediatric patients being served by the clinical site. Include individuals with co-infections and co-morbid conditions, individuals with exposure to other mycobacterial diseases, such as leprosy, and individuals who have received childhood vaccination with BCG.

5) *Study Participant Recruitment and Retention*: Provide a plan for the recruitment and retention of study participants, including collaborative arrangements with local investigators, clinicians and institutions to serve as a source of referrals; identify anticipated recruitment and retention problems and provide recommendations for overcoming or minimizing such problems.

b. Describe proposed plans for:

1) determining the need for additional clinical study sites based on the specific type of investigational diagnostic to be evaluated, availability of and access to appropriate study populations, and other factors,
2) identifying potentially qualified organizations, and
3) assessing the adequacy and appropriateness of site experience, qualifications, capabilities and access to necessary study populations.

c. Describe proposed plans to serve as a resource to the TB research community to provide advice and support for moving TB diagnostics forward in the clinical setting.

2. CDRC Data Management Center

a. *Clinical Database System*:

1) Describe the proposed clinical database system and its capacity to provide the features specified in the Statement of Work, including security against potential data loss.

2) Provide proposed policies and procedures for the collection, management, quality control and reporting of all clinical study data, training of clinical study site personnel, and required interactions with and coordination among clinical study sites to obtain and verify study data.

3) Describe organizational experience over the past 5 years in providing data management services for projects of similar size, scope and complexity, particularly

projects involving multi-national collaborations and foreign sites in resource-limited countries. Include a description of database systems established and maintained; identify the number and geographic locations of the participating clinical sites; and describe training activities conducted for clinical site personnel and methods employed to ensure appropriate interaction with and among clinical sites. In addition, discuss problems and deficiencies encountered in ensuring the timeliness, completeness and accuracy of clinical data, particularly for foreign clinical sites in resource-limited countries, and actions implemented to correct deficiencies and resolve/minimize problems.

b. *Statistical Design and Analysis*:

1) Describe plans for the provision of statistical design and analysis assistance for CDRC clinical protocols, including the integration of such assistance into the CDRC's collaborative protocol design and development process.

2) Describe organizational experience over the past 5 years in providing statistical design and analysis assistance to clinical investigators for projects of similar size, scope and complexity involving studies of human TB with an emphasis on protocols for investigational diagnostics and multi-national collaborative studies involving foreign sites in resource-limited countries. Include a list of clinical protocols for which statistical design and analysis assistance has been provided over the past 5 years, indicating: investigational product/device/test; sample size and number and location of participating sites; overall study design; duration; status (completed, ongoing or in development); and, if publicly available, a brief summary of the results of final study analyses performed.

3) Identify and discuss methodological considerations, challenges, and potential limitations in statistical design and analysis for clinical studies of investigational TB diagnostics conducted in TB-endemic countries. Include a discussion of the impact of current clinical diagnostic algorithms and local health care practices. In addition, provide recommendations for minimizing or overcoming such challenges and limitations, and discuss the level of data quality required to provide information to improve further diagnostic development and to maximize the suitability of new diagnostic tools for use in TB-endemic countries.

B. Solicitation, Review, Prioritization and Approval of Proposals for CDRC Diagnostic Studies

Provide a plan for the solicitation, review and prioritization of proposals to evaluate diagnostics submitted to the CDRC by third parties. Include descriptions of the following:

1. The process for soliciting proposals, including descriptive materials, frequency of solicitations and target audiences.
2. The submission process, including documentation required.
3. The review process, including timelines and criteria to be used to assess scientific, clinical and technical merit and feasibility.
4. The prioritization process to be used to make recommendations on the order in which diagnostic clinical studies should be conducted.

C. Clinical Study Protocols

1. Protocol Development

   a. Describe the offeror's organizational experience over the past 5 years in designing and developing protocols of similar size, scope and complexity for clinical studies of human TB, particularly for multi-national studies of TB diagnostics in TB-endemic countries. Include a list of all relevant clinical studies, completed, ongoing and in development, for which the offeror has served as lead or has played a major role with respect to protocol design/development. For each study identified, indicate:

      1) experimental product/device/test evaluated;
      2) duration;
      3) study population and sample size;
      4) key design features;
      5) number and location of participating clinical study sites;
      6) status;
      7) sponsor; and
      8) responsibilities for protocol design/development.

   b. If publicly available, briefly summarize the findings/outcomes of the clinical studies identified.

   c. Describe the process to be used to provide for substantial involvement of clinical study site investigators and clinicians from TB-endemic countries in the development of CDRC protocols and protocol-related documents, including their role on Protocol Teams, and to address current health care practices in the context of protocol design. Also identify problems or obstacles that may be encountered by using a collaborative, multi-institutional protocol development process and recommend approaches for resolving or minimizing such problems and obstacles.

2. Clinical Study Plans and Protocols for Initial Diagnostics

   a. Provide Clinical Study Plans for two investigational diagnostics proposed for evaluation by the CDRC, which should include abbreviated Clinical Study Protocols. Clinical Study Protocols are limited to a maximum of 25 pages each *[to be included in the total page limitations]* and should provide sufficient detail to allow for evaluation of feasibility, relevance and soundness. Offerors are encouraged to utilize protocol templates and other protocol development tools available at: http://www3.niaid.nih.gov/research/resources/DMIDClinRsrch/ to develop Clinical Study Protocols. Clinical Study Protocols submitted as part of the Technical Proposal may serve as the basis for final study protocols or may undergo significant revision post-award and prior to approval by the Project Officer for implementation by the CDRC.

      For each of the two initial diagnostics, the Clinical Study Plan and Protocol should include the following:

      1) a detailed description of the investigational device or assay;
      2) if applicable, a summary of how the technology has been used in a diagnostic setting for any other pathogens or diseases;
      3) data demonstrating preliminary specificity and sensitivity against the target organism(s), including any relevant data from laboratory studies;

4) data to demonstrate appropriate quality assurance of the prototype
5) the scientific basis/rationale for testing the specific diagnostic modality
6) study design, including:

    a) rationale for the proposed study population(s);
    b) sample size and justification;
    c) inclusion and exclusion criteria;
    d) study control/comparator groups;
    e) study endpoints;
    f) any confounding variables, e.g., co-infections and co-morbid conditions;
    g) type and quantity of clinical specimens to be collected;
    h) schedule of events;
    i) safety assessments (elements and time points) and safety monitoring plan; and
    j) statistical analysis plan

7) proposed clinical study sites; documentation of availability of and access to study participants, including published and expected epidemiological data to demonstrate access to sufficient numbers of patients; and a plan for the recruitment and retention of study participants
8) a description of the clinical diagnostic algorithms utilized by the proposed clinical study sites and how the investigational technology is expected to improve TB diagnosis and/or identification of drug resistance in the host countries
9) laboratory support services and technical personnel necessary to conduct the proposed clinical study
10) a discussion of how the proposed clinical study can be expected to yield novel data, contribute to direct improvements in the further design and testing of the investigational diagnostic, and/or improve the feasibility of implementation of the investigational diagnostic
11) proposed timelines for all clinical study activities, including protocol development, obtaining clearances from in-country human subject review boards, study completion and analysis of final study data
12) a description of any proposed collaborations with academia and/or industry, including the conduct of proposed clinical studies in conjunction with planned or ongoing clinical trials supported through other mechanisms and sponsored by other entities, and a description of how such collaborations will be legally controlled.
13) identification of the source of the investigational diagnostic and consortium agreement dictating terms for product availability and intellectual property agreements, where appropriate
14) identification of in-country collaborators, including local TB control programs, and letters of collaboration with all such in-country entities

D. Protocol Implementation, Management, Oversight, Reporting and Analysis

1. Provide a plan for the oversight of CDRC clinical studies, including: (a) adherence to regulatory requirements and protocol-specific requirements and procedures; (b) maintaining currency in GCP; (c) the provision of protocol-specific training for clinical site personnel; (d) data management and quality control of study data; and (e) assuring compliance with biosafety requirements.

2. Describe proposed policies and procedures to be implemented to ensure the timely initiation and completion of CDRC studies and how real and potential problems in study progress will be identified and corrected.

3. Describe potential circumstances under which requests for modifications in originally proposed timelines may be justified.

E. Publications, Presentations and Data Dissemination

1. Describe proposed approaches and methods for disseminating data and major findings/conclusions resulting from CDRC studies, in accordance with agreements with third party suppliers, to the research community as a whole to improve the development of TB diagnostics and the effectiveness of the implementation of new TB diagnostics in the clinic.

2. Describe proposed approaches to and avenues for interacting with scientific groups, including other NIAID TB contractors, to maximize resources and provide advice to investigators outside of the contract to aid in the development and clinical implementation of new TB diagnostics.

SECTION 4: SCIENTIFIC AND TECHNICAL PERSONNEL

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

A. Principal Investigator (PI): include experience, qualifications and knowledge of the PI with respect to: planning, managing, and directing multi-national collaborative clinical research projects involving multiple clinical study sites and centralized data management services; designing, implementing and overseeing multi-national collaborative clinical studies of TB diagnostics conducted in TB-endemic countries and within the local health care practices and clinical diagnostic algorithms of those countries; diagnostic development and the requirements for moving an investigational diagnostic into the clinical setting; and the ability to serve as a resource to the TB research community to provide advice and support for moving TB diagnostics forward in the clinical setting.

B. Other Scientific and Technical Personnel:

Include the following proposed other scientific and technical personnel, provide documentation of licensure in the state/country where clinical studies will be conducted for all proposed physicians, document current GCP training for all proposed clinical study personnel, and document appropriate biosafety training and experience for all proposed personnel working with pathogenic mycobacteria and possibly blood-borne pathogens.

1. Clinical Study Site Personnel, including: Lead Clinical Investigators, other clinical site investigators, nurse coordinators, laboratory technicians and data entry personnel.

2. CDRC Data Management Center Personnel, including: statisticians, database management personnel for quality assurance/quality control of clinical and laboratory data, and Information Technology (IT) personnel for database maintenance and security against anticipated risks.

3. Other scientific and technical personnel of the offeror to participate in multiple functions, including: evaluation of investigational diagnostics proposed by third parties; protocol design and development; management, oversight and reporting for CDRC clinical studies; conduct of assays and analyses; and IT support.

SECTION 5: FACILITIES, EQUIPMENT AND OTHER RESOURCES

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

A. Location and features of facilities, including a floor plan and a list of equipment and resources dedicated to the project, for the offeror and all proposed subcontractors (lease or ownership information should be provided). This includes: (1) clinical study site research facilities and equipment for patient screening, enrollment, administration of investigational diagnostics and safety monitoring, access-controlled storage facilities for confidential clinical records, laboratory facilities for performance of protocol-required tests, and facilities for labeling and storage of clinical specimens; (2) laboratory facilities of the offeror for conducting assays and analyses; and (3) the central data management facility and off-site back-up facility.

B. Identification and description of ALL support resources (including Information Technology systems) which will be required to effectively complete the SOW.

C. Documentation of the safety of all facilities and equipment in accordance with the most recent Guidelines for Biosafety in Microbiology and Biomedical Laboratories (BMBL) and a thorough summary of safety practices to be utilized to assure a safe working environment for all personnel handling or in contact with pathogenic mycobacteria.

SECTION 6: PROJECT MANAGEMENT

A. Provide a plan for project organization, staffing, and management in relation to the planning, initiation, implementation, conduct, monitoring and completion of tasks identified in the Statement of Work.

B. Describe in detail the responsibilities and level of effort for all proposed personnel who will be assigned to the contract, including proposed subcontractors and consultants.

C. Provide an administrative and technical framework indicating clear lines of authority and responsibility for all proposed personnel.

D. If consultants and/or subcontractors are proposed, include a plan to manage, coordinate, and oversee the work performed by consultants and/or subcontractor(s).

E. Include a chart of the proposed organizational/management structure for the project.

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

G. Outline how the PI will communicate with the Project Officer and the Contracting Officer and how the PI will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).

SECTION 7: OTHER CONSIDERATIONS

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.

A. 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.

B. Biological Agents or Toxins

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

C. Obtaining and Disseminating Biomedical Research Resources

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

D. 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 RFP.

E. 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 RFP.

ATTACHMENT 7: UNIFORM COST ASSUMPTIONS

Tuberculosis Clinical Diagnostics Research Consortium (CDRC)
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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 RFP is intended to provide uniform cost assumptions and business clarifications.

Offerors are advised to give careful consideration to the Statement of Work, all reference material provided as attachments, the Technical Evaluation Criteria, and, the RFP as a whole, in the development of your proposal. The information requested in these instructions should be used as a guide for the development and formatting of your Business Proposal. Offerors should consider and include the information requested here, as well as **any other** information which will benefit the proposal.

BUSINESS PROPOSAL – TABLE OF CONTENTS

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

SECTION 2 – COST OR PRICE SUPPORT

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

SECTION 3 – UNIFORM COST ASSUMPTIONS

A. Technical Cost Assumptions

Assume 2 additional clinical diagnostic studies will be performed per year, depending on size and complexity of proposed study.

B. Travel and Meetings/Teleconferences

Assume:

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

2. One trip per year to Bethesda, MD for one and one-half days with five contract personnel to meet with the NIAID Project and Contracting Officer.

3. Attendance at a total of three meetings (two domestic and one international) per year for four-day trips for two contract personnel each to present contract data at scientific and collaborative meetings or conferences.

4. Travel and per diem for a maximum of four contract personnel to live and work at non-U.S. contract sites at one time. Include travel for data management and clinical exchange personnel to train or work in TB endemic countries under "other travel."

5. Travel and per diem for three domestic and two international experts who serve as members of the TB CDRC External Scientific Advisory Group to attend one annual contract meeting in Bethesda, MD with NIAID staff. Government-published allowances (http://www.gsa.gov/Portal/gsa/ep/home.do?tabId=0) for lodging and per-diem shall be used.

6. Four, three-day clinical site monitoring visits per year to non-U.S. clinical trial sites.

7. A minimum of one multi-line teleconferences each month to update the NIAID Project Officer on contract performance and potential issues.

C. Government Furnished Equipment (GFE)

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

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

A. 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.

B. 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.

C. Past Performance Data (including references)

Section L of the RFP specifies the minimum documentation requirements for providing past performance information. This information should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.