SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1. Purchase Authority: Public Law 92-218 as amended		
2. **Request for Proposal (RFP) No.** BAA-NIAID-DAIDS-NIHAI2008027	3. **Issue Date:** August 1, 2008	4. **Set Aside:** [X] No [ ] Yes See Part IV Section L
5. Title : Rapid HIV Point-of-Care Diagnostic Device for Resource-Limited Settings		
6. ISSUED BY: Office of Acquisitions National Institute of Allergy and Infectious Diseases National Institutes of Health 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612		7. SUBMIT OFFERS TO: See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.
8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 3:00 P.M. local time on December 2, 2008. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.		
9. THIS SOLICITATION REQUIRES DELIVERY OF PROPOSALS TO THE OFFICIAL POINT OF RECEIPT. FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY, THE ADDRESS PROVIDED FOR THE OFFICE OF ACQUISITIONS AS STATED IN ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL" SHOULD BE NOTED. 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.		
10. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. http://www.ccr.gov		
11. FOR INFORMATION CALL: Contract Specialist PHONE: 301-496-0612 e-MAIL: Butlerce@niaid.nih.gov COLLECT CALLS WILL NOT BE ACCEPTED.		
		Eileen Webster-Cissel Contracting Officer Office of Acquisitions National Institute of Allergy and Infectious Diseases

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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

This BAA solicitation for Rapid HIV point-of-care Diagnostic Device for resource-limited settings (hereinafter referred to as rapid virus test) seeks to fund a consortium of scientists with a breadth of complementary skills and expertise in clinical HIV research, the associated molecular technology, diagnostics, validation testing, GMP manufacturing and project management to develop a simple to use, rapid, point-of-care (POC) HIV diagnostic devices with candidate vaccine constructs and developed vaccine-induced antibodies in the absence of true HIV-1 infections and HIV-infected infants. The diagnostic technology must demonstrate feasibility for use in resource-limited settings and in POC clinics without the use of supporting laboratory equipment such as centrifuges, vortexes or pipettes. In addition, if proposed testing requires processing of patient samples for downstream applications, the processing must be self-contained and require limited sample manipulation and safe containment of potentially infectious material. The output should be in a visual format, without ambiguity, and include a full process negative and internal positive control. It is anticipated that 1 to 2 cost reimbursement, completion type contracts will be awarded on August 3, 2009 for a period of up to five years for the base period and options in years 3 and 4 for additional services; studies for a similar device to make limited treatment decisions based on viral load.

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

a. The estimated cost of this contract is $_____.

b. The fixed fee for this contract is $_____. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer, and subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract. Payment of fixed fee shall not be made in less than monthly increments.

c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee, is $_____.

d. Total funds currently available for payment and allotted to this contract are $_____, of which $_____ represents the estimated costs, and of which $_____ represents the fixed fee. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses.

e. It is estimated that the amount currently allotted will cover performance of the contract through _____.

f. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

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 he 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 14 calendar days prior to the issuance of the press release.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

SEE NEXT PAGE

ARTICLE C.1. STATEMENT OF WORK

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

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in hard copy format. In addition, one (1) hardcopy of each report shall be submitted to the Contracting Officer, unless otherwise specified.

a. **Technical Progress Reports**

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

   For proposal preparation purposes only, it is estimated that in addition to the required electronic version(s) 1 hard copies of these reports will be required as follows:

   [ ] Monthly
   [X] Quarterly
   [ ] Semi-Annually
   [X] Annually
   [ ] Annually (with a requirement for a Draft Annual Report)
   [X] Final - Upon final completion of the contract
   [ ] Final - Upon final completion of the contract (with a requirement for a Draft Final Report)

2. **Summary of Salient Results**

   The Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This report will be required on or before the expiration date of the contract.

3. **Goals and Milestones Achievement Reports**

   To facilitate the monitoring of contract progress, milestones and their expected accomplishment dates will be re-established annually by discussion and agreement between the Project Officer and the PI; these milestones will not be written into the contract document. The Contractor shall submit Goals and Milestones Achievement Reports for these milestones during the contract period as specified by consultation with the Project Officer. For for-profit Contractors, since the payment of contract fee portions will be tied to the accomplishment of predetermined goals and fee-based milestones specified in the contract, the Contractor shall submit similar Goals and Milestones Achievement Reports for fee-attached milestones prior to invoicing for fee payments. Some management milestones may also be fee-based and, in that case, only one report will be required to cover both.

The original hard copy of each milestone achievement report shall be submitted to the Contracting Officer, and 1 hard copy and 1 electronic copy to the Project Officer. Each report must consist of:

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

2) Reports shall include at a minimum:

a) Section A - An introduction describing the goal or milestone in detail

b) Section B - A complete description of the results. The description shall include pertinent data and/or figures in sufficient detail to explain any significant results from analysis and scientific evaluation of data accumulated to date under the goal or milestone.

4. **Annual Site Visit Review Report**

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

5. **Source Code and Object Code**

Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

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 expiration 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 expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
National Institutes of Health
National Institute of Allergies and Infectious Diseases
Office of Acquisitions
6700-B Rickledge 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. If special instructions regarding packaging, marking and shipping are required, these will be developed after receipt of proposals as a result of finalization of the Statement of Work during negotiations. Special instructions, if applicable, will be provided to offerors in the Attachment entitled "Additional Technical Proposal Instructions."

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 AIDS
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Bethesda, Maryland 20892

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

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

FAR Clause ***52.246-9, 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 Description 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:

a. 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:

Item	Reports	Recipients	Delivery Schedule
1.	Quarterly Progress Report	1 original to CO 1 elec. copy to PO and CO	First report required after 3 full calendar months. A Quarterly Progress Report shall not be submitted when an Annual Progress Report is due.
2.	Annual Progress Report	1 original to CO 1 elec. copy to PO and CO	Annually; due on/before 15 th day after the anniversary date. An Annual Progress Report is not due when the Final Report is due.
3.	Final Invention Statement	1 electronic copy to CO	Due on/before completion date of the contract.
4.	All reports and documentation including the invention disclosure report, the confirmatory license, and the government support certification	1 electronic copy to OPERA	As required by FAR Clause 52.227-11.
5.	Final Report and Summary of Salient Results	1 original to CO 1 electronic copy to CO and PO	The summary of salient results (not to exceed 200 words) achieved during the performance of the contract and due with the Final Report. Final Report is due on/before the completion date of the contract.
6.	Goals and Milestones Achievement Reports	1 original to CO 1 electronic copy to CO and PO	Specific dates will be negotiated with the PO
7.	Annual Site Visit Review Report	1 original to CO 1 electronic copy to CO and PO	Within 3 weeks follos

b. The above items shall be addressed and delivered to:

Addressee
Project Officer National Institute of Allergies and Infectious Diseases, Division of AIDS National Institutes of Health 6700-B Rockledge Drive Bethesda, Maryland 20892-7612

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 Project Officers will be specified prior to award:

Project Officer
NIH/NIAID
6700-B Rockledge Dr., Room 5130, MSC 7628
Bethesda, MD 20892-7628
301-496-0612

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 is considered to be essential to the work being performed hereunder:

Name	Title

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
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 National Institute of Allergies and Infectious Diseases .

   b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NIAIDOAInvoices@niaid.nih.gov .

   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.

PAYMENT PHONE

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

c. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H of the above referenced contract."

ARTICLE G.4. INDIRECT COST RATES

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

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

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

ARTICLE G.5. GOVERNMENT PROPERTY

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

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

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) shall be submitted at a minimum of one every two years.

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

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

b. Electronic Access to Contractor Performance Evaluations

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

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

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

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

ARTICLE H.2. HUMAN MATERIALS

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

ARTICLE H.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. 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.5. 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.6. 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.7. 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.8. 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.9. 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.10. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-8, Option to Extend Services set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost of the contract will be increased

as set forth in the ESTIMATED COST [plus fixed fee] of the contract will be increased as set forth in the ESTIMATED COST [PLUS FIXED FEE] Article in SECTION B of this contract.

ARTICLE H.11. 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 due on the following dates for the entire life of this contract:

   April 30th
   October 30th
   Expiration 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:

webstere@niaid.nih.gov
Contracting Officer

ARTICLE H.12. 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

[ ] Administrative, Management and Support Information

[X] Mission Based Information

b. Security Categories and Levels

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

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

c. Position Sensitivity Designations

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:

N/A

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.13. CONFIDENTIALITY OF INFORMATION

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

Confidential information, as used in this clause, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

(b) In addition to the types of confidential information described in paragraph (a) of this clause, information which might require special consideration with regard to the timing of its disclosure may derive from studies or research, during which public disclosure of preliminary unvalidated findings could create erroneous conclusions which might threaten public health or safety if acted upon.

ARTICLE H.14. 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 Allergies and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. _____"

ARTICLE H.15. 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.16. SHARING RESEARCH DATA

[The data sharing plan submitted by the Contractor is acceptable/The Contractor's data sharing plan, dated 08/03/2009 is hereby incorporated by reference.] The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to serve health. this contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

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

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

ARTICLE H.17. 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.18. 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.19. REGISTRATION FEES FOR NIH SPONSORED SCIENTIFIC, EDUCATIONAL, AND RESEARCH-RELATED CONFERENCES

In accordance with the NIH Reform Act of 2006, P.L. 109-482, the NIH may authorize a Contractor procured to assist in the development and implementation of a scientific, educational or research-related conference to collect and retain registration fees from Non-HHS Federal and Non-Federal participants to defray the costs of the contract.

Whenever possible, the Contracting Officer, prior to each conference, shall provide the Contractor with uniform assumptions of the government's estimate of the registration fee offset to include in the costs estimate for the conference. This offset should be deducted from the total cost of the conference.

Prior to each conference, the Contractor shall submit a completed "Contractor Pre-Conference Expense Offset Worksheet" (Attachment provided in SECTION J) to the Project Officer and Contracting Officer. After the conference is held, the Contractor shall submit a completed "Post-Conference Expense Offset Worksheet" (Attachment provided in SECTION J) to the Project Officer and Contracting Officer.

The Contractor shall collect and maintain current and accurate accounting of collected conference fees and conference expenses. The Contractor shall immediately notify the Project Officer and Contracting Officer, in writing, if it appears the total registration fees collected will exceed the estimated total cost of the conference. If the registration fees collected are in excess of the total actual conference expenditures, the contractor shall return the excess funds to the Contracting Officer to be deposited as miscellaneous receipts into the U.S. Treasury.

If the registration fees collected are in excess of the uniform assumptions provided by the Contracting Officer, the Contracting Officer, shall, as necessary, modify the contract price to reflect the decrease in conference costs. If the registration fees collected are less than the uniform assumptions provided by the Contracting Officer, the Contracting Officer shall, as necessary, modify the contract price to reflect the increase in conference costs.

Although Contractors may bill for allowable conference costs as they are incurred, they may not submit a final invoice for the total costs of the conference until the "Post-Conference Expense Offset Worksheet" has been approved by the Project Officer.

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

General Clauses for a Cost-Reimbursement Research and Development Contract

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

a. FAR 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. FAR Clause **52.227-14, Rights in Data-General** (December 2007) is deleted in its entirety.

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

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

1. FAR Clause **52.203-13, 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 **52.217-9, Option to Extend the Term of the Contract** (March 2000).

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

   "c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 7 YEARS."

5. 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."

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

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

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

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

10. **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:

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

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

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

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

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

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

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

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

19. 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 **352.333-7001, 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).*

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)

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 BAA
Attachment 2:	Proposal Intent Response Sheet	Attached to BAA
Attachment 3:	Broad Agency Announcement Description	Attached to BAA
Attachment 4:	Broad Agency Announcement Background and Introduction	Attached to BAA
Attachment 5:	Research and Technical Objectives	Attached to BAA
Attachment 6:	Reporting Requirements and Other Deliverables	Attached to BAA
Attachment 7:	Additional Technical Proposal Instructions	Attached to BAA
Attachment 8:	Uniform Cost Assumptions	Attached to BAA

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
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:	Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 12:	Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Attachment 13:	Small Business Subcontracting Plan	http://www.hhs.gov/osdbu/read/SampleSubcontractingPlan.doc
Attachment 14:	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 15:	Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Attachment 16:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 17:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 18:	Safety and Health, HHSAR Clause 352.223-70	http://rcb.cancer.gov/rcb-internet/forms/safety&health-1-06.pdf
Attachment 19:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Attachment 20:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf
Attachment 21:	Commitment to Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Attachment 22:	Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Attachment 23:	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 541712.
2. The small business size standard is 500.

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

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

It is anticipated that one award will be made from this solicitation and that the award will be on/about AUGUST 3, 2009.

It is anticipated that the award from this solicitation will be a multiple-year Cost-Reimbursement type Completion contract with a Period of Performance of five years, and that incremental funding will be used (See Section L.2.c. Business Proposal Instructions).

d. **ESTIMATE OF EFFORT**

In accordance with the Broad Agency Announcement (BAA) design, the Government has issued a general announcement of the agency's research interest. Submissions in response to this BAA will represent each offeror's creative and innovative approach to the specific research. Therefore, the Government is unable to provide an estimate of effort but reminds all offerors that they shall propose effort that is consistent with the nature and complexity of their proposed research.

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 Institutes of Health
National Institute of Allergies and Infectious Diseases Room 3214
Bethesda, MD 20892 MSC 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.

a. Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).
b. Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
c. Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).
d. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
e. Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

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. **Evaluation of Proposals**

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

6. **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.

7. **Use of the Metric System of Measurement**

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

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

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

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

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

8. **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.

9. **Selection of Offerors**

a. The acceptability of the scientific and technical portion of each research and development 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. Based on the written recommendations of the technical review committee/peer review group/source evaluation panel, the Contract Officer will, in concert with Program Staff, establish an Order of Merit Ranking. This ranking will be based upon the scientific/ technical merit, scientific priority, programmatic balance, and the availability of funds.

2. Communications will be held with offerors whose proposals are the most highly rated. All aspects of the proposal are subject to discussion, including cost, technical approach, and contractual terms and conditions. At the conclusion of discussion, each offeror still being considered for award shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct limited negotiations to finalize details of the award with the selected source(s) in accordance with HHSAR 315.370.

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.

10. **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.

11. **Past Performance Information**

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

A list of the last 5 contracts completed during the past Three years and THE LAST 3 CONTRACTS AWARDED 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 that exceeds $650,000..

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.

12. ***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. *Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).*

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

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

1. Objectives

Offerors are required to provide a Statement of Work in accordance with the Attachment entitled "Research and Technical 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. 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. **Tech[X] Mission Based Information:nical Evaluation**

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

   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.

4. **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 Research and Technical Objectives Statement of Work (RTSOW) 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

      [ ] Administrative, Management and Support Information:

      [X] Mission Based Information:

Scientific and Technical Research and Innovation

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

NOTE: OFFERORS ARE REQUESTED TO SUBMIT THE ISSP WITH THEIR BUSINESS PROPOSAL.

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.

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.

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.

SECTION M - EVALUATION FACTORS FOR AWARD

1. **1. GENERAL**

   Proposals will be evaluated against the following four evaluation factors in the order of importance: technical, cost, past performance, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, cost/price, past performance, and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The estimated cost of an offer must be reasonable for the tasks to be performed and will be subject to analysis by the Government.

   The merit of each technical proposal will be evaluated by a peer review group. The Government reserves the right to convene multiple peer review groups to evaluate proposals. Offerors must demonstrate in their proposals that they have the necessary expertise and capabilities for conducting the proposed research. The evaluation will be based on the demonstrated capabilities of the Offerors in relation to the needs of the project as set forth in the BAA. Each proposal must demonstrate the feasibility of successful implementation of its approach and its relevance to the Research and Technical Objectives of the BAA. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria.

   Following the peer review, the Government will establish an Order of Merit Ranking of all proposals. Negotiations are conducted with Offerors selected from the Order of Merit Ranking to address identified weaknesses, questions, and areas for clarification, as well as to refine the proposed Statement of Work. The selection of proposals for award is based upon the evaluation factors, importance to the agency programs (programmatic balance), and fund availability.

   PRE-AWARD SITE VISIT OR SITE AUDIT

   Offerors selected for negotiations from the Order of Merit Ranking may be subject to auditing of their facilities and Quality Assurance/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 considered 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.

2. **EVALUATION OF OPTIONS**

   It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

   In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

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 order of merit ranking (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to 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.

CRITERIA	WEIGHT
CRITERION 1: SCIENTIFIC RATIONALE	**30**
A. Soundness of the scientific rationale for the development of the proposed diagnostic device including test-of-concept studies for HIV-1 and innovation of the proposed concept as an HIV POC diagnostic device for use in resource-limited settings. B. Soundness of the rationale for acceptability of the HIV POC diagnostic device for use in resource-limited settings.	
CRITERION 2: COMPREHENSIVE STRATEGIC DIAGNOSTIC DEVICE DEVELOPMENT PLAN	**30**
1) The suitability and feasibility of the proposed key objectives and milestones for optimizing the HIV POC diagnostic concept. 2) The soundness and feasibility of the proposed qualitative and quantitative criteria for deciding whether and when to proceed to the next phase of the product development process for submission of the HIV POC diagnostic device toward a FDA PMA. 3) The soundness, adequacy and feasibility of the proposed steps for development, characterization and qualification of reagents and assays for preclinical research including plans to ensure research conducted is not human subjects research according to NIH policies and guidelines. 4) The status of patents, intellectual property and licensing issues for the technology that will be used to complete all the contract objectives.	
CRITERION 3: TECHNICAL PLAN/APPROACH	**35**
A. Work Plan: 1) Suitability and appropriateness of the proposed approaches and methodologies to complete the tasks and stages outlined in the Comprehensive Strategic Diagnostic Device Development Plan and to comply with the specifications set forth in the Research and Technical Objectives section of this BAA. 2) Suitability and appropriateness of plans to overcome or reduce scientific and technical problems or obstacles, including plans for modifying key objectives and milestones based on adverse	

CRITERIA	WEIGHT
experimental or production results, or on new scientific findings along the development pathway . 3) Suitability and appropriateness of the plans for commercialization, as documented in the Offeror's Commercialization Plan and evidenced by the Offeror's record of successfully commercializing its prior research projects, and any other indicators of commercial potential for the proposed research. 4) Appropriateness of plans to ensure adequate training of end users in correct implementation of the proposed HIV POC diagnostic devise in resource-limited settings. B. Offeror's Proposed SOW: 1) The adequacy of the proposed Statement of Work to describe all the necessary activities, services, personnel, equipment and facilities to be provided by the Offeror and any proposed subcontractors to perform the proposed activities. 2) The suitability, completeness and timeliness of the list of deliverables provided in the proposed Statement of Work and the description of deliverables to be provided to the Government during the performance of the contract.	
CRITERION 4: QUALIFICATIONS OF PROPOSED SCIENTIFIC AND TECHNICAL PERSONNEL	**25**
A. Principal Investigator (PI): Adequacy and appropriateness of the education, training, experience, expertise and level of effort of the proposed PI with respect to planning, coordinating and directing a diagnostic product development project encompassing preclinical research, product manufacturing, and testing with clinical specimens. B. Other Scientific and Technical Personnel: Adequacy and appropriateness of the education, training (cGLP or GCLP, QA/QC, biosafety), experience, expertise and level of effort of other proposed scientific and technical personnel of the Offeror and all proposed subcontractors with respect to the following: design, conduct and analysis of studies to evaluate and optimize diagnostic products and their platforms; production of diagnostic products under cGMP; and design, conduct and analysis of clinical specimens of diagnostic products.	
CRITERION 5: FACILITIES, EQUIPMENT AND OTHER RESOURCES	**15**
Documented availability and adequacy of facilities, equipment, and other resources necessary to safely	

CRITERIA	WEIGHT
and successfully perform all phases of the proposed project, including: A. Adequacy of available facilities for the duration of the contract, including documentation/schematic of the floor plans, and resources to perform FDA-required validation studies, produce the diagnostic devices under GMP conditions and obtain, add or delete facilities as necessary due to progress or lack thereof during the course of product development B. Adequacy of plans for compliance with all safety guidelines and regulations, including training and monitoring of personnel for exposure to infectious and other hazardous materials. C. Adequacy of other research support resources (including Information Technology systems) that will be required to effectively complete the Offeror's proposed Statement of Work.	
CRITERION 6: PROJECT MANAGEMENT	**15**
A. Adequacy of the Project Management Plan in terms of staffing, organization, responsibilities, leadership and lines of authority including plans for PI communication with the Project Officer and the Contracting Officer, and lines of communication between all performance sites. B. Suitability of systems proposed for tracking project activities and monitoring progress, timelines and budgets.	
C. Suitability of the plan for soliciting, evaluating, negotiating, awarding and managing any proposed subcontractor in accordance with Federal regulations including identifying and remediating problems in subcontractor performance. D. Suitability of the plan to organize Annual Review Meetings and provide for a thorough assessment of contract status, problems and approaches to their resolution, and future plans. E. Adequacy of the plan to protect and share confidential information with Independent External Advisory Group members. F. Completeness of Letters of Understanding between collaborating parties to address intellectual property, facilitate development of commercialization, and resolve disputes.	

CRITERIA	WEIGHT
TOTAL POSSIBLE POINTS:	**150**
EVALUATION OF OPTIONS	**10**
The soundness and appropriateness of the proposed synopsis of plans to further develop the HIV POC diagnostic device to perform additional studies for expanded viral load detection, including deviations in technology and timeline for completion .	
TOTAL POSSIBLE WEIGHT (with Options):	**160**

Other Factors:

- EVALUATION OF DATA SHARING PLAN
- EVALUATION OF FOREIGN CURRENCY OFFERS, FAR 52.225-17, (FEBRUARY 2000)

Use when foreign currency offers are anticipated and allowed. This factor describes the currency conversion procedures.

- PAST PERFORMANCE FACTOR
- EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION
- SUBCONTRACTING PROGRAM EVALUATION CRITERIA

Use when additional evaluation of the Offeror's subcontracting program is warranted and desired.

5. **PAST PERFORMANCE FACTOR**

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

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

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

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

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

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

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

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

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

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

Offers will be evaluated on the following sub-factors:

a. Extent to which SDB concerns are specifically identified

b. Extent of commitment to use SDB concerns

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

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

PACKAGING AND DELIVERY OF THE PROPOSAL

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

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

A. EXTERNAL PACKAGE MARKING:

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

"**BAA-NIAID-DAIDS-NIHAI2008027 Rapid HIV Point-of-Care Diagnostic Device for Resource-Limited Settings"**

"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
Cecil Butler, III Office of Acquisitions, DAIDS, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20817	Cecil Butler, III Office of Acquisitions, DAIDS, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612

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

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

C. NUMBER OF COPIES:

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

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

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

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

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

CREATING AND NAMING ELECTRONIC FILES:

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

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

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

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

3. CDs should be named using the following format:

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

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

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

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

Document	Number of Copies	Page Limits
Technical Proposal and all Appendices	**PAPER** One (1) unbound SIGNED ORIGINAL. Four (4) unbound COPIES **ELECTRONIC FILES ON CD** Fifteen (15) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices)	**Not to Exceed 150 pages (inclusive of all Attachments and Appendices)**
Business Proposal	**PAPER** One (1) unbound SIGNED ORIGINAL. Four (4) unbound COPIES **ELECTRONIC FILES ON CD** Fifteen (15) 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 Technical Proposal Cost Summary to access the Excel Workbook.**	N/A

PROPOSAL INTENT RESPONSE SHEET

RFP No.: BAA-NIAID-DAIDS-NIHAI2008027
RFP Title: Rapid HIV Point-of-Care Diagnostic Device for Resource-Limited Settings

Please review the attached Request for Proposal. Furnish the information requested below and return this page by **November 3, 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: Cecil Butler, III
BAA-NIAID-DAIDS-NIHAI2008027
FAX# (301) 402-0972
Email: Butlerce@niaid.nih.gov

ATTACHMENT 3: BROAD AGENCY ANNOUNCEMENT DESCRIPTION

RAPID HIV POINT-OF-CARE DIAGNOSTIC DEVICE FOR RESOURCE-LIMITED SETTINGS
NIAID-DAIDS-BAA-NIHAI2008027

BROAD AGENCY ANNOUNCEMENT INFORMATION

You are invited to submit a proposal in accordance with the requirements of this BROAD AGENCY ANNOUNCEMENT (BAA). The BAA is authorized by Federal Acquisition Regulation (FAR) 6.102 and further described in FAR 35.016 as well as the NIH Policy Manual, Manual Chapter 6035, Broad Agency Announcements. A BAA may be used as a solicitation mechanism for basic and applied research directed toward advancing the state-of-the-art or increasing knowledge or understanding and that part of development not related to the development of a specific system or hardware procurement. BAA's are general in nature identifying areas of research interest and shall only be used when meaningful proposals with varying technical/scientific approaches can be reasonably anticipated.

Offers submitted in response to this BAA must present detailed technical and business proposals designed to meet the Research and Technical Objectives described. The Statement of Work, including the specific technical requirements and performance specifications, is developed and proposed by the Offeror, not the Government.

Proposals are NOT evaluated against each other since they are not submitted in accordance with a common Statement of Work issued by the Government. Instead, Research and Technical Objectives are provided in the BAA that describe the research areas in which the Government is interested. Proposals received in response to the BAA are evaluated in accordance with Evaluation Factors for Award specified in Section M. The NIAID will assess whether the work proposed should be redirected, removed, and/or whether schedule or budget adjustments should be made. As a result, during discussions with Offerors, the NIAID reserves the right to modify or delete proposed milestones, decision points, research plans, process, schedule, budget or product. The selection of proposals for award is based upon the evaluation factors, importance to the agency programs (programmatic balance), and fund availability.

The NIAID estimates awarding $1.5 million in total costs (direct plus indirect) per base year of the contract for all awards. However, it is anticipated that the total cost for the award(s) may vary depending upon the scope of the project and the technical objectives of the award(s). The length of time for which funding is requested should be consistent with the nature and complexity of the proposed research. The period of performance proposed by an Offeror should not exceed 5 years.

ATTACHMENT 4: BACKGROUND and INTRODUCTION

RAPID HIV POINT-OF-CARE DIAGNOSTIC DEVICE FOR RESOURCE-LIMITED SETTINGS
NIAID-DAIDS-BAA-NIHAI2008027

The National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) supports and conducts research that strives to understand, treat and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives. NIAID supports extramural research to control and prevent diseases caused by virtually all infectious agents. This includes basic biomedical research, such as studies of microbial physiology and antigenic structure; immunity; applied research, including the development of diagnostic tests; and clinical trials to evaluate experimental drugs and vaccines.

Vaccine Trial Needs

Large scale vaccine test-of-concept clinical trials to assess the potential of an HIV vaccine to elicit protective immunity against HIV-1 are being planned for the near future. Currently, HIV-1 screening and diagnosis is accomplished through the use of rapid tests and/or by serological tests (Enzyme Immunoassay (EIA) and Western Blot (WB)). The complex mixture of HIV-1 epitopes (peptides, proteins, DNA expression plasmids, and recombinant viral vectors) present in the vaccine, can elicit persistent antibody responses in vaccinated volunteers that are detectable by FDA-licensed HIV-1 detection kits. Vaccine-induced antibody responses may result in false assumption of HIV infection or indeterminate reactivity when sera of vaccinated volunteers are tested using existing serological detection assays.

A test that does not rely on detecting patient HIV-specific antibodies, e.g. based on molecular nanotechnology, needs to distinguish between vaccine recipients that test positive by immune responses to vaccine from those that test positive due to HIV-1 infection. In developed countries HIV-1 infection is often confirmed by detecting HIV proviral DNA in infected cells using polymerase chain reaction (PCR), or by quantifying HIV viral RNA in plasma using reverse transcription-PCR (RT-PCR) and other techniques. This is difficult in resource-limited settings due to the high cost of equipment and reagents, the lack of trained staff, and the need for complex laboratory infrastructure to perform these assays. Furthermore, it may take several days to weeks from the time a blood sample is drawn to the time a PCR result is obtained from the laboratory. A quick turn-around time has important implications with regard to volunteer retention and tracking at point-of-care (POC) settings.

Additional Public Health Needs

A rapid viral detection assay could facilitate the identification of acutely-infected persons as well as aid in infant HIV-1 diagnosis. It is well known that seronegative patients acutely infected with HIV are highly viremic and are more likely to transmit virus than patients who have seroconverted. Therefore, identifying acute infections enables the infected individual to access appropriate risk reduction counseling and/or treatment programs and serves as an important public health intervention tool to limit secondary spread of HIV. In addition, rapid

POC diagnostic technologies are critically needed to identify HIV-infected infants versus uninfected infants.
The uninfected infants carry maternal HIV antibodies that would react with the current antibody-based rapid tests, making current tests unsuitable for diagnosing their infection status. Early diagnosis of HIV-infected infants and their mothers will facilitate access to treatment programs and provide reassurance to families of uninfected infants. Finally, identifying HIV-infected individuals allows earlier access to treatment regimens and would be an important tool for therapeutics research and programs in resource-limited settings.

Point of Care Diagnostic Device

Many simple POC diagnostic devices exist to monitor host biomarkers for disease, to manage various health parameters and to detect different pathogens. To adapt these technologies for use in the HIV field it would be necessary to: (a) bridge the reagents for specific application to HIV-1; (b) simplify sample preparation and procedures for detecting virus from biological fluids; (c) conduct studies to demonstrate reagent stability over a wider temperature range and in rapid turn-around times; (d) conduct validation studies in laboratory-controlled environments and in field conditions; (e) evaluate positive (M, N and O subtypes) and negative samples from target populations; (f) file for regulatory approval with the FDA; and (g) address technical, manufacturing, commercialization and distribution issues.

The purpose of this BAA is to develop a simple-to-use, rapid HIV POC diagnostic device for use in resource-limited settings that is capable of distinguishing HIV-infected individuals from those who have been vaccinated with candidate vaccine constructs and subsequently developed vaccine-induced seropositivity. Additional technological applications include identifying acutely HIV-infected individuals and HIV-infected infants. The end result will improve the level of care by earlier initiation of treatment, potentially curbing new infections by counseling acutely-infected patients, and reducing the cost and time to obtain laboratory analysis.

Resource-limited settings include the home, rural, urban and outreach community public health care clinics in geographical regions of the world that lack the necessary infrastructure, medical capacity and trained personnel to adequately diagnose HIV-1 infected individuals of that community. POC diagnostics for resource-limited settings are tests that are performed near the patient and at-home/self-tests that require quick turn around time and do not require permanently dedicated space in a clinical laboratory. Examples of research include improved self-collection methodology, single unit swab and fluid processing, non-sterile collection devices with preservation capability, and integrated collection and processing methods for use in home-based test kits and/or for public health-based POC diagnostic testing.

An Option to perform additional studies to further develop the proposed HIV POC diagnostic device so that it can inform treatment decisions may be exercised by the Government. Viral load is not used to monitor HIV-infected patients in most resource-limited settings because assay performance is complex, requires sophisticated equipment and the cost of trained personnel overall exceeds the cost of treatment.

Currently, treatment initiation and switching to salvage therapies is carried out using clinical staging tables without laboratory support, or in some cases with limited CD4 data. Furthermore, recent evidence indicates that HIV-1 viral load predicts disease progression better than CD4 T cell counts. Therefore, a device with a broader range of sensitivity, corresponding to a predetermined higher viral load for use by health care workers, in association with clinical parameters, to assist in making treatment decisions regarding therapy modification for HIV-infected patients is highly desired.

ATTACHMENT 5: RESEARCH AND TECHNICAL OBJECTIVES

RAPID HIV POINT-OF-CARE DIAGNOSTIC DEVICE FOR RESOURCE-LIMITED SETTINGS
NIAID-DAIDS-BAA-NIHAI2008027

RESEARCH and TECHNICAL OBJECTIVES

NIAID invites research proposals for product development activities that will lead to simple-to-use, rapid HIV POC diagnostic devices for use in resource-limited settings capable of 1) distinguishing HIV-infected individuals from those who have been vaccinated with candidate vaccine constructs and developed vaccine-induced antibodies in the absence of true HIV-1 infection, and 2) identifying acute HIV-1 infections and HIV-1 infected infants.

The scope of product development activities to be supported includes the following:

- optimize the performance of the diagnostic device
- perform validation testing using archived or prospectively collected clinical specimens in the early phases of development
- perform reagent and device acceptability studies in resource-limited settings to identify critical design features
- preclinical studies
- test HIV-spiked samples in biological fluids (e.g. whole blood or mucosal transudates)
- qualify and validate the assay using appropriate clinical specimens from on-going or completed vaccine studies, and complete a development report
- submit a pre-Investigation Device Exemption (IDE) to the FDA
- regulatory support or scale-up Current Good Manufacturing Practices (cGMP) manufacturing to produce kits for testing and clinical trial evaluation of an Investigational Use Only (IUO) device
- assist in the development of a training program on the use of the HIV POC diagnostic device
- preparation of a Premarket Approval (PMA) package for submission to the FDA for regulatory approval of the HIV POC diagnostic device

The Offeror must propose to advance a rapid, HIV POC diagnostic device along a milestone-driven development path to a diagnostic product. Offerers are required to adopt and further develop a previously identified candidate POC diagnostic device for use with HIV and include preliminary data that includes relevant information on a sample preparation, collection, processing, assay performance and cost-effectiveness to demonstrate the feasibility of the technology. The HIV POC diagnostic device may be positioned at any point in the product development pipeline, ranging from the initial transition from basic to translational research through later stages close to final product evaluation. Plasma or other bodily fluids that require laboratory manipulation prior to use in the HIV POC diagnostic device are not within the scope of this BAA and are not responsive since the device must be CLIA-waived. The HIV POC diagnostic device should test clinical specimens in parallel with currently available, validated laboratory tests. Clinical specimens can include archived specimens or specimens from an ongoing clinical trial to evaluate the diagnostic device under field conditions.

A mechanism for requesting archived specimens is available through the HIV Vaccine Trials Network at http:\\www.HVTN.org . The Offeror must provide assurances to the Government that all clinical samples obtained for use in development of the

HIV POC diagnostic device are not individually identifiable from the original source and that all proposed research is therefore not classified as human subjects research according to NIH policies and guidelines (Department of Health and Human Services (HHS) regulations for the protection of human subjects 45 CFR 46.102(f)(2)). The HIV POC diagnostic device must be advanced through the product development process and into assessment with clinical trial specimens for submission toward an FDA Pre-Market Approval (PMA) by the end of the award period. In addition, the Government may exercise the option within the contract to add new parameters to the diagnostic device that can make it capable of providing treatment decisions.

The HIV POC diagnostic device must demonstrate feasibility for use in resource-limited settings and at the POC without the use of supporting laboratory equipment such as centrifuges, vortexes or pipettes. Any processing of patient samples for downstream applications must be self-contained within the HIV POC diagnostic device and require limited sample manipulation. The HIV POC diagnostic device must include safe containment of potentially infectious material.

The specifications required for the diagnostic device to be successfully implemented in the field are summarized in Table 1.

Table 1. Key specifications and ranges for a rapid, HIV POC diagnostic device:

Feature	Specifications	Target requirements
Sample	Type	Non-invasive or Invasive
	Volume (ml)	0.1 -0.2
	Preparation	One to three-step
Assay	LOD (cps/ml blood equivalent)	200 -1000
	Sensitivity (%)	90 -95
	Specificity (%)	99.5 -99.9
	Viral subtypes	M, N, O
Diagnostic	Time to result (minutes)	90 -120
	Shelf life at 37°C (months)	12 -24
	Humidity (%)	70%
	Transportation stress	50°C for 48-72 hours
Controls	Full process negative Internal positive	
Biosafety	Closed, self contained system	Only unprocessed sample transfer
	No biosafety cabinet required	No open handling of material
Instrument	Handheld	Portable
	Power requirements (V)	0 to 9
Cost	Per test result ($US)	≥12 ≤20
Training	Community health worker (hrs)	≤1
	High school diploma (hrs)	≤8
Reporting	Database interface flexibility	Capture, store & integrate

Activities NOT covered under this BAA:

- Basic research to support the initial development of POC diagnostics
- Phase I, II and III Clinical or field trials

Proposals may be submitted by the same organization for more than one HIV POC diagnostic device but a separate Technical and Business Proposal will be required for each proposed HIV POC diagnostic device.

2) COMPREHENSIVE STRATEGIC DIAGNOSTIC DEVICE DEVELOPMENT PLAN

As part of product development activities for a HIV POC diagnostic device, Offerors must include a Comprehensive Strategic Diagnostic Development Plan in the Technical Proposal (refer to Appendix 6 – Additional Technical Proposal Instructions).

INDEPENDENT EXTERNAL ADVISORY GROUP

Within 3 months of the effective date of the contract, the Contractor shall establish an Independent External Advisory Group to periodically review performance and progress toward achieving defined technical and strategic goals and milestones based on negotiated objectives. The membership of the Independent External Advisory Group shall be proposed by the Contractor after award and agreed to by the Project Officer.

ANNUAL REVIEW MEETINGS

At the end of each year of the base period of performance, the Contractor shall plan and conduct one full day site visit review for NIAID contract and program staff and the Independent External Advisory Group. The Principal Investigator (PI) and all senior Contractor and subcontractor staff shall attend these annual meetings. An update and summary of progress shall be presented.

OPTION

In addition to the objectives outlined above to be provided for in the basic requirement, an Option for additional services under the contract may be exercised at the discretion of the Government and is defined as follows:

When the Contractor has completed the validation phase and develop an HIV POC diagnostic device feasible for use in a clinical trial, the Government reserves the right to exercise the option to provide additional funds for up to 2 years, to perform additional studies to further develop the HIV POC diagnostic device for expanded viral load detection to inform treatment decisions. The diagnostic device must be capable of detecting virus over the limit-of-detection, which, for this purpose is set to 10,000 HIV equivalent copies/ml in blood, as determined by an FDA-approved viral load assay. Therefore, viral loads below 10,000 copies per ml would not react, and would suggest that the treatment is controlling virus replication in the HIV-infected individual. However, a positive reaction would indicate a viral load in excess of 10,000 copies per ml, and suggest loss of virological control, and, in association with other clinical information, provide rationale for switching to salvage therapy.

a) Perform additional reagent modifications and optimization procedures, as needed, to adapt the design of the HIV POC diagnostic device such that:

Feature	Specifications	Target requirements
Assay	LOD (cps/ml blood equivalent)	≥10,000
	Sensitivity (%)	≥95%
	Specificity (%)	≥98%
Diagnostic	Time to result (minutes)	≤120

Other key specifications and product development activities supported are identical to those defined for the base period.

Propose a Development Plan for this option.

ATTACHMENT 6: REPORTING REQUIREMENTS AND OTHER DELIVERABLES

RAPID HIV POINT-OF-CARE DIAGNOSTIC DEVICE FOR RESOURCE-LIMITED SETTINGS
NIAID-DAIDS-BAA-NIHAI2008027

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one (1) hardcopy of each report shall be submitted to the Contracting Officer, unless otherwise specified.

a. Technical Reports

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

The Contractor shall submit to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during each reporting period. These reports are subject to technical inspection and requests for clarification by the Project Officer. These reports shall be brief and factual and prepared in accordance with the format described below.

Format of Cover page: All reports shall include a cover page prepared in accordance with the following format:

- Contract Number and Project Title
- Period of Performance Being Reported
- Contractor's Name and Address
- Author(s)
- Date of Submission
- Delivery Address

(1) 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) Quarterly Progress Report

This report shall include a summation of the monthly progress reports 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 three months of performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full calendar months.

(3) Semi-Annual Progress Report

(a) This report shall include a [summation of the monthly progress reports 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 and quarterly reports will not be submitted the month the semi-annual report is due.

(4) Annual Progress Report

This report shall include 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 Quarterly Semi-Annual] Progress Report shall not be submitted when an Annual Progress Report is due.

(5) 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," that 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: .

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.

(6) Final Report

This report shall 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 Progress Report will not be required for the period when the Final Report is due.

(7) 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.

(8) Goals and Milestones Achievement Reports

To facilitate the monitoring of contract progress, milestones and their expected accomplishment dates will be re-established annually by discussion and agreement between the Project Officer and the PI; these milestones will not be written into the contract document. The Contractor shall submit Goals and Milestones Achievement Reports for these milestones during the contract period as specified by consultation with the Project Officer. For for-profit Contractors, since the payment of contract fee portions will be tied to the accomplishment of predetermined goals and fee-based milestones specified in the contract, the Contractor shall submit similar Goals and Milestones Achievement Reports for fee-attached milestones prior to invoicing for fee payments. Some management milestones may also be fee-based and, in that case, only one report will be required to cover both. The original hard copy of each milestone achievement report shall be submitted to the Contracting Officer, and 1 hard copy and 1 electronic copy to the Project Officer. Each report must consist of:

1. A cover page identifying the contract, Contractor, addressee, date of submission, and milestone
2. Reports shall include at a minimum:
   a) Section A – An introduction describing the goal or milestone in detail
   b) Section B – A complete description of the results. The description shall include pertinent data and/or figures in sufficient detail to explain any significant results from analysis and scientific evaluation of data accumulated to date under the goal or milestone.

(9) Annual Site Visit Review Report

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

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.

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

Invention Report Requirement

Source Code and Object Code

Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

SECTION D – PACKAGING, MARKING, AND SHIPPING

Cannot be determined at this time
Temperature controlled environment is required
Shipments will be time sensitive/time critical
International shipping will apply
Shipping insurance is required
Hazardous Materials shipping is applicable
Other (list as necessary) _____
N/A to this solicitation

ARTICLE F - DELIVERIES

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

The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract. will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below [and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract]:

a. Technical Reports

Item	Reports	Recipients	Delivery Schedule
1.	Quarterly Progress Report	1 original to CO 1 elec. copy to PO and CO	First report required after 3 full calendar months. A Quarterly Progress Report shall not be submitted when an Annual Progress Report is due.
2.	Annual Progress Report	1 original to CO 1 elec. copy to PO and CO	Annually; due on/before 15th day after the anniversary date. An Annual Progress Report is not due when the Final Report is due.
3.	Final Invention Statement	1 electronic copy to CO	Due on/before completion date of the contract.

4.	All reports and documentation including the invention disclosure report, the confirmatory license, and the government support certification	1 electronic copy to OPERA	As required by FAR Clause 52.227-11.
5.	Final Report	1 original to CO	Final Report is due on/before the completion date of contract.
6.	Summary of Salient Results	1 elec. copy to PO and CO	The summary of salient results (not to exceed 200 words) achieved during the performance of the contract and due with the Final Report.
7.	Goals and Milestones Achievement Reports	1 original to CO 1 elec. copy to PO	Specific dates will be negotiated with the PO.
8.	Annual Site Visit Review Report	1 original to CO 1 elec. copy to PO	Within 3 weeks following the site visit.

ATTACHMENT 7: ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS

RAPID HIV POINT-OF-CARE DIAGNOSTIC DEVICE FOR RESOURCE-LIMITED SETTINGS.
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It is strongly recommended that Offerors use the following template as the format for the Technical Proposal. All information presented in the Technical Proposal should be presented in the order specified below.

These Additional Technical Proposal Instructions reflect the requirements of the BAA and provide specific instructions and formatting for the Technical Proposal. While Section L.2.b. of the BAA provides a generic set of Technical Proposal Instructions applicable to all NIH R&D solicitations, these Additional Technical Proposal Instructions are tailored to the specific requirements of the BAA. The information requested in these instructions should be used along with Section L of the BAA 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 BAA, and include the information requested here.

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

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

Offerors must refer to the BAA Attachment entitled "Packaging and Delivery of the Proposal," which details strict guidelines, including page limitations, formatting and layout of proposals, and prohibits the Offerors' use of links to internet web site addresses (URLs) to direct readers to alternate sources of information.

FORMAT FOR TECHNICAL PROPOSAL

1. **PROPOSAL TITLE PAGE**. Include BAA title and number, name of organization, DUNS number, proposal part, and identify if the proposal is an original or a copy.

2. **GOVERNMENT NOTICE FOR HANDLING PROPOSALS** (See SECTIONS and L of the BAA.)

3. **TABLE OF CONTENTS** (Each Offeror's Technical Proposal shall include a Table of Contents.)

4. **OVERVIEW** (suggested 3-page maximum)

Provide a brief description of the proposed project, including:

A. A 1-4 sentence summary describing the HIV POC diagnostic device the Offeror is proposing to develop.
B. A summary describing the scope of the proposed development activities and the period of contract funding requested.
C. A description of the activities to be performed by the Offeror and those that shall be provided by any proposed subcontractor, including the identification of the proposed subcontractors and a list of key personnel of the Offeror and the proposed subcontractors with degrees and titles.
D. A brief description of the facilities, floor plan of work space, and other resources to be made available by the Offeror and any proposed subcontractors.
E. A milestone summary and Gantt chart for the whole project.
F. A summary of the proposed budget for each year in both direct and indirect costs.

5. **SCIENTIFIC RATIONALE FOR THE DEVELOPMENT OF THE HIV POC DIAGNOSTIC DEVICE**

The Technical Proposal shall provide the following with respect to the HIV POC diagnostic device proposed for development:

1. Justification to warrant the effort of optimization, production and testing of the proposed HIV POC diagnostic device, including the scientific rationale for: why the diagnostic device is particularly suited for use as a HIV POC device in resource-limited settings; the selection of biological fluids for testing; and the rationale proposed to advance the HIV POC diagnostic device through the product development/product production process
2. A comparison of the Offeror's concept/device with closely related concepts/devices in use or under development (e.g. proof-of-concept data to demonstrate feasibility of a candidate POC diagnostic device).
3. Innovation of the proposed HIV POC diagnostic device in terms of design, acceptability, and use in resource-limited settings.

6. **COMPREHENSIVE STRATEGIC DIAGNOSTIC DEVICE DEVELOPMENT PLAN**

The Technical Proposal shall provide a proposed Comprehensive Strategic Diagnostic Device Development Plan, including the following:

1. Key objectives and milestones for optimization of the HIV POC diagnostic device.
2. For each milestone, a description of the process for making decisions to proceed or not proceed (go/no-go), i.e., specific qualitative and quantitative criteria for advancement of the HIV POC diagnostic device through each stage of development and validation.
3. Steps required for development, characterization, and qualification of reagents and assays necessary for the clinical and preclinical evaluation of the HIV POC diagnostic device.

4. Plans to assure that all clinical samples obtained for use in development of the HIV POC diagnostic device are not individually identifiable from the original source and that all proposed research is therefore not classified as human subjects research according NIH policies and guidelines (Department of Health and Human Services (HHS) regulations for the protection of human subjects 45 CFR 46.102(f)(2)).
5. Patent status or other protection of project intellectual property.

7. TECHNICAL PLAN / APPROACH

A. WORK PLAN

The Work Plan should include details of the approaches and methodologies to complete the tasks and stages outlined in the Comprehensive Strategic Diagnostic Device Development Plan and comply with the specifications set forth in the Research and Technical Objectives section including identification and discussion of anticipated scientific and technical problems or obstacles and proposed approaches to resolve or reduce identified problems and obstacles.

A sample timeline of activities required for development of a rapid, HIV POC diagnostic device is provided below (see Table 2).

Table 2. Sample timeline for advancing a rapid, HIV POC diagnostic device:

Developmental path	**Research phase requirements**
Proof-of-concept phase (Month 0-24)	- Identify and procure specific test reagents, including plans for securing access to clinical specimens. - Define, procure and test biological fluids and virus clades for testing. - Develop specifications for reagent acceptance criteria, and reagent stability studies. - Develop and optimize sample processing technology with HIV-spiked biological fluids along with internal controls. - Optimize amplification and/or detection technology proposed for the application.
Validation phase (Month 12-36)	- Evaluate acceptability in resource-limited settings to identify critical design issues. - Evaluate analytical laboratory assay parameters as defined by ICH and the US Pharmacopea guidelines. - Evaluate clinical assay parameters (e.g. accuracy, sensitivity, specificity, reproducibility) using defined clinical specimens from vaccine trials, acute infection panels, and infant blood samples.
Test-of-concept phase (Month 36-60)	- Compare prototype using a standard HIV viral load test in a diagnostic lab. - Utilize archived or prospectively collected human samples from phase IIb/III efficacy

	trials to perform clinical evaluation. - Develop training package for end users in correct implementation of the HIV POC diagnostic device in resource-limited settings.

B. COMMERCIALIZATION

Provide a detailed Commercialization Plan describing approaches to product marketing and distribution and plans for post-marketing surveillance of the HIV POC diagnostic device in resource-limited countries.

a) Explain how the product would integrate with the overall business plan and the significance of any non-commercial impact it may have on social, cultural, educational and scientific needs.

b) Describe the markets and provide a brief profile of potential customers. Define any strategic alliances, partnerships or licensing agreements in place and indicate your distribution strategy for entering these areas. Explain potential hurdles to overcome in order to gain market/customer acceptance of the proposed detection device.

c) Briefly describe the organization's marketing and sales strategy. Give an overview of the current competitive landscape and any potential competitors over the next several years. What is the plan to protect the IP resulting from the proposed detection device?

d) Describe the financial plan in order to secure the requisite financing to launch the proposed detection device and secure a revenue stream, either by delineating specific steps to secure funding, or by submitting a letter of intent, commitment, or support of the project, should the contract be successful and the market need continue.

C. ANNUAL REVIEW MEETINGS

The Technical Proposal must include a plan for how the Contractor will plan, organize and conduct Annual Review Meetings that will include the NIAID program and contract staff, the Independent External Advisory Group, the PI, key subcontractor staff, and principal scientists involved on the contract.

D. <u>INDEPENDENT EXTERNAL ADVISORY GROUP</u>

The Technical Proposal should describe the types of expertise the Offeror proposes to include on the Independent External Advisory Group. It must also include a plan that describes the process the Independent External Advisory Group will follow for review of performance and progress based on negotiated objectives, HIV POC diagnostic device development activities and milestones and the agreements to be put in place with members of the Independent External Advisory Group in order to safeguard confidentiality of data and information that may be shared with these external advisors at the Annual Review Meetings.

<u>DO NOT PROPOSE MEMBERS OF THE EXTERNAL ADVISORY GROUP IN THE TECHNICAL PROPOSAL</u>.

8. OFFEROR'S PROPOSED STATEMENT OF WORK (maximum 15 pages)

In contracts awarded under this BAA, the Statement of Work shall be the Statement of Work proposed by the Offeror and negotiated and accepted by the NIAID. This section of the Offeror's Technical Proposal should outline the activities to be performed by the Contractor during performance of the contract using an outline format. The Offeror's proposed Statement of Work should begin as follows: "Independently, and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below. Specifically, the Contractor shall:" The opening paragraph should be followed by a full Statement of Work describing each activity that the Contractor shall perform after the award of the contract. The Statement of Work shall include all activities required to develop a simple to use, rapid, POC HIV diagnostic device that is able to distinguish HIV-infected individuals from those who have been vaccinated with candidate vaccine constructs and developed vaccine-induced antibodies in the absence of true HIV-1 infection and identifying acute HIV-1 infection and HIV-1 infected infants. The Statement of Work should also include a description of all items to be delivered to the Government during performance of the contract, such as progress reports, financial reports, end products, and other deliverables and a timetable for their delivery.

The Statement of Work is distinguished from the Work Plan in that it describes what the Contractor shall provide, while the Work Plan describes the specific detailed plan for implementation of the development of the HIV POC diagnostic device for use in resource-limited settings. Each activity described in the Statement of Work will begin with the words "The Contractor shall…" Where appropriate, divide the Statement of Work into separate Activities and Sub-activities.

The Contractor shall carry out activities within the contract's Statement of Work only as requested and approved by the Project Officer, and may not conduct work on the contract without prior approval from the Project Officer. Approval to carry out specific activities will be linked to approval by the Project Officer of the Comprehensive Strategic Diagnostic Device Development Plan following contract award and approval of Quarterly and Annual Progress Reports.

9. SCIENTIFIC AND TECHNICAL PERSONNEL

The Technical Proposal should include all information relevant to document individual training, education, experience, qualifications and expertise necessary for the successful completion of all contract requirements. Proposals should include a Staffing Plan for the conduct of the Statement of Work with role descriptions and level of effort of scientific and technical personnel, including scientific and technical personnel of all proposal subcontractors. Clearly identify who is to be assigned as Key Personnel.

Limit CVs to 2-3 pages and provide selected references for publications relevant to the scope of the BAA, and include experience with projects of similar scope, size and complexity carried out by the offeror and any proposed subcontractors over the past 5 years.

1) **Principal Investigator (PI),** including experience and qualifications of the PI to plan, manage, and direct the activities to be carried out under this contract.
2) **Other Scientific and Technical Personnel,** including experience, expertise, qualifications with respect to design, conduct and analysis of studies to evaluate and optimize diagnostic products and their platforms; production of diagnostic products under cGMP; and design, conduct and analysis of clinical specimens of diagnostic products.

10. **FACILITIES, EQUIPMENT AND OTHER RESOURCES**

The Technical Proposal should document availability and adequacy of facilities, equipment, space and other resources necessary to carry out the Statement of Work, including:

1) Location and features of facilities including a floor plan and a list of equipment and resources dedicated to the project for the prime contractor and any proposed subcontractors (lease or ownership information should be provided).

2) Identification and description of ALL support resources (including Information Technology systems) that will be required to effectively complete the Statement of Work.

3) Plans and procedures to be utilized for compliance with all safety guidelines and regulations including training and monitoring of personnel for exposure to infectious and other hazardous materials.

4) Plans for obtaining, adding or deleting facilities as necessary due to progress during the course of product development.

5) Documentation of the availability of appropriate facilities for supporting development, optimization, and validation of prototype assays, and the production of diagnostic device(s) under GMP guidelines.

6) Description of provisions for ensuring safe facilities and resources and for conducting work in accordance with biosafety guidelines.

11. **PROJECT MANAGEMENT**

1) Provide a plan for project organization, staffing, and management including a detailed description of the responsibilities and level of effort for all proposed personnel who will be assigned to the contract, including proposed subcontractors and consultants, and provide an administrative and technical framework indicating clear lines of authority and responsibility for all proposed personnel. If consultants and/or subcontractors are proposed, include a plan to manage, coordinate, and oversee the work performed by consultants and/or subcontractor(s) efforts. Include a chart of the proposed organizational/management structure for the project.

Provide details to substantiate the feasibility and adequacy of proposed plans for managing the research activities to ensure a cooperative, integrated and focused scientific effort.

2) 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.

3) Outline how the PI (or Program Manager) will communicate with the Project Officer and Contracting Officer and how the PI (or Program Manager) will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).

4) Provide a plan for soliciting, evaluating, negotiating, awarding and managing subcontracts in accordance with FAR Clause 52.244.2.

5) Describe experience and education of contract management staff in the acquisition and management of subcontracts under Federal contracts.

6) Describe experience with identification and remediation of subcontractor performance problems or noncompliance with subcontract terms and conditions.

12. **OPTIONS**

The Government reserves the right to request additional studies to further develop the HIV POC diagnostic device for expanded viral load detection to inform treatment decisions. Provide a brief synopsis of plans to further develop the HIV POC diagnostic device with a broader range of sensitivity. Identify key personnel and other resources for work to be performed under this option including a projected timeline and any deviations in technology from the base period Comprehensive Product Development Plan. Since this is an extension to a successful contract, it is understood that the technical proposal to complete this task may be similar and would not need to be recapitulated in the Comprehensive Product Development Plan.

13. **OTHER CONSIDERATIONS**

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

1) Sharing Research Data (Plan)

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

2) Information Technology (IT) Systems Security

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

ATTACHMENT 8: UNIFORM COST ASSUMPTIONS

RAPID HIV POINT-OF-CARE DIAGNOSTIC DEVICE FOR RESOURCE-LIMITED SETTINGS
NIAID-DAIDS-BAA-NIHAI2008027

In addition to the instructions and format requirements for the proposal that are contained in Section L of the BAA, the information presented in this attachment is intended to provide uniform cost assumptions that apply to the subject BAA.

Offerors are advised to give careful consideration to the Broad Agency Announcement Description, Background and Introduction, Research and Technical Objectives, all reference material provided as attachments, the technical evaluation criteria, and, the BAA as a whole, in the development of your proposal. The information requested here should be used as further guidance for the development of your proposal. Offerors should consider and include the information provided below in the development of their Technical and Business Proposal.

UNIFORM COST ASSUMPTIONS

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

SECTION 3 – UNIFORM COST ASSUMPTIONS

1) Technical Cost Assumptions

NIAID estimates the average total annual cost (direct and indirect cost combined) to be a maximum of $1.5 million per base-year for all contract awards. For the option, Offerors must provide a budget proposal not to exceed $1.0 million in total costs (including direct and indirect costs) for all contract awards.

2) Travel

a) Contract Initiation Meeting: Travel and per diem costs for the Principal Investigator and no more than five (5) key personnel and three (3) subject matter experts to attend a one (1) day Contract Initiation Meeting to be held in the Bethesda, Maryland area should be included.

b) Work-related Travel: Travel for activities related to Project Management is allowed, but must be justified and costed out in the proposal.

c) Annual Review Meetings: The Offeror is expected to host 1 annual review meeting that extends for 2 days per contract year. The budget should reflect the cost for hosting the meeting and travel for 3 members of the Independent External Advisory Group. Travel costs for Government employees must be reimbursed from Government funds and should not be included in Offerors' budget proposals.

3) Other

It is likely that within the first two years of the base period of performance the Offeror will be required to budget for and host a cGMP compliance audit as instructed by the Project Officer.

SECTION 4 – OPTIONS

A separate business proposal must be submitted for the Option to perform additional studies to further develop the HIV POC diagnostic device for expanded viral load detection to inform treatment decisions.

SECTION 5 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

1) Small Business Subcontracting Plan

Section L of the BAA specifies the minimum documentation requirements for completing a subcontracting plan. This plan should be submitted with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

2) Extent of Small Disadvantaged Business Participation

Section L of the BAA specifies the minimum documentation requirements for small disadvantaged business utilization. This information should be submitted with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

3) Past Performance Data, including references

Section L of the BAA specifies the minimum documentation requirements for providing past performance information. This information should be submitted with the original proposal. All related documentation should be included in the proposal in a clearly marked section.