

SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1. Purchase Authority: Public Law 92-218 as amended			
2. Request for Proposal (RFP) Number: NIH-NIAID-DMID-08-18	3. Issue Date: August 2, 2007	4. Just in Time: [X]No []Yes See Part IV Section L	5. Set Aside: [X]No []Yes See Part IV Section L
6. Title : Clinical Proteomics Centers for Infectious Diseases and Biodefense			
7. ISSUED BY: Office of Acquisitions National Institute of Allergy and Infectious Diseases National Institutes of Health _____ _____ _____ _____		8. SUBMIT OFFERS TO: See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.	
9. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 4:00pm local time on November 15, 2007. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.			
10. THIS SOLICITATION REQUIRES DELIVERY OF PROPOSALS TO TWO DIFFERENT LOCATIONS. THE OFFICIAL POINT OF RECEIPT FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY IS THE ADDRESS PROVIDED FOR THE OFFICE OF ACQUISITIONS AS STATED IN ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH HHSAR CLAUSE 352.215-70, ENTITLED, "LATE PROPOSALS, AND REVISIONS" LOCATED IN SECTION L.1. OF THIS SOLICITATION.			
11. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. http://www.ccr.gov			
12. FOR INFORMATION CALL: Robert Singman PHONE: 301-451-2607 e-MAIL: rs485j@nih.gov COLLECT CALLS WILL NOT BE ACCEPTED.			
		Robert J. Singman 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.

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SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The objective of the Clinical Proteomics Centers for Infectious Diseases and Biodefense is discovery, qualification, and verification of candidate pathogen and host protein biomarkers using proteomic technologies for infectious diseases with a focus on NIAID Category A-C biodefense pathogens (http://www3.niaid.nih.gov/biodefense/bandc_priority.htm) and emerging/re-emerging infectious disease pathogens.

ARTICLE B.2. PRICES/COSTS

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

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

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

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

Confidentiality and Material Transfer

It is anticipated that some reagents and data provided to the Center will be proprietary in nature. NIAID's experience has shown that third parties are reluctant to provide their proprietary information or materials without complete assurance that their intellectual property rights are protected. Therefore, the NIAID requires the Contractor, its subcontractors and its collaborators to safeguard the proprietary materials, data and other information of the third party suppliers. The Contractor shall therefore establish Material Transfer Agreements (MTAs) and/or Confidential Disclosure Agreements (CDAs) with third party suppliers, as needed.

Notwithstanding the foregoing, all such MTAs and CDAs will allow the Contractor to deliver materials, data and other deliverables specified under the contract and will not conflict with the contract. If the Contractor is uncertain if terms of an MTA or CDA conflict with the contract, the Contractor shall consult with the Contracting Officer. The Contractor shall submit copies to the Project Officer and Contracting Officer of any MTAs and CDAs that the Contractor or its subcontractors and the third party have agreed upon.

In addition, the Contractor shall ensure that all deliverables under the contract are delivered without any encumbrances. Furthermore, the Contractor shall acquire any and all necessary proprietary rights, consents and/or releases from its subcontractors, its collaborators and/or third parties to permit the public dissemination and/or sharing of data, protocols, technologies, materials, reagents, bioinformatics and computational software tools, source codes and other resources, and to fulfill all other requirements of the contract.

Should inventions arise from the contract, they shall be subject to laws governing federally funded inventions. The Government retains, for government purposes, a non-exclusive, irrevocable, paid-up license to federally funded inventions.

Data Usage and Confidential Information

The Contractor agrees that the use of data and information generated by the Contractor, as well as those provided to the Contractor by third parties or by the Government for activities performed under this contract, shall be restricted to projects within the scope of the contract and shall not be released (except by the publication provisions of this contract) to any other party without approval of the Project Officer. This restriction applies until the data and

information are publicly released to the scientific community in accordance with the publication provisions of this contract.

The Contractor agrees that manuscripts/abstracts containing data/information generated under this contract by the Contractor, or containing third party data already published or otherwise publicly available, will not be submitted for publication until Project Officer has reviewed and commented upon the manuscript/abstract. The Contractor will submit for review and comment a copy of any manuscript or abstract based only on data/information generated by Contractor, or containing third party data already published or otherwise publicly available no later than 30 calendar days prior to the submission to the journal or conference organization. The Project Officer will review the submitted documents in a period of time not to exceed 15 calendar days from receipt and shall only be able to make recommended changes, which Contractor will incorporate if reasonable.

The Contractor agrees that manuscripts/abstracts containing unpublished or not otherwise publicly available data/information generated or provided to the Contractor by third parties under this contract will not be submitted for publication until Project Officer clearance has been received in writing. For all manuscripts/documents containing unpublished or not otherwise publicly available data/information generated or provided to the Contractor by third parties, the Contractor shall submit for review, comments and approval, a copy of any manuscript or abstract no later than 30 calendar days prior to the submission to the journal or conference organization. In addition, the Contractor shall provide the Project Officer with evidence (i.e. email exchanges, manuscript authors list, collaboration letter) that the third party supplier of the data/information is aware of the Contractor's intention to publish and has approved it. The Project Officer will review the submitted documents in a period of time not to exceed 15 calendar days from receipt and will either grant approval in writing and/or make recommended changes, which the Contractor will incorporate if reasonable.

A publication is defined as an issue of printed material offered for distribution or any communication or oral presentation of information.

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 five (5) calendar days prior to the issuance of the press release.

Confidential Treatment of Government Sensitive/Proprietary Information

If the Government determines that some information/data that the Contractor will be provided by the Government or a third party during performance of the contract may be of a sensitive/proprietary nature, the Contractor shall guarantee strict confidentiality of the information/data that is provided by the Government during the performance of the contract. Similarly, if the Government determines that data/information generated under the contract at the Government's request is deemed to be sensitive/proprietary, the Contractor shall guarantee strict confidentiality of the information/data during the performance of the contract. The rights and obligations of the parties with respect to such information shall be governed by the following terms:

Sensitive/Proprietary Information refers to data/information of any kind which is disclosed by the Government or a third party to the Contractor, or that is generated at the request of the Government with the consent of the Contractor and deemed by the Government to be "Sensitive/Proprietary Information". Such data shall be treated as "Confidential" and will be identified with the appropriate marking. The Government shall identify, in advance of the initiation of the requested activity, the data types and datasets that would be considered to be Sensitive/Proprietary Information. In the event that sensitive/proprietary information is provided visually or orally, obligations of confidentiality shall attach only to that information which is identified as "Confidential" at the time of disclosure.

Limitations on use The Contractor shall use the Government's sensitive/proprietary information solely for the purposes of the contract. It is agreed by the Government and the Contractor that the disclosure of Sensitive/Proprietary Information shall not be construed as granting any right or license with respect to such information except as set forth herein or in a duly executed license agreement.

In order to protect against the inadvertent disclosure of Confidential Information as it is described in FAR Clause 352.224-70 (a) it is understood by both parties the following action will be taken:

(A) The Contractor agrees not to disclose in any publication/presentation any Confidential Information (as defined in 352.224-70 (a)).

(B) All proposed publications by the Contractor and any reports/material/data developed under the contract will be submitted to appropriate academic publications or presented at academic conferences; however, disclosure of Sensitive/Proprietary information or data, in whole or in part, generated by the Contractor at the request of the Government can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

- a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated August 2, 2007, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

a. Technical Progress Reports

1. Technical Reports

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

The Contractor shall submit to the Contracting Officer and 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.

All reports shall be submitted in paper and electronic form compatible with the current DMID supported software (Microsoft Word™ and Microsoft Excel™) and approved by the Project Officer. Electronic files shall be sent by e-mail or on computer discs (CD) by U.S. mail or courier service.

All reports shall include a cover page containing the contract title and number, title of report, period of performance being reported, the Contractor's name, address, telephone, fax, and e-mail, the author(s) and date of submission.

1. Semi-Annual Technical Progress Report

a. An introduction covering the purpose and scope of the contract effort.

b. A detailed description of outreach activities to promote awareness of the clinical proteomics services provided to the broad scientific community.

c. A list of all pre-proposals submitted by the scientific community and the status of their review and approval.

d. A list of all inquiries regarding and requests from members of the broad scientific community to work with the Center to develop Project Plans for clinical proteomics research projects to be undertaken by the Center.

e. A detailed description of progress made on the initial clinical proteomics research project by the Contractor and subsequent clinical proteomics research projects being undertaken by the Center. Include a description of problems encountered, the difference between planned and actual progress, cause(s) of the difference, and proposed or completed corrective actions. Include a description of materials and reagents generated during the reporting period and discuss efforts to make these items available to the scientific community.

f. A description of the activities related to establishment and/or maintenance of the IT infrastructure, data management systems, security systems, public web portal, algorithms and software applications.

- g. A summary of all meetings, in person or via teleconference, with the Project Officer, Contracting Officer, and Scientific Working Group (SWG).
- h. Proceedings of the SWG review meetings, including documentation of Project Plan recommendations, a list of all approved pre-proposals and Project Plans submitted, and a brief summary describing the results and rationale for decisions to recommend for approval.
- i. Updates to all ongoing and approved Project Plans.
- j. A description of progress on administration and management issues (e.g., establishment of subcontracts), including problems encountered, and proposed or completed corrective actions.
- k. Disclosure of all patents and copyrights or patent and copyright applications filed in or outside the United States by the Contractor, subcontractor and collaborators for activities derived from, or established by work supported by the contract.
- l. Copies of preprints and reprints of papers, abstracts, book chapters and any other type of publication not provided in final form during the previous reporting period.
- m. A work plan including, timeline and description of the work proposed for the next 6 month reporting period.
- n. An updated list (recommended 2 pages) of all the Contractor's staff members, including those at subcontract locations and consultants, and a 2-3 paragraph description of each individual's roles in ongoing projects and their percent effort committed to the project and discussion about any personnel issues that seriously impair the Centers' activities.
- o. A detailed account of the financial status of the contract. This shall include cumulative spending for each project as well as a breakdown of expenditures for each project, including: personnel (number of hours expended for each project and cumulative overall), fringe benefits, consultants (identify specific role), materials and supplies, equipment (specify), staff travel (identify project and purpose of travel), and other direct costs.
- p. An inventory of facilities maintenance, supplies, equipment, materials and reagents. Document efforts to maintain a state-of-the-art facility.
- q. Other pertinent contract information as requested by the Project Officer or the Contracting Officer.

2. Annual Technical Progress Report

This report shall include a summation of the results of the entire contract work for the period covered. This report shall also include all of the sections provided in the Semi-Annual Technical Progress Report, an additional section to summarize all work conducted during the reporting period, and a section to address the anticipated work plan and budget for the coming year.

3. Draft Final Report

The Contractor shall provide to the Project Officer and Contracting Officer the Draft Final Report 120 calendar days prior to the expiration date of the contract. The Project Officer will review the Draft Final Report and provide the Contractor with comments within 30 calendar days after receipt. The Draft Final Report shall be corrected by the Contractor, if necessary.

4. Final Report

Within 60 calendar days of the expiration date of the contract, the Contractor shall submit a comprehensive Final Report. This report shall consist of the work performed and results obtained. This report shall be in sufficient detail to describe comprehensively the results achieved.

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. Annual Technical Progress Report for Clinical Research Study Populations

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

The contractor shall submit the report in accordance with 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 III clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website:

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

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

b. **Other Reports/Deliverables**

1. **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.

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

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

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

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. The final invention statement (see FAR 27.303(a)(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 Allergy and Infectious Diseases
Office of Acquisition
6700 B Rockledge Drive
MSC 7612, Room 3214

Bethesda, Maryland 20892- 7612

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above. To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (<http://www.iedison.gov>), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

SECTION D - PACKAGING, MARKING AND SHIPPING

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

SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, The Project Officer is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:
National Institutes of Health
National Institute of Allergy and Infectious Diseases
6610 Rockledge Drive
Bethesda, MD 20817

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

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

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

SECTION F - DELIVERIES OR PERFORMANCE**ARTICLE F.1. DELIVERIES**

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work 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]:

Progress Reports:

Item	Description	Quantity	Delivery Schedule
(1)	Semi-Annual Technical Progress Report	2 hard copies and 1 electronic copy to PO 1 hard copy to CO	Semiannually; due on the 15th of the month following the end of each 6-month period beginning with the start of the contract. A Semi-Annual Technical Progress Report will not be due when an Annual Technical Progress Report or Final Report is due.
(2)	Annual Technical Progress Report	3 hard copies and 1 electronic copy to PO 1 hard copy and 1 electronic copy to CO	Annually; submitted within 30 calendar days after the anniversary date of the contract. An Annual Technical Progress Report is not due when a Final Report is due.
(3)	Draft Final Report	2 hard copies and 1 electronic copy to PO 1 hard copy and 1 electronic copy to CO	120 calendar days prior to the completion date of contract
(4)	Final Report	3 hard copies and 1 electronic copy to PO 1 hard copy and 1 electronic copy to CO	Within 60 calendar days of the completion date of the contract
(5)	Summary of Salient Results	3 hard copies and 1 electronic copy to PO 1 hard copy and 1 electronic copy to CO	This report will be required on or before the expiration date of the contract.

Other Reports:

Item	Description	Quantity	Delivery Schedule
(6)	Human Subjects IRB Annual Review Report	3 copies to PO 1 copy to CO	Annually; submitted 30 days after the anniversary date.

(7)	Invention Report	3 copies to PO 1 copy to CO 1 copy to OPERA	As required
(8)	Ad Hoc Reports	3 copies to PO 1 copy to CO	As required
(9)	Draft Final Transition Plan	3 hard copies and 1 electronic copy to PO 1 hard copy and 1 electronic copy to CO	12 months prior to the completion date of the contract
(10)	Final Transition Plan	3 hard copies and 1 electronic copy to PO 1 hard copy and 1 electronic copy to CO	Within 14 calendar days after receipt of and agreement on comments on the Draft Final Transition Plan from the PO

Other Deliverables

Item	Deliverable	SOW Reference	Quantity	Delivery Schedule
(11)	Plan for Initial Clinical Proteomics Research Project	Item 2.a.	3 hard copies and 1 electronic copy to PO	Within 30 calendar days of contract award Revised Plan due within 14 calendar days of receipt of PO comment
(12)	Pipeline Completion Report	Item 2.c.4)	1 hard copy and 1 electronic copy to PO 1 hard copy to CO	Within 15 calendar days of completion of each step in the proteomics pipeline
(13)	Plan for Clinical Proteomics Services to the Scientific Community	Item 3.b.1)	1 hard copy and 1 electronic copy to PO 1 electronic copy to CO	Within 30 calendar days of contract award Revised Plan due within 14 calendar days of receipt of PO comment
(14)	Evaluation Criteria for Clinical Proteomics Research Project Plans	Item 3.d.1)	1 hard copy and 1 electronic copy to PO 1 electronic copy to CO	Within 45 calendar days of contract award Revised Plan due within 14 calendar days of receipt of PO comment
(15)	Plan to Manage Receipt and Review of Clinical Proteomics Research Project Plans	Item 3.d.2)	1 hard copy and 1 electronic copy to PO 1 electronic copy to CO	Within 45 calendar days of contract award Revised Plan due within 14 calendar days of receipt of PO comment
(16)	Revised Project Plan for Clinical	Item 3.e.	1 hard copy and 1 electronic copy to PO	Within 14 calendar days of PO approval of the Clinical

	Proteomics Research Projects			Proteomics Research Project
(17)	Agenda, meeting materials and summaries for SWG meetings/ teleconferences	Item 4.c	1 hard copy and 1 electronic copy to PO	Agenda and meeting materials due 14 calendar days prior to meeting; summaries due within 7 calendar days of meeting
(18)	Quality Assurance/Quality Control Plan	Item 5.a	1 hard copy and 1 electronic copy to PO	Within 14 calendar days of award Revised Plan due within 10 calendar days of receipt of PO comments.
(19)	System Security Plan	Item 6.d	1 hard copy and 1 electronic copy to PO 1 hard copy to CO	Within 90 calendar days of contract award As required with the Annual Technical Progress Report
(20)	Plan to Share Resources with the Scientific Community	Item 7.a.1)	1 hard copy and 1 electronic copy to PO	Within 90 calendar days of contract award Revised Plan due within 14 calendar days of receipt of PO comments; thereafter annually
(21)	Deposit study-generated materials and reagents into public repositories	Item 7.a.3)	1 electronic copy to PO	Within 90 calendar days of conclusion of study
(22)	Public web portal	Item 7.b	1 electronic copy to PO	Within 90 calendar days of contract award
(23)	Program Development Plan I - first two years	Item 9.b.	1 hard copy and 1 electronic copy to PO	Within 90 calendar days of contract award
(24)	Program Development Plan II - final three years	Item 9.b.	1 hard copy and 1 electronic copy to PO	Two years and 90 calendar days from contract award date
(25)	Agenda, meeting materials and summaries of Monthly meetings/ teleconferences	Item 9.c.1)	1 electronic copy to PO	Agenda and meeting materials due 5 calendar days prior to the meeting; summaries due within 7 calendar days of conclusion of the meeting or teleconference

(26)	Annual Site Visit Report	Item 9.c.2)(a)	1 electronic copy to PO	Within 30 calendar days of completion of the site visit
(27)	Agenda, meeting materials and summaries for Annual Programmatic Meetings	Item 9.c.2)(b)	1 electronic copy to PO	Agenda and meeting materials due 14 calendar days prior to meeting; summaries due within 7 calendar days of conclusion of the meeting

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

Addressee	Deliverable Item No	Quantity
Project Officer Division of Microbiology and Infectious Diseases National Institutes of Allergy and Infectious Diseases, NIH 6610 Rockledge Drive, MSC 6603 Bethesda, MD 20892-6603	1, 2, 3, 4, 5, 6, 8, 9, 10, 11,12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24,25, 26, and 27	See table above
Contracting Officer Office of Acquisitions National Institute of Allergy and Infectious Diseases, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892 - 7612	1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 12, 13, 14, 15, and 19	See table above
OPERA Office of Extramural Inventions and Technology Resources Branch OPERA, NIH 6705 Rockledge Drive, Room 1040 A, MSC 7980 Bethesda, Maryland 20892-7980	7	See table above

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

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

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

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

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

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

The Government may unilaterally change its Project Officer designation.

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

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

(End of Clause)

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

Name	Title

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:

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

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

- (a) Name of the Office of Acquisitions. The Office of Acquisitions for this contract is NIAID.
 - (b) Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NIAIDOAInvoices.
 - (c) Vendor Identification Number. This is the 7 digit number that appears after the Contractor's name in Block 7 of Standard Form 26. (Note: This only applies to new contracts awarded on/after June 4, 2007, and any existing contract modified to include the number.)
 - (d) DUNS number or DUNS+4 that identifies the Contractor's name and address exactly as stated on the face page of the contract.
 - (e) Identification of whether payment is to be made using a two-way or three-way match. This contract requires a two-way match.
- (3) Inquiries regarding payment shall be directed to the designated billing office, (301) 496--6088.

- a. 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 P.L. _____ and the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H of the above referenced contract." .

ARTICLE G.4. GOVERNMENT PROPERTY

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

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

ARTICLE G.5. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

- a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The 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 3 years from contract award.

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

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

- b. Electronic Access to Contractor Performance Evaluations

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

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

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

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

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

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

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

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

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

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

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

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

ARTICLE H.3. HUMAN MATERIALS

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.4. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

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

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance

to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

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

ARTICLE H.5. RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (Including Human Gene Transfer Research)

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

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

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

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

ARTICLE H.6. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

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

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

b.

Public Law and Section No.	Fiscal Year	Period Covered
[applicable information to be included at award]		

ARTICLE H.7. NEEDLE EXCHANGE

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

b.

Public Law and Section No.	Fiscal Year	Period Covered
[applicable information to be included at award]		

ARTICLE H.8. PRESS RELEASES

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

b.

Public Law and Section No.	Fiscal Year	Period Covered
[applicable information to be included at award]		

ARTICLE H.9. ANTI -LOBBYING

a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall only be used for normal and recognized executive-legislative relationships. Contract funds shall not be used, for publicity or propaganda purposes; or for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.

b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c.

Public Law and Section No.	Fiscal Year	Period Covered
[applicable information to be included at award]		

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

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

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

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

(End of clause)

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

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

ARTICLE H.11. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at:

<http://grants1.nih.gov/grants/olaw/references/phspol.htm>.

ARTICLE H.12. OMB CLEARANCE

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

ARTICLE H.13. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

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

b. Subcontracting Reports

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

1. Individual Subcontract Reports (ISR)
Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:
April 30th
October 30th
2. Summary Subcontract Report (SSR)
Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

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

Contracting Officer

ARTICLE H.14. SALARY RATE LIMITATION LEGISLATION PROVISIONS

- a. Pursuant to the P.L.(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown or the applicable Executive Level for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as "indirect costs" or "facilities and administrative (F & A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The 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.

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

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

[*Applicable information to be included at award]

ARTICLE H.15. ENERGY STAR REQUIREMENTS

Executive Order 13123, "Greening the Government Through Efficient Energy Management" and FAR 23.203 require that when Federal Agencies acquire energy using products, they select, where life-cycle cost-effective, and available, ENERGY STAR® or other energy efficient products.

Unless the Contracting Officer determines otherwise, all energy-using products acquired under this contract must be either an ENERGY STAR® or other energy efficient product designated by the Department of Energy's Federal Energy Management Program (FEMP).

For more information about ENERGY STAR® see <http://www.energystar.gov/>

For more information about FEMP see <http://www.eere.energy.gov/>

ARTICLE H.16. CONFIDENTIALITY OF INFORMATION

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

ARTICLE H.17. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.270-6, Publications and Publicity** incorporated by reference in SECTION I of this contract, the contractor shall acknowledge the support of the National Institutes of

Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

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

ARTICLE H.18. 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.19. YEAR 2000 COMPLIANCE

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

1. Service Involving the Use of Information Technology

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

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

(End of Clause)

2. Noncommercial Supply Items Warranty

YEAR 2000 WARRANTY--NONCOMMERCIAL SUPPLY ITEMS

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

YEAR 2000 COMPLIANT ITEMS

(End of Clause)

3. Commercial Supply Products Warranty YEAR 2000 WARRANTY--COMMERCIAL SUPPLY ITEMS

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

YEAR 2000 COMPLIANT ITEMS

(End of Clause)

ARTICLE H.20. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at : <http://ott.od.nih.gov/NewPages/64FR72090.pdf> is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

Note: For the purposes of this Article, the terms, "research tools", "research materials", and "research resources" are used interchangeably and have the same meaning.

Sharing of Model Organisms for Biomedical Research

The contractor's plan for sharing model organisms, dated TBD, is hereby incorporated by reference. The contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan

ARTICLE H.21. SHARING RESEARCH DATA

The contractor's data sharing plan, dated TBD 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.22. POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

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

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

For prime or subcontract awards to **foreign institutions** that possess, use, and/or transfer Select Agents under this contract, before using NIH funds for any work directly involving the Select Agents, the foreign institution must provide information satisfactory to the NIAID, NIH that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: (http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf)

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

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

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

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

ARTICLE H.23. 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.24. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

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

ARTICLE H.25. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

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

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

ARTICLE H.26. CONSTITUTION DAY

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

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/clauses.jsp>

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. **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.
- b. **Alternate II** (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (September 2006) is added.
- c. FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefor. **[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]**

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

1. *FAR Clause 52.208-9, Contractor Use of Mandatory Sources of Supply (July 2004).*
2. *FAR Clause 52.216-15, Predetermined Indirect Cost Rates (April 1998).*
3. *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."*
4. *FAR Clause 52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting (October 1999).*
5. *FAR Clause 52.222-29, Notification of Visa Denial (June 2003).*
6. *FAR Clause 52.224-1, Privacy Act Notification (April 1984).*
7. *FAR Clause 52.224-2, Privacy Act (April 1984).*
8. *FAR Clause 52.226-1, Utilization of Indian organizations and Indian-owned Economic Enterprises (June 2000).*
9. *FAR Clause 52.227-14, Rights in Data - General (June 1987).*
10. **Alternate V** (June 1987), *FAR Clause 52.227-14, Rights in Data--General (June 1987).*
 Specific data items that are not subject to paragraph (j) include:
11. *FAR Clause 52.227-16, Additional Data Requirements (June 1987).*
12. *FAR Clause 52.227-17, Rights in Data--Special Works (June 1987).*
13. *FAR Clause 52.230-2, Cost Accounting Standards (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 (April 2005).*

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 **52.245-19, Government Property Furnished "As Is"** (April 1984).
19. FAR Clause **52.247-63, Preference for U.S. Flag Air Carriers** (June 2003).
20. FAR Clause **52.247-64, Preference for Privately Owned U.S. Flag Commercial Vessels** (February 2006).
21. FAR Clause **52.247-68, Report of Shipment (REPSHIP)** (February 2006).
22. FAR Clause **52.251-1, Government Supply Sources** (April 1984).
23. **THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.**

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

1. HHSAR Clause **352.223-70, Safety and Health** (January 2006).
2. HHSAR Clause **352.224-70, Confidentiality of Information** (January 2006).
3. HHSAR Clause **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).
4. HHSAR Clause **352.270-8(b), Protection of Human Subjects** (January 2006).
5. HHSAR Clause **352.270-9(b), Care of Live Vertebrate Animals** (January 2006).
6. HHSAR Clause **352.333-7001, Choice of Law (Overseas)** (March 2005).

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

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

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

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

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

This contract incorporates the following clauses in full text.

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

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

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

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

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

Notice to Employees

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

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

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

National Labor Relations Board

Division of Information

1099 14th Street, N.W.

Washington, DC 20570

1-866-667-6572

1-866-316-6572 (TTY)

To locate the nearest NLRB office, see NLRB's website at <http://www.nlr.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)

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

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

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

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

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

[To be filled in by the Contracting Officer]

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal (R & D)	http://www.niaid.nih.gov/contract/eproposal.htm#pack
Attachment 2:	Proposal Intent Response Sheet	http://rcb.cancer.gov/rcb-internet/forms/intent.pdf
Attachment 3:	Statement of Work	See Attachment Section at the end of this RFP
Attachment 4:	Additional Technical Proposal Instructions, Format for Technical Proposal, and Table of Contents	See Attachment Section at end of this RFP
Attachment 5:	Additional Business Proposal Instructions and Uniform Cost Assumptions	See Attachment Section at end of this RFP

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 6:	Targeted/Planned Enrollment Table	http://rcb.cancer.gov/rcb-internet/forms/enroll-table.pdf
Attachment 7:	Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Attachment 8:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Attachment 9:	Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
Attachment 10:	Protection of Human Subject Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (Formerly Optional Form 310)	http://rcb.cancer.gov/rcb-internet/forms/of310.pdf
Attachment 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	rcb.cancer.gov/rcb-internet/forms/SBA_Plan_Nov_2005.pdf
Attachment 14:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	http://oamp.od.nih.gov/contracts/BUSCOST.HTM

- Attachment 15: Offeror's Points of Contact
 Attachment 16: Disclosure of Lobbying Activities, OMB Form SF-LLL

<http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls>
<http://www.niaid.nih.gov/contract/forms.htm>
<http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf>

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 17:	Invoice/Financing Request Instructions-CR-NIH(RC)-1	http://rcb.cancer.gov/rcb-internet/forms/rc1.pdf
Attachment 18:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 19:	Privacy Act System of Records	http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm
Attachment 20:	Safety and Health, HHSAR Clause 352.223-70	http://rcb.cancer.gov/rcb-internet.nci.nih.gov/forms/safety&health-1-06.pdf
Attachment 21:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Attachment 22:	Inclusion Enrollment Report	http://rcb.cancer.gov/rcb-internet/forms/inclusion-enrollment.pdf
Attachment 23:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.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.

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).

(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.

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.

(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 541710.
2. The small business size standard is 500 Employees.

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

c. TYPE OF CONTRACT AND NUMBER OF AWARDS

It is anticipated that multiple award(s) will be made from this solicitation and that the award(s) will be made on/about August 1, 2008.

It is anticipated that the award(s) from this solicitation will be a multiple-year Cost-Reimbursement type Completion contract with a Term of 5 Years and that incremental funding will be used (See Section L.2.c. Business Proposal Instructions).

d. ESTIMATE OF EFFORT

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 10.45 FTEs per year. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

e. COMMITMENT OF PUBLIC FUNDS

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

f. COMMUNICATIONS PRIOR TO CONTRACT AWARD

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

g. RELEASE OF INFORMATION

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

h. COMPARATIVE IMPORTANCE OF PROPOSALS

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

i. PREPARATION COSTS

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

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

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

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

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

(End of Provision)

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

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

(End of provision)

2. INSTRUCTIONS TO OFFERORS

a. **GENERAL INSTRUCTIONS**

INTRODUCTION

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

1. Contract Type and General Clauses

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

2. Authorized Official and Submission of Proposal

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

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

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

4. Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See SECTION J, Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY.) However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

5. Alternate Proposals

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

6. Evaluation of Proposals

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

7. Potential Award Without Discussions

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

8. Use of the Metric System of Measurement

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

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

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

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

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

9. Standards for Privacy of Individually Identifiable Health Information

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

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

10. Privacy Act - Treatment of Proposal Information

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

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

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

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

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

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

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

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

11. Selection of Offerors

- a. The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b. The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d. If the Government intends to conduct discussions prior to awarding a contract -
 1. Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain. Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.
 2. The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range. While it is NIAID's policy to conduct discussions with all offerors in the competitive range, NIAID reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient

competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

- e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.
- f. The NIAID reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIAID requirements. Synopses of awards exceeding \$25,000 will be published in FedBizOpps.

12. Institutional Responsibility Regarding Conflicting Interests of Investigators

- **EACH INSTITUTION MUST:**

- a. Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.
- b. Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.
- c. Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.
- d. Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.
- e. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.
- f. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
- g. Certify, in each application/proposal for funding to which the regulations applies, that:

1. there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;
2. prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;
3. the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and
4. the Institution will otherwise comply with the regulations.

- **Institutional Management of Conflicting Interests**

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

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

- i. public disclosure of significant financial interests;
 - ii. monitoring of research by independent reviewers;
 - iii. modification of the research plan;
 - iv. disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
 - v. divestiture of significant financial interests; or
 - vi. severance of relationships that create actual or potential conflicts of interests.
- b. An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

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

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

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

purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

14. Past Performance Information

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

A list of the last 3 contracts completed during the past Three years and THE LAST 5 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 first tier subcontractor.

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. Standard Industrial 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.

15. **Electronic and Information Technology Accessibility, HHSAR 352.270-19(a) (January 2006)**

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

- a. *Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and*
- b. *Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.*
This requirement includes the development, procurement, maintenance, and/or use of EIT products/services; therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards. Information about Section 508 is available at <http://www.section508.gov/>.
(End of provision)

16. Prohibition on Contractor Involvement with Terrorist Activities

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

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

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

1. Technical Discussions

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

a. Project Objectives, NIH-1688-1

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

- For an **Institution of Higher Education**: The form MUST be completed in its entirety.
- For **OTHER** than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank. The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled, "**INSTRUCTIONS** ."

b. Statement of Work

1. Objectives

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

2. Approach

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

3. Methods

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

4. Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the 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. Multiple Principal Investigators

The NIH now provides offerors the opportunity to propose a multiple Principal Investigator (PI) model on research and development contracts. The multiple PI model is intended to supplement, and not replace, the traditional single PI model. The NIH chose this RFP as a candidate for the multiple PI model. Ultimately, the decision to submit a proposal using the multiple PI versus single PI is the decision of the investigators and their institutions. The decision should be consistent with and justified by the scientific goals of the project.

It is essential that organizations consider all aspects of this approach before submitting a proposal. While there are some projects that clearly are appropriate for the multiple PI model, the "fit" of other projects may not be so clear. Offerors should base the selection of either the single PI or multiple PI option on the research proposed, to ensure optimal facilitation of the science. Projects suitable for the multiple PI model could include as few as two PIs who are jointly responsible for the scientific and technical direction of the project. The multiple PI option is based on the proposed project, not on the number of performance sites or the number of participating institutions.

Multiple PIs under research contracts shall use the Subcontract Model. In this approach, offerors submit a single proposal, and a single award is made to the prime contractor. The prime contractor, when appropriate, will award subcontracts to fund the components of the project at the other institutions. The relationship between the contractor and subcontractors must be designed to support all components of the project.

To facilitate communication with the NIH, the offeror must designate a Contact PI at the time of proposal submission. The Contact PI must be employed at the prime contractor's organization. The designation of the Contact PI may rotate on an annual basis. However, this rotation is restricted to PIs located at the prime contractor's organization. The Contact PI is responsible for: relaying communications between all of the PIs and the NIH, and coordinating progress reports for the project. Being named Contact PI does not confer any special authority for the project.

Leadership Plan

Offerors proposing multiple PIs will need to submit a Leadership Plan as part of the Technical Proposal. The Leadership Plan shall describe the governance and organizational structure of the research project including communication plans, process for making decisions on scientific direction, allocation of resources, publications, intellectual property issues, and procedures for resolving conflicts. The Leadership Plan shall follow the Table of Contents provided below:

I. Rationale

Include a discussion of how the project will be enhanced by the multiple PI approach.

II. Identification of all proposed PIs

Identify the proposed PIs, their point of contact information and affiliated organizations, and the percentages of time proposed for this project. Identify the Contact PI and plans for rotation of that role, if any.

III. Roles and Responsibilities

Identify both the scientific and administrative roles and responsibilities of all named PIs.

IV. Approach to Fiscal and Management Coordination

Describe how the project will be performed and monitored from a fiscal and management perspective. Discuss organizational administrative coordination and support.

V. Project Direction and Resource Allocation

Address how decisions will be made regarding scientific direction, and, how resources will be allocated and redistributed if needed during performance. Address plans for shared resources such as IT or other shared data considerations. If joint standard operating procedures will be developed, describe this process.

VI. Communication and Lines of Authority

Address communication and lines of authority within and among PIs and within and among organizations.

VII. Data sharing, Intellectual Property, Publication, and other Proprietary Considerations

Data sharing plans, intellectual property considerations, publication agreements, and any other proprietary or confidential information sharing should be addressed in this section.

VIII. Conflict Resolution

Address how conflicts will be avoided, identified, and resolved.

IX. Other

Address any other information relative to the leadership approach to Multiple PI projects.

Offerors submitting single PI proposals do not need to submit a Leadership Plan.

3. 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.

4. 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.

5. Resumes

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

2. Technical Evaluation

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

3. Additional Technical Proposal Information

- a. Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.
- b. The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

4. Other Considerations

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

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

IMPORTANT NOTE TO OFFERORS: The following 11 paragraphs 5 through 15 shall be addressed, as applicable, in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

5. Human Subjects

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

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

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The

regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR Part 46.

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

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

*(e) In accordance with 45 CFR Part 46, prospective Contractors being considered for award shall be required to file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. The contracting officer will direct the offeror/contractor to the OHRP IRB Registration and Assurance Filing website, found at <http://www.hhs.gov/ohrp/> or to the physical address if the offeror/contractor cannot access the Internet. HHS regulations for the protection of human subjects (45 CFR Part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information can be accessed at the OHRP Web site:
<http://www.hhs.gov/ohrp/>.*

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

6. Instructions to Offerors Regarding Protection of Human Subjects

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

a. Risks to the subjects

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

- Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.
- Potential Risks:
 - Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.
 - Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.
- b. Adequacy of Protection Against Risks
- Recruitment and Informed Consent:
 - Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.
 - Protection Against Risk:
 - Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
 - Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.
 - In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.
- c. Potential Benefits of the Proposed Research to the Subjects and Others
- Discuss the potential benefits of the research to the subjects and others.
 - Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.
 - Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.
- d. Importance of the Knowledge to be Gained
- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
 - Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.
- Note:** If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.
- Collaborating Site(s)**

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

7. Required Education in the Protection of Human Research Participants

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

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

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

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

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

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

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

8. Inclusion of Women and Minorities in Research Involving Human Subjects

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

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

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

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

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

Information Required for ALL Clinical Research Proposals

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

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

The proposal must include the following information:

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

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

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

Standards for Collecting Data. When you, as a contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in OMB Directive No. 15. The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When you collect race and ethnicity separately, you must collect ethnicity first. You shall offer respondents the option of selecting one or more racial designations. When you collect data on race and ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple responses, you shall make available, at a minimum, the total number

of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

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

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

*The definition of an "**NIH-Defined Phase III clinical trial**" can also be found at this website.)

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

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

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

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups,
OR
- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups,
OR
- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

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

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

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

9. Inclusion of Children in Research Involving Human Subjects

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

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

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

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

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

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

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

Justifications for Exclusion of Children

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

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

Definition of a Child

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

The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations

(45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

10. Research Involving Prisoners as Subjects

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

b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

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

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

1. The sole purposes are:

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

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

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

For more information about this Waiver see

[http://www.hhs.gov/ohrp/special/prisoners/Prisoner waiver 6-20-03.pdf](http://www.hhs.gov/ohrp/special/prisoners/Prisoner%20waiver%206-20-03.pdf)

11. Research Involving Human Fetal Tissue

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

The governing federal statute is the Public Health Service Act, 42 U.S.C. 289g 1 and 289g 2.

Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and <http://grants1.nih.gov/grants/guide/notice-files/not93-235.html> and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

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

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

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

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

The NIH Guidelines for Research Involving Recombinant DNA Molecules at:

(<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html> and the May 28, 2002 Notice, Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules at:

(<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html>)

and any subsequent revisions to the Guide Notice) stipulates biosafety and containment measures for recombinant DNA research and delineates critical, ethical principles and key safety reporting requirements for human gene transfer research (See Appendix M of the NIH Guidelines). These guidelines apply to both basic and clinical research studies.

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

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

As specified in Appendix M 1 C 4 of the NIH Guidelines, any serious adverse event must be reported immediately to the IRB, the IBC, the Office for Human Research Protections (if applicable), and the NIH Office for Biotechnology Activities (OBA), followed by the filing of a written report with each office/group and copies to the project officer and contracting officer, at:

(http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm#_Toc7255836).

13. **Care of Live Vertebrate Animals**

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

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

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

Welfare Assurance with those Contractor(s). For further information contact OLAW, at NIH, Bethesda, Maryland 20892 (301-496-7163).

(End of Provision)

The following specific address for OLAW is provided for ease of contact:

Office of Laboratory Animal Welfare

National Institutes of Health

RKL 1 - Suite 360, MSC 7982

6705 Rockledge Drive

Bethesda, MD 20892-7982 (For Hand-delivered/express mail use Zip code 20817)

FAX copies of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at <http://www.grants.nih.gov/grants/olaw/olaw.htm>.

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

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

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

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

14. Possession, Use and Transfer of Select Biological Agents or Toxins

Notice to Offerors of Requirements of: 42 CFR Part 73, Possession, Use, and Transfer of Select Agents and Toxins (relating to public health and safety):

(http://www.cdc.gov/od/sap/42_cfr_73_final_rule.pdf);

7 CFR Part 331, Possession, Use, and Transfer of Select Agents and Toxins (relating to plant health or plant products) (http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf); and, 9 CFR Part 121, Possession, Use, and Transfer of Select Agents and Toxins (relating to human and animal health, animal health or animal products)

(http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) - March 18, 2005.

These regulations implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and the Agricultural Bioterrorism Protection Act of 2002. They are designed to improve the ability of the United States Government to prevent, prepare for, and respond to bioterrorism and other public health emergencies. These regulations establish requirements regarding registration, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections, and notifications.

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

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

For foreign institutions, see the NIAID Select Agent Award information (http://www.niaid.nih.gov/ncn/clinical/default_biodefense.htm).

If the proposed contract will not involve Select Agents, the offeror must include a statement in its technical proposal that the work does not now nor will it in the future (i.e. throughout the life of the award) involve Select Agents.

Domestic Institutions

For prime or subcontract awards to domestic institutions that possess, use, and/or transfer Select Agents under this contract, the domestic institution must:

- include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.
- comply with 42 CFR part 73, 7 CFR part 331 and/or 9 CFR part 121 at: http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf, as required, before using NIH funds for research involving Select Agents. No NIH funds can be used for research involving Select Agents if the final registration certificate is denied.

Foreign Institutions

For prime or subcontract awards to foreign institutions that possess, use, and/or transfer Select Agents under this contract, the foreign institution must:

- include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.
- when requested during negotiations, provide information satisfactory to the NIAID/NIH that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf for U.S. institutions are in place and will be administered on behalf of all Select Agent work under the resulting contract. The process for making this determination includes inspection of the foreign laboratory facility by an NIAID representative. During this inspection, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents.

An NIAID chaired committee of U.S. federal employees (including representatives of NIH grants/contracts and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will ultimately assess the results of the facility inspection, the regulations, policies, and procedures of the foreign institution for equivalence to the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at:

http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf.

The committee will provide recommendations to the DEA Director, NIAID. The DEA Director will make the approval decision and notify the Contracting Officer. The Contracting Officer will inform the prime contractor of the approval status of the foreign institution. No NIH funds can be used for research involving Select Agents at a foreign institution until NIAID grants this approval.

15. Obtaining and Disseminating Biomedical Research Resources

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research

tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

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

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

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

a. Sharing Research Data

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

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

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

If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan.

b. Sharing of Model Organisms for Biomedical Research

The NIH Research Tools Policy (http://www.ott.nih.gov/policy/research_tool.html) also referred to as NIH Principles and Guidelines for Sharing of Biomedical Resources: Final Notice, December 1999, supports the concept of timely sharing and distribution of research resources. In accordance with NIH Guide Notice NOT-OD-04-042 at:

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>), dated May 7, 2004, and the September 10, 2004 extension of this policy NOT-OD-04-066 at:

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-066.html>),

the NIH provides further sharing guidance with particular attention on model organisms for biomedical research. Such organisms include, but are not limited to: mammalian models such as the mouse and rat, and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

Offerors must include in their technical proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, OR provide appropriate reasons why such sharing is restricted or not possible. A reasonable time frame for periodic disposition of material and associated data must be specified in the proposal. In addition, the plan must address if, or how, offerors will exercise their intellectual property

rights while making model organisms and research resources available to the broader scientific community. At a minimum, the plan should address the following:

- Will material transfers be made with no more restrictive terms than in a Simple Letter Agreement (SLA) at:
(
http://ott.od.nih.gov/forms_model_agreements/forms_model_agreements.html#MTACTA)
for the transfer of materials or the Uniform Biological Material Transfer Agreement (UBMTA) (<http://www.autm.net/aboutTT/> , then search "Implementing Letter")
- How will inappropriate "reach-through" requirements (as discussed in the NIH Research Tools Policy) on materials transferred be discussed?
- How will technologies remain widely available and accessible to the research community, for example, if any intellectual property rights arise for which a patent application may be filed?

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

16. TECHNICAL QUESTIONS

16. Offerors should submit all technical questions concerning this solicitation in writing to the contract specialist. NIAID should receive all questions no later than 45 calendar days after the date of this solicitation. NIAID will answer questions which may affect offers in an amendment to the solicitation. NIAID will not reference the source of the questions.

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 proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. Travel

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

10. Other Costs

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

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

(a) Exceptions from cost or pricing data.

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

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

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

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

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

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

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

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

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15.2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406.2.

(End of provision)

5. Salary Rate Limitation in Fiscal Year 2007

Offerors are advised that pursuant to P.L. 110-005**, no NIH Fiscal Year 2006 (October 1, 2006 - September 30, 2007) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An 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. 110-005** applies only to Fiscal Year 2007 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an 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. 110-005** states in pertinent part:

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

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

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

****Public Law 110-005, Revised Continuing Appropriations Resolution, 2007, extends the legislative provisions provided in the FY 2006 Appropriations Act (Public Law 109-149) through the end of FY 2007. Therefore, the provision that restricts the amount of direct salary to Executive Level I of the Federal Executive Pay Scale continues through FY 2007. The Executive Level I annual salary rate**

was \$183,500 for the period January 1 through December 31, 2006. Effective January 1, 2007, the Executive Level I salary rate increased to \$186,600.

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 (SF 294 and SF 295) to the Government.
11. List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

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

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

23% for Small Business; 5% 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. Total Compensation Plan

a. Instructions

1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors [INCLUDED IN THE COMPETITIVE RANGE WILL BE REQUIRED TO SUBMIT/AS A PART OF THEIR BUSINESS PROPOSAL WILL SUBMIT] a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.
2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

b. Evaluation

1. Total Compensation Plan (Professional Employees)

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

2. Cost (Professional Compensation)

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

3. Other (Labor Relations)

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

4. Federal Acquisition Regulation Clauses incorporated by Reference

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

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. **Other Administrative Data**

a. **Property**

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

- a. An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the

purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

- b. No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.
2. The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.
3. The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b. Royalties

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

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

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

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

d. Financial Capacity

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

e. Incremental Funding

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the

contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provision is applicable:

Incremental Funding, HHSAR 352.232-75 (January 2006)

(a) It is the 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)

f. Facilities Capital Cost of Money, FAR 52.215-16, (June 2003)

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

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

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

[]Fac Cap Cost of Money (Has Not)***has not** specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.*

12. 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>

13. Proposer's Annual Financial Report

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

14. 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>

15. 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.

16. Certification of Visas for Non-U.S. Citizens

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

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

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

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

2. HUMAN SUBJECT EVALUATION

This research project involves human subjects. NIH Policy requires:

a. Protection of Human Subjects from Research Risks

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

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

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

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

b. Women and Minorities

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm , Definitions -

Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups,
OR
- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged),
OR
- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

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

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

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:
 - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
 - overriding factors dictate selection of subjects); or
 - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.
- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
 - inclusion of those groups would be inappropriate with respect to their health; or
 - inclusion of those groups would be inappropriate with respect to the purpose of the research.
- For NIH-defined Phase III clinical trials, reviewers will also consider whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or

public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

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

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

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

c. **Children**

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

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

Based on the reviewers' evaluation of the offeror's response, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance with NIH policy guidelines) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

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

3. **EVALUATION OF DATA SHARING PLAN**

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy. If your proposal does not include a plan or if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision

(FPR). If your data sharing plan is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

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

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

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

5. **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.

OFFERORS AND REVIEWERS ARE ADVISED TO REFER TO ATTACHMENT 4 - Additional Technical Proposal Instructions - OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATION RELATED TO THE PREPARATION OF PROPOSALS.

CRITERIA WEIGHT

CRITERION 1: Technical Approach 40 Points

Adequacy, appropriateness, and feasibility of the scientific and technical approaches to providing proposed clinical proteomics activities.

1. Adequacy, appropriateness, and feasibility of proposed plans for establishing, operating, and maintaining a state-of-the art, high throughput Clinical Proteomics Center for Infectious Diseases and Biodefense for discovery, qualification, and verification of candidate pathogen and host protein biomarkers including the proposed technical approach for providing the capability for and conducting all aspects of bioinformatics and computational activities required for a state-of-the art clinical proteomics facility; proposed approaches and strategies for identifying, developing, evaluating, and implementing improvements in existing proteomics technologies, platforms and resources and efficiency of production to maintain a state-of-the-art proteomics facility; procedures to ensure quality assurance/quality control for all contract activities; procedures for receipt, storage and distribution of contract materials; and problems/obstacles likely to occur with operating and maintaining a clinical proteomics facility and proposed approaches for addressing such problems/obstacles.
2. Adequacy, appropriateness, and feasibility of the proposed Initial Clinical Proteomics Research Project Plan, including documentation of a sustained source of well-characterized human clinical samples necessary to conduct the proposed project.
3. Adequacy, appropriateness, and feasibility of the proposed procedures to obtain and ensure a sustained source of well-characterized clinical samples from cases and controls necessary to conduct clinical proteomics research projects; including the ability to obtain a sustained source of well-characterized clinical samples.
4. Adequacy, appropriateness and feasibility of proposed technical approaches for conducting clinical proteomics research projects to discover, qualify and verify protein biomarkers using high-throughput proteomic technologies and platforms including preparing and processing human clinical samples, for performing high-throughput comparative and quantitative protein profiling assays, and for performing verification studies; problems/obstacle encountered in conducting clinical proteomics research projects and strategies used to

overcome the problems/obstacles; collaborations established for successful implementation and completion of clinical proteomics research projects; and relevance of clinical proteomics research projects conducted to produce potentially clinically useful pathogen and host protein candidate biomarkers for infectious diseases.

CRITERION 2: Clinical Proteomics Services to the Scientific Community

20 Points

Adequacy, appropriateness, and feasibility of plans to provide clinical proteomics services and resources to the scientific community.

1. Adequacy, appropriateness, and feasibility of the proposed plan for the request and review of clinical proteomics research pre-proposals including outreach activities to the broad scientific community to promote awareness of the Center and the availability of its resources, the process the broad scientific community will use to submit pre-proposals including the design and content of the pre-proposals, and the review and evaluation process the Center will use to select pre-proposals.

2. Adequacy, appropriateness, and feasibility of plans for working with members of the scientific community to design Clinical Proteomics Research Project Plans for clinical proteomics research projects to be undertaken by the Center, and to develop ethical, safe and implementation-ready clinical plans for all approved clinical proteomics research projects.

3. Adequacy, appropriateness, and feasibility of the plan to manage receipt and review of Clinical Proteomics Research Project Plans including web-based receipt of Project Plans, tracking and reporting on Project Plan status, and the review and evaluation process of the Scientific Working Group including the proposed evaluation criteria.

4. Adequacy, appropriateness, and feasibility of plans for the establishment and use of a Scientific Working Group to ensure close interaction with the scientific community, and to evaluate Project Plans for clinical proteomics research projects.

5. Adequacy, appropriateness, and feasibility of the proposed plan for sharing and disseminating to the scientific community data, protocols, technologies, reagents, bioinformatics tools, and software source codes generated under this contract.

CRITERION 3: Scientific and Technical Personnel

20 Points

Appropriateness and relevance of the documented training, education, experience, expertise and availability of proposed scientific and technical personnel in relation to their specific duties and responsibilities required to perform the Statement of Work.

1. Principal Investigator: Documented training, scientific and technical skills, and managerial competence to successfully plan, manage, conduct and direct projects having goals, size and complexity similar to those of the proposed Clinical Proteomics Center for Infectious Diseases and Biodefense, including appropriateness of the proposed time commitment of the Principal Investigator as well as demonstrated ability to establish collaborations in order to obtain clinical samples for proteomics projects.

2. Project Manager: Documented training, leadership skills, and technical and managerial competence to successfully oversee, coordinate, integrate and manage a project of a comparable size and complexity, including appropriateness of the proposed time commitment.

3. Other Scientific and Technical Staff: Documented training, expertise, related experience, and availability of the proposed other clinical and non-clinical scientific and technical staff, including subcontractors and consultants, their documented capacity to perform their proposed responsibilities and their prior experience with similar projects.

CRITERION 4: Facilities, Equipment, Safety, and Training

10 Points

1. Adequacy, appropriateness and availability of facilities and other resources including equipment, computation facilities, and software tools dedicated to the Center for the prime contractor and any proposed subcontractors as well as ownership/lease information for the facility that demonstrates availability for the duration of the proposed contract to conduct clinical proteomics research projects to discover, qualify, verify, and optimize assays for candidate host and pathogen protein biomarkers.
2. Adequacy and appropriateness of plans for compliance with all safety guidelines and regulations, including providing training, protective garments and monitoring of personnel for exposure to infectious and hazardous reagents.

CRITERION 5: Project Planning, Initiation, and Management

10 Points

1. Adequacy, appropriateness, and feasibility of the proposed organization and staffing of the Center to ensure efficient planning, initiation, implementation, conduct, and completion of all activities carried out under this contract.
2. Adequacy, appropriateness, and feasibility of the proposed project management and financial management systems to track activities and quality control methods for effective initiation, implementation, management and oversight of contract requirements.
3. Adequacy, appropriateness, and feasibility of plans for communication and interaction between the Principal Investigator and the Project Officer and Contracting Officer as well as communication with other Center staff (including subcontractors) and other Center Principal Investigators.
4. Adequacy, appropriateness, and feasibility of plans for developing, implementing, populating, maintaining and updating a project database management system to include a Laboratory Information Management System (LIMS) and a system for tracking receipt and storage of sample information while maintaining their confidentially and anonymity.
5. Adequacy, appropriateness, and feasibility of plans for a network infrastructure for Center investigators to access computational and database resources and software to facilitate data sharing within the Center

TOTAL POSSIBLE POINTS: 100

6. PAST PERFORMANCE FACTOR

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

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

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

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

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

for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

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

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

7. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

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

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

Offers will be evaluated on the following sub-factors:

- a. Extent to which SDB concerns are specifically identified
- b. Extent of commitment to use SDB concerns

STATEMENT OF WORK

BACKGROUND AND INTRODUCTION:

The National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) supports research related to the basic understanding, treatment and ultimately prevention of infectious, immunologic and allergic diseases that threaten millions of human lives. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports a comprehensive extramural research program focused on the prevention and control of diseases caused by virtually all infectious agents (with the exception of the Human Immunodeficiency Virus). This includes basic research, such as studies of microbial biology and physiology; applied research, including the development of medical diagnostics, therapeutics and vaccines; and clinical trials to evaluate experimental drugs and vaccines.

The NIAID/DMID has made a significant investment in genomic-related activities that provide comprehensive genomic, bioinformatic, and proteomic resources and reagents to the scientific community for basic and applied research in infectious diseases and to rapidly address the Institute's mission and the Nation's biodefense needs (<http://www.niaid.nih.gov/dmid/genomes/>). NIAID-supported genomic research programs include:

- *Microbial Genome Sequencing Centers* - provide rapid and cost-efficient production of high-quality genome sequences of human pathogens and invertebrate vectors of diseases;
- *Pathogen Functional Genomics Resource Center* - provides functional genomic resources, data and reagents, including DNA microarrays, protein expression clones, genotyping for comparative genomics of pathogenic species, and comparative protein profiling;
- *Bioinformatics Resource Centers* - provide a robust point of entry for access to genomic and related data in a user-friendly format, and include databases of host microbial genomic data, as well as analysis centers to develop and provide bioinformatic software tools;
- *Proteomics Research Centers* - characterize the proteomes of pathogens and/or host cells; identify proteins associated with the biology of microbes, mechanisms of microbial pathogenesis, and host response to infection; and discover targets for potential candidates for the next generation of vaccines, therapeutics, and diagnostics.

Until now, however, NIAID has not invested in development of clinical proteomic resources and reagents that will enable clinical researchers to exploit the potential of applied proteomics to advance research related to clinically important fundamental problems in infectious diseases and biodefense. NIAID is now launching a five-year initiative to establish large-scale *NIAID Clinical Proteomics Centers for Infectious Diseases and Biodefense*.

The objective of the Clinical Proteomics Centers for Infectious Diseases and Biodefense is discovery, qualification, and verification of candidate pathogen and host protein biomarkers using proteomic technologies for infectious diseases with a focus on NIAID Category A-C biodefense pathogens (http://www3.niaid.nih.gov/biodefense/bandc_priority.htm) and emerging/re-emerging infectious disease pathogens. For the purposes of this contract, a proteomic technology is defined as an instrument, tool or device capable of measuring characteristics of peptides or proteins. A proteomic platform is defined as the multi-step process for the identification and analysis of proteins/peptides, which uses several technologies and may involve such operations as: sample collection and preparation/processing, separation/capture of proteins and/or peptides of interest,

their experimental analysis (typically including protein identification and quantification), as well as post-measurement bioinformatics data processing and data mining. While augmentation of existing proteomic technologies and/or the creation of novel technologies for the identification of potential candidate protein biomarkers will be supported, proteomic technology development alone, in the absence of using the technology to enhance discovery of protein biomarkers, will not be supported.

A comprehensive protein biomarker pipeline is considered to be comprised of: 1) discovery, 2) qualification, 3) verification, 4) validation, and 5) clinical assay development. This contract will only support the discovery, qualification, and verification of candidate human protein biomarkers as defined below and will not support studies to validate candidate biomarkers or develop clinical assays. In addition, identification and characterization of the complete proteome of the microbe or host will not be supported.

Discovery involves the unbiased semi-quantitative identification of a large number of differentially expressed proteins or peptides in case versus control clinical samples.

Qualification involves the initial confirmation of discovery phase candidate proteins/peptides and confirms the differential expression of the candidate protein biomarkers in case and control samples using additional and alternative methods.

Verification extends the qualification step to include a broader range and number of case and control samples that are representative of the relevant population. In addition biomarker candidate sensitivity is affirmed and assessment of specificity begins. Further validation proceeds on a substantially reduced list of candidate protein biomarkers, each of which has been consistently detected and shown to have measurable differential expression between case and control samples.

Candidate human protein biomarkers will be made widely available to the scientific community for use as reagents for further development with the potential to be used clinically to detect infectious diseases and predict and/or monitor responses to therapeutic interventions and susceptibility to infection.

SCOPE:

The scope of the Clinical Proteomics Centers for Infectious Diseases and Biodefense (hereinafter also referred to as “Centers”) is discovery, qualification, and verification of candidate protein biomarkers to be made widely available to the scientific community for use as reagents for further development, with the potential to be used clinically to improve detection and diagnosis, and to monitor therapeutic and vaccine responses and susceptibility to infection for diseases caused by NIAID Category A-C biodefense (http://www3.niaid.nih.gov/biodefense/bandc_priority.htm) and emerging/re-emerging infectious disease pathogens. The Centers will provide high throughput, state-of-the-art proteomics facilities as a resource to NIAID and the broad scientific community for the conduct of clinical proteomics research projects proposed in collaboration with clinical infectious disease researchers to identify candidate protein biomarkers.

The contract will NOT provide funds to support:

- Clinical trials (see http://grants2.nih.gov/grants/funding/phs398/instructions/phs398instructions.htm#p2_hum_an_subjects_definitions.htm for definition of clinical research versus clinical trial).

- Proteomic technology development alone in the absence of use of the technology to enhance the discovery of protein biomarkers.
- Studies to validate candidate biomarkers or develop clinical assays.
- Identification and characterization of the complete proteome of the microbe or host.

TECHNICAL REQUIREMENTS:

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

1. CLINICAL PROTEOMICS FACILITIES AND SCIENTIFIC/TECHNICAL TEAM

Provide the facilities, equipment, methodology, technologies, and scientific and technical expertise to establish a Clinical Proteomics Center for Infectious Diseases and Biodefense for the conduct of clinical proteomics research projects to identify candidate protein biomarkers to be made widely available to the scientific community.

- a. Provide established, high throughput, state-of-the art proteomics facilities and the equipment, methodology, and technologies required for discovery, qualification, and verification of candidate protein biomarkers to be made publicly available to the scientific community that have the potential to be useful for clinical research of infectious diseases and biodefense.
- b. Provide a scientific/technical team to implement the discovery, qualification, and verification of clinical proteomics biomarkers. The scientific/technical team shall have expertise in molecular biology, clinical infectious diseases, preparation of samples for proteomic analysis, proteomic technologies and platforms, bioinformatics (computational biology and computer science), software engineering, biostatistics, and information technology (IT) administration.
- c. Provide the bioinformatics and computational facilities, and software tools required to track clinical samples and reagents, to manage and analyze data; and to store, visualize and release data to the scientific community.
- d. Develop, evaluate, and incorporate improvements in existing proteomics technologies, platforms and resources and efficiency of production to maintain a high throughput, state-of-the-art proteomics facility.

2. CLINICAL PROTEOMICS PIPELINE

Conduct clinical proteomics research projects to discover, qualify and verify protein biomarkers from well-characterized human clinical samples, using high-throughput proteomic technologies and platforms.

- a. Initial Clinical Proteomics Research Project

- 1) Within 30 calendar days from contract award, prepare and submit to the Project Officer for approval, a Project Plan to undertake an initial, clinical proteomics research project. This Project Plan shall reflect any changes to the Initial Clinical Proteomics Research Project in the original Technical Proposal resulting from Scientific Review Group recommendations and final negotiations with the Contracting Officer. The Project Officer will provide approval and/or comments that must be addressed within 10 calendar days of receipt of the Project Plan. Within 14 calendar days after receipt of and agreement on Project Officer comments, modify the Project Plan as necessary to incorporate Project Officer recommended revisions and provide the revised Project Plan to the Project Officer for approval. The first clinical proteomics research project shall be initiated within 60 calendar days of the effective date of the contract. The Project Plan shall address the following:
 - (a) *Significance*, i.e., the scientific rationale and justification for the proposed clinical proteomics research project including the relevance of the proposed protein biomarkers to be identified as reagents for the broad scientific community and their potential for clinical utility in the diagnosis and treatment of diseases caused by NIAID Category A-C priority pathogens or emerging/re-emerging infectious diseases.
 - (b) *Approach*
 - i. Goals and objectives
 - ii. Study design, including:
 - (1) Clinical samples:
 - (i) Source: obtained through clinical studies to collect clinical samples specifically for use in the proposed clinical proteomics research project and/or previously accumulated for other purposes.
 - (ii) Information for each sample: diagnosis, concurrent diseases, gender, age, race, and method of sample collection.
 - (iii) Plan to ensure a sustained source of the quantity of well-characterized clinical samples from cases and controls necessary to conduct the proposed clinical proteomics research project.
 - (2) Clinical endpoints and their relevance to answering the question(s) being addressed
 - (3) Justification of proposed sample size and detailed statistical analysis plan
 - (4) Technical approach
 - (5) Plan for quality assurance and quality control
 - (6) Proposed timelines, milestones and deliverables
 - (c) *Investigators* - Qualifications of the scientific and technical personnel proposed including relevant experience, time commitment, and role in the project.
 - (d) *Plan for Dissemination* – Description of the plan to disseminate data and reagents generated in the proposed clinical proteomics research project to the broad scientific community.

(e) *Other Considerations*

- i. Documentation that the clinical studies, including those conducted at affiliated clinical sites, will be done in accordance with all Federal regulations and requirements, and NIAID Clinical Terms of Award (<http://www3.niaid.nih.gov/research/resources/DMIDClinRsrch/policies.htm>)
 - ii. Documentation of appropriate informed consent for the proposed use
 - iii. Documentation indicating that samples are anonymous in compliance with 45CFR46.102(f)(2)
 - iv. How potential confidentiality and intellectual property issues regarding data and materials shall be managed
- 2) Implement the Initial Clinical Proteomics Research Project upon receipt of written approval from the Project Officer.

b. Source of Clinical Samples

- 1) Obtain and ensure a sustained source of well-characterized human clinical samples from cases and controls necessary to conduct clinical proteomics research projects. Samples may have been previously collected for purposes other than the proposed clinical proteomics research projects. Alternately, clinical studies may be undertaken to collect clinical samples specifically for use in the clinical proteomics research projects to be undertaken by the Center. Sources of clinical samples may be sought from clinical infectious disease research collaborators. Ensure the following information is available for each clinical sample:

(a) Minimum data elements:

- i. Diagnosis
- ii. Gender
- iii. Age
- iv. Race
- v. Method of sample collection and handling
- vi. Information on concurrent diseases

(b) Documentation of appropriate informed consent for the proposed use.

(c) Documentation indicating that samples are anonymous in compliance with 45CFR46.102(f)(2).

- 2) Ensure that all clinical studies undertaken to collect samples, including those conducted by collaborators, are conducted in accordance with all Federal regulations and requirements, and NIAID Clinical Terms of Award (<http://www3.niaid.nih.gov/research/resources/DMIDClinRsrch/policies.htm>)

c. Discovery, Qualification, and Verification of Candidate Biomarkers

- 1) *Preparation of Samples*: Prepare and process human clinical samples for use in protein profiling assays.

- 2) *Discovery and Qualification:* Perform high-throughput comparative and quantitative protein profiling assays for use in discovery and qualification of protein biomarkers by means of, but not limited to, protein fractionation and separation and analytical techniques such as protein solubilization, two-dimensional gel electrophoresis, high performance liquid chromatography, and liquid chromatography/mass spectroscopy platforms such as LC-MS/MS and matrix-assisted laser desorption and ionization time-of-flight (LC MALDI-TOF MS); and immunoassays.
- 3) *Verification:* Perform verification studies by means of, but not limited to, cloning and protein expression and purification to generate high quality DNA and/or protein arrays, and immunoassays.
- 4) *Pipeline Completion Reports:* Within 15 calendar days of completion of each step in the proteomics pipeline, prepare and submit to the Project Officer and Contracting Officer for approval, a Pipeline Completion Report that includes a detailed description of the progress on the project related to the completion of the step in the proteomics pipeline including data generated to complete the step in the pipeline. Include a description of differences between the planned and actual progress, causes of the difference and proposed changes in the next steps in the pipeline.

3. CLINICAL PROTEOMICS SERVICES TO THE SCIENTIFIC COMMUNITY

Provide a clinical proteomics resource that offers the Center's technologies, resources and scientific and technical expertise to the broad scientific community who will propose clinical proteomics research projects that have the potential to identify candidate protein biomarkers for clinical utility in diagnosis and treatment of infectious diseases.

Clinical proteomics research projects to be undertaken by the Center shall be proposed either by the Contractor or by the scientific community in collaboration with the Contractor. The Project Officer will approve and prioritize all projects for identifying candidate protein biomarkers for infectious diseases. Once a project is approved and initiated, the Project Officer will approve proceeding to the next step of the proteomics pipeline from discovery to qualification to verification, and can recommend halting a clinical proteomics research project.

a. Conduct Outreach

Promote awareness of the clinical proteomics services provided to the broad scientific community through electronic and print media, through posters and oral presentations at scientific meetings, symposia and workshops, brochures or advertisement in relevant scientific journals. The Contractor shall submit to the Project Officer for approval, all media to be used for purposes of promoting awareness of the Center.

b. Request and Review of Clinical Proteomics Pre-Proposals

- 1) *Plan for Clinical Proteomics Services to the Scientific Community.* Within 30 calendar days of contract award, and in collaboration with the other Center(s), develop and submit to the Project Officer for approval, a Plan for Clinical Proteomics Services to the Scientific Community, describing the request process the broad scientific community should use to submit pre-proposals for clinical proteomics research projects for identifying candidate protein biomarkers to the Center, and the

review process the Center shall use to recommend approval of proposed pre-proposals. The Project Officer will review and provide comments within 10 calendar days of receipt of the Plan. Within 14 calendar days of receipt of and agreement on Project Officer comments, modify the Plan as necessary and submit the revised Plan to the Project Officer for approval. The Plan shall delineate:

- (a) Outreach activities to promote awareness of the clinical proteomics services provided to the broad scientific community and the request process the scientific community should use to submit pre-proposals
 - (b) Procedures for Web-based receipt of pre-proposals
 - (c) Information required in the pre-proposal including the proposed candidate biomarker to be discovered, the source of clinical samples, the collaborative group, and a brief scientific rationale and justification for the proposed clinical proteomics research project including the relevance of the proposed protein biomarkers to be identified as both reagents for the broad scientific community and their potential for clinical utility in the diagnosis, treatment and prevention of diseases caused by NIAID Category A-C priority pathogens or emerging/re-emerging infectious diseases.
 - (d) Information required for the Center to accept and review pre-proposals
 - (e) Evaluation criteria for selecting pre-proposals and recommending approval to the Project Officer
 - (f) Turnaround time to review pre-proposals
- 2) Implement the Plan for Clinical Proteomics Services to the Scientific Community within 60 calendar days of receipt of written approval by the Project Officer.
- 3) Provide recommendations for approval of pre-proposals to the Project Officer. Development of clinical proteomics research Project Plans shall not proceed until written approval of pre-proposals by the Project Officer.
- c. Clinical Proteomics Research Project Plans
- 1) Work with members of the broad scientific community to develop Project Plans for clinical proteomics research projects to be undertaken by the Center. Project Plans shall be developed for (i) projects proposed by the Contractor and (ii) projects proposed by the scientific community whose pre-proposals have been approved by the Project Officer. Clinical proteomics research Project Plans shall address the following:
- (a) *Significance*, i.e., the scientific rationale and justification for the proposed clinical proteomics research project including the relevance of the proposed protein biomarkers to be identified as reagents for the broad scientific community and their potential for clinical utility in the diagnosis and treatment of diseases caused by NIAID Category A-C priority pathogens or emerging/re-emerging infectious diseases.
 - (b) *Approach*
 - i. Goals and objectives
 - ii. Study design, including:
 - (1) Clinical samples:

- (i) Source: obtained through clinical studies to collect clinical samples specifically for use in the proposed clinical proteomics research project and/or previously accumulated for other purposes.
 - (ii) Information for each sample: diagnosis, concurrent diseases, gender, age, race, and method of sample collection.
 - (iii) Plan to ensure a sustained source of the quantity of well-characterized clinical samples from cases and controls necessary to conduct the proposed clinical proteomics research project.
 - (2) Clinical endpoints and their relevance to answering the question(s) being addressed
 - (3) Justification of proposed sample size and detailed statistical analysis plan
 - (4) Technical approach
 - (5) Plan for quality assurance and quality control
 - (6) Proposed timelines, milestones and deliverables
 - (c) *Investigators* - Qualifications of the scientific and technical personnel proposed including relevant experience, time commitment, and role in the project.
 - (d) *Plan for Dissemination* – Description of the plan to disseminate data and reagents generated in the proposed clinical proteomics research project to the broad scientific community.
 - (e) *Other Considerations*
 - i. Documentation that the clinical studies, including those conducted at affiliated clinical sites, will be done in accordance with all Federal regulations and requirements, and NIAID Clinical Terms of Award (<http://www3.niaid.nih.gov/research/resources/DMIDClinRsrch/policies.htm>)
 - ii. Documentation of appropriate informed consent for the proposed use
 - iii. Documentation indicating that samples are anonymous in compliance with 45CFR46.102(f)(2)
 - iv. How potential confidentiality and intellectual property issues regarding data and materials shall be managed
- d. Receipt and Review of Clinical Proteomics Research Project Plans
- 1) *Criteria to Evaluate Project Plans*: Within 45 calendar days from contract award, and in collaboration with the other Center(s), develop and submit to the Project Officer for approval, criteria to evaluate proposed clinical proteomics research Project Plans. Within 14 calendar days after receipt of and agreement on comments from the Project Officer, modify the proposed criteria as necessary to incorporate Project Officer recommended revisions and provide the final criteria to the Project Officer for approval.

- 2) *Plan to Manage Receipt and Review of Project Plans.* Within 45 calendar days from contract award, and in collaboration with the other Center(s), develop and submit to the Project Officer for approval, a Plan to Manage Receipt and Review of Project Plans to conduct clinical proteomics research projects in collaboration with the Center. Within 14 calendar days after receipt of and agreement on comments from the Project Officer, modify the Plan as necessary to incorporate Project Officer recommended revisions and provide the revised Plan to the Project Officer and Contracting Officer for approval. The Plan shall outline processes and the information technology systems required to support them for:
 - (a) Web-based receipt of Project Plans on or before 3 designated receipt dates per year.
 - (b) Tracking the receipt and review of Project Plans, and reporting results to applicants.
 - (c) Review by the Scientific Working Group (SWG) (see SOW paragraph 4) for scientific and technical merit 3 times per year, including turnaround time and maintenance of confidentiality.
 - (d) Reporting SWG recommendations based on scientific and technical merit to the Project Officer for selection of clinical proteomics projects to be undertaken by the Center.
 - (e) Reporting feedback to requestors regarding the status of their Project Plans.
 - 3) Within 30 calendar days of receipt of written approval by the Contracting Officer and Project Officer, implement the Plan to Manage Receipt and Review of Project Plans.
 - 4) Provide recommendations to the Project Officer for selection of clinical proteomics research projects to be undertaken by the Center based on scientific and technical merit, and programmatic relevance.
- e. Revised Project Plan for the Conduct of Clinical Proteomics Research Projects
- 1) Within 14 calendar days of Project Officer approval of clinical proteomics research projects, prepare and submit to the Project Officer, a revised Project Plan that includes any changes to the original Project Plan based on SWG and Project Officer comments and recommendations. In addition, the Project Plan shall contain a plan for the implementation and management of the clinical proteomics research project in relation to the overall proteomics activities of the Center.
 - 2) Within 30 calendar days of receipt of written approval of the Revised Project Plan by the Project Officer, implement the Project Plan.
 - 3) The Contractor shall update the Project Plan on a semi-annual basis as part of the Semi-Annual Technical Progress Reports. The Project Officer and Contracting Officer will review the revised Project Plan and approve it accordingly.

4. SCIENTIFIC WORKING GROUP (SWG)

- a. Establish a Scientific Working Group (SWG) in conjunction with the Project Officer, composed of approximately 7 investigators drawn from academia, government, and industry. These individuals shall be independent of the Center and possess expertise and experience in the discovery, qualification, and verification aspects of the clinical

proteomics pipeline; biostatistics; bioinformatics; clinical microbiology; and infectious diseases related to diverse organisms and pathogens. The SWG shall:

- 1) Provide advice to the Contractor on the needs of the scientific community regarding clinical proteomics reagents and resources and on the management, operations and planning of future directions of the Center;
 - 2) Three times per year, review clinical proteomics research Project Plans and make recommendations based on scientific and technical merit for collaborative clinical proteomics research projects to be undertaken by the Center.
- b. Within 60 calendar days of contract award, recommend to the Project Officer, names of individuals for SWG membership and provide information on their area of expertise and other relevant selection factors. The Contractor shall NOT contact individuals regarding service on the SWG until final approval by the Project Officer.
- c. Organize the first SWG meeting within 6 months of contract award to solicit advice on the needs of the scientific community regarding clinical proteomics reagents and resources and on the management, operations and planning of future directions of the Center. Thereafter, organize meetings 3 times per year to continue soliciting advice on the needs of the scientific community regarding clinical proteomics reagents and resources and to review the management, operations and planning of future directions of the Center and to also review clinical proteomics research Project Plans and make recommendations based on scientific and technical merit for collaborative clinical proteomics research projects to be undertaken by the Center. One meeting per year shall be held at the Contractor's site; the other two meetings may be held via teleconference.
- 1) Provide a draft meeting agenda and background materials to the Project Officer for review 30 calendar days prior to the SWG meeting or teleconference. Upon approval by the Project Officer, distribute the meeting agenda and background materials to all meeting participants at least 14 calendar days in advance of the meeting or teleconference.
 - 2) Prepare and provide summary reports of all meetings and teleconferences to the Project Officer within 7 calendar days of the meeting or teleconference, and include these summaries as part of the Semi-Annual Technical Progress Report.

The Project Officer will participate in SWG meetings and teleconferences as an external member of the group.

5. QUALITY ASSURANCE/ QUALITY CONTROL

a. Quality Assurance/Quality Control Plan

- 1) Develop and implement a Quality Assurance/Quality Control (QA/QC) Plan to standardize contract processes and ensure the conduct of all proteomics activities meets the requirements of the contract. The QA/QC Plan shall include standard operating procedures (SOPs), a process for maintaining version control of SOPs; and procedures for review and approval of, and training of Contractor staff on, updated and new SOPs prior to distribution and use.

- 2) Within 14 calendar days of contract award, submit a QA/QC Plan for Project Officer review and approval. The Project Officer will provide comments on the QA/QC Plan within 14 calendar days of receipt of the Plan. Within 10 calendar days after receipt of and agreement on comments from the Project Officer, modify the QA/QC Plan as necessary to incorporate Project Officer recommended revisions and provide the revised QA/QC Plan to the Project Officer for approval. Any proposed modifications to the QA/QC Plan, including SOPs, shall be submitted to the Project Officer for review and approval prior to implementation.

b. Quality Control of Reagents and Tools

Provide for quality control of reagents and tools generated during the contract. Quality control includes evaluation of reagents, as directed by the Project Officer. At a minimum, evaluation for quality control shall include the following:

- 1) For DNA and protein microarrays – validation of content for each lot produced
- 2) For protein expression – sequence verification of clones and measuring protein expression
- 3) For antibodies generated – titer and conditions tested (native, denatured, etc.) and confirmed specificity
- 4) For peptides – mass spectroscopy profile verification
- 5) For bioinformatics and computational tools and software – proposed functionality

6. INFORMATION TECHNOLOGY AND DATA MANAGEMENT SYSTEMS

- a. Provide and maintain a secure, internal IT system architecture and computational infrastructure to support the data management, data analysis and other computational needs of the Center. The Contractor's institutional security policies and guidelines must be followed.
- b. Provide and maintain a secure network infrastructure that allows the Center investigators access to the computational and database resources and software applications, and facilitates data sharing and electronic communication exchanges within the Center.
- c. Provide, implement, populate, maintain, and update a database management system for the Center to include a Laboratory Information Management System (LIMS) and a system for tracking receipt, processing, and storage (timing, temperature, any freezing thawing cycles etc.) of clinical samples and information related to their characterization, while maintaining their confidentiality and anonymity. These databases shall have web and graphical user interfaces and support all data types and experimental results generated by, or related to, all steps of the clinical proteomics pipeline. The databases shall provide the Center with the capability to conduct queries and analyses, export data in a variety of formats, disseminate data, and submit experimental data to public repositories.
- d. The Contractor shall provide their institution's System Security Plan (SSP) within 90 calendar days of contract award to the Project Officer and the Contracting Officer. The

SSP will identify the system and detail the management, operational, and technical controls of the Contractor's system. The Contractor shall provide an updated SSP with their Annual Technical Progress Report following a major change to the Center infrastructure or revision to their SSP.

7. INFORMATION DISSEMINATION AND PROVISION OF CONTRACT-GENERATED RESOURCES

a. Information Dissemination to Public Databases and Repositories

- 1) *Plan to Share Resources with the Scientific Community.* Within 90 calendar days of contract award, develop and submit to the Project Officer, a Plan to Share Resources, such as proteomic data, protocols, technologies, reagents, bioinformatics and computational software tools and source codes generated under this contract, in a timely fashion to the scientific community. Within 14 calendar days after receipt of and agreement on comments from the Project Officer, modify the Plan as necessary to incorporate Project Officer recommended revisions and provide the revised Plan to the Project Officer for approval. The Project Officer will review the Plan annually and suggest modifications as needed. The Plan shall detail:
 - (a) How data generated under this contract shall be released to a publicly accessible database site or selected few database sites, as specified by the Project Officer, including the Center's public web portal described below, or NIAID Bioinformatics Resource Centers (<http://www.niaid.nih.gov/dmid/genomes/brc/default.htm>). Include a timeline for making the data available in the public domain within 90 calendar days of conclusion of a study.
 - (b) A process for decisions on what types of experimental data shall be placed in the public domain, including experimental data related to sample preparation, protein expression, cloning, purification, biochemical and biophysical characterization, mass spectroscopy, liquid chromatography, two-dimensional gel electrophoresis, protein array analysis and experimental protocols and quality control procedures of both completed and discontinued clinical proteomics research projects.
- 2) Within 30 calendar days of receipt of written approval by the Contracting Officer and the Project Officer, implement the Plan to Share Resources with the Scientific Community.
- 3) Deposit materials and reagents (e.g. physical clones, expression constructs, monoclonal antibodies, and polyclonal sera) generated during the study into public repositories, such as the NIAID Biodefense and Emerging Infections Research Resources Repository (<http://www.beiresources.org/>), within 90 calendar days of the conclusion of a study, or as directed by the Project Officer, for distribution to the broad scientific community. The Contractor shall keep sufficient materials and reagents to finish any ongoing study, but must deposit the remainder of the material and reagents for use by the scientific community.

b. Public Web Portal

Within 90 calendar days of contract award establish, maintain and make publicly available a web portal, to provide the following:

- 1) Information of general interest about the Center and its activities, staff members, Center's publications, news and events;
- 2) Summary statistics and status for each selected clinical proteomics research project in the protein biomarker pipeline;
- 3) Links to other public database resources hosting information about the candidate protein biomarkers generated by the Center; and
- 4) Source codes and executables of all software applications and algorithms newly developed or enhanced under the contract.

The Project Officer will approve information provided through the public web portal prior to live posting.

8. RECEIPT, STORAGE, SHIPPING, AND INVENTORY

- a. Develop and maintain efficient and effective procedures to support contract activities for receiving, storing, shipping, archiving and retrieving protein expression constructs, antibodies, peptides, and human clinical samples, such as serum, blood, urine, and stool, obtained from patients with infectious diseases.
- b. Obtain appropriate licenses and permits required by local, State, and Federal authorities for the safe transport and storage of clinical materials.
- c. Provide for safe packing, labeling, and shipping of materials and reagents to public repositories so that shipments are coordinated for timely receipt.
- d. Provide shipping containers that comply with domestic postal regulations. The shipping containers shall provide a sufficient margin of safety for maintaining appropriate environmental safeguards and desired refrigeration levels for specific products in transit, depending on the mode of transportation employed.
- e. Provide secure, safe and stable storage of materials and reagents under the required conditions (e.g. Biosafety Level) in a way that will maintain their activity and viability, and that meet local, State and Federal regulations:
 - 1) Provide facilities with aseptic and/or sterile conditions, as well as biosafety containment, as appropriate.
 - 2) Provide, maintain and operate facilities for the storage of bulk and packaged reagents at 2 to 8 degrees C, at -10 to -20 degrees C, at -70 to -90 degrees C, liquid nitrogen conditions.
 - 3) Supply uninterruptible power to accommodate the refrigerators/freezers and other equipment.

- 4) House the units in an air-conditioned facility with the capacity to maintain a room temperature of 66 to 72 degrees F.
 - 5) Provide freezers connected to a central alarm system that is monitored 24 hours per day, seven days per week by qualified Contractor staff. Emergency standby refrigerators and freezers shall be available in case of mechanical failure of storage space. The facility must have an auxiliary electric generator capable of operating all storage equipment, the security system, and the necessary lighting for at least 48 hours for back up in the event of utility company power failure. The back-up generator must be tested monthly under continuous full load for at least one hour.
 - 6) Provide an automated temperature monitoring system composed of individual temperature probes for 24 hours per day, 7 days per week monitoring. Identify measures to ensure that necessary personnel are notified in the event of a refrigerator/freezer malfunction. The Contractor shall be responsible for repairing malfunctioning equipment or for arranging for the prompt repair to ensure sample quality is not compromised.
 - 7) Maintain 24-hour per day, 7 days per week security that provides an appropriately secure environment for employees and materials within the facility.
- f. Establish and maintain an electronic inventory of all materials and reagents received, produced, stored, and shipped, in the Center's project database management system that includes searchable information, such as amounts available, storage locations, shipping data and other biological and chemical characteristics of the material.

9. PROJECT PLANNING, INITIATION, AND MANAGEMENT

a. Overall Project Management

Provide the technical and administrative infrastructure needed to ensure the efficient planning, initiation, implementation and management of all activities carried out under this contract, including effectively communicating with the Project Officer and the Contracting Officer. This infrastructure shall include:

- 1) A Principal Investigator (PI) with ultimate responsibility for the scientific and technical leadership of the Center and the management, coordination and integration of all contract activities, including directing the research, managing subcontracts and equipment purchases and making a wide range of decisions about staffing, standard protocols, pipeline priorities, intellectual property issues, preparing required reports, deliverables and other official documentation.
- 2) A Project Manager (PM) with overall responsibilities for project management, including ensuring quality assessment/quality control, fostering internal/external communications, tracking of projects in the clinical proteomics pipeline, preparing progress reports and other deliverable documentation, monitoring the budget, and making recommendations for changes to the Center activities and their timelines.

b. Program Development Plan

Prepare and submit 2 Program Development Plans (PDPs) for the Center to the Project Officer for review and approval. The first plan shall cover the initial 2 years of the contract and be submitted 90 calendar days after contract award. The second plan shall cover the final 3 years of the contract period and shall be submitted 2 years and 3 months from contract award. The PDPs shall:

- 1) Define the vision for and goals of the Center.
- 2) Describe the facilities, technology, personnel, and resource requirements, experimental protocols, quality control procedures and computational approaches of the Center and identify those that would best allow the Center to meet the objectives of the Statement of Work and needs of the scientific community.
- 3) Describe special or extraordinary facilities and resource requirements beyond the initial inception phase that would best allow it to meet the needs of the community.
- 4) Establish performance metrics and utilization measures of the Center as well as propose methods for gathering data to monitor them.

c. Meetings and Teleconferences

1) Monthly Meetings/Teleconferences

Plan and conduct meetings of the Contractor's Principal Investigator and Project Manager with the Project Officer and Contracting Officer at a minimum of monthly intervals, either in person or via teleconference, to discuss progress, problems, proposed solutions and any matter that is relevant to the scientific and financial administration of the Center and future activities. The schedule for those meetings will be established by the Project Officer and the Contracting Officer after contract award. The Contractor shall prepare and submit the meeting agenda and background materials to the Project Officer for review and approval 5 calendar days prior to the meeting, distribute the agenda and background materials to all meeting participants at least 2 calendar days in advance of the meeting, prepare and provide a summary of all meetings and teleconferences to the Project Officer within 7 calendar days of the conclusion of the meeting/teleconference, and include each summary in the Semi-Annual Technical Progress Reports.

2) Annual Meetings/Teleconferences

- (a) Annual Site Visits - Arrange for and conduct annual site visits for NIAID contract and program staff to review and discuss: project progress; problems and obstacles and approaches to overcoming identified problems and obstacles; recommendations for modifications in project timelines, objectives, and research approaches/methodologies based on outcomes to date; and future plans. These site visits shall be attended by the Principal Investigator, the Project Manager, the Contractor's business representative, and all key personnel. The Contractor shall be responsible for:
 - i. Planning and submitting the agenda to the Project Officer for approval;
 - ii. Developing written and oral presentation materials;

- iii. Arranging for the logistics associated with the site visits and for travel costs for all non-Government site visit attendees; and
- iv. Preparing and submitting Annual Site Visit Reports to the Project Officer and Contracting Officer within 30 calendar days of completion of each annual site visit.

(b) Programmatic Meetings

Organize and conduct, in conjunction with the Principal Investigator(s) of the other Center(s), an annual programmatic meeting of the Centers' investigators to share methodologies and findings and to discuss progress, problems, and proposed solutions. The meetings shall be attended by a maximum of 5 individuals from each Center, including subcontractor personnel, unless directed by the Project Officer, as well as the Project Officer, the Contracting Officer and other key NIAID and NIH staff. The meeting location and logistical arrangements shall be the responsibility of the Contractor. The Contractor shall prepare and submit the meeting agenda and background materials to the Project Officer for review and approval 14 calendar days prior to the meeting, distribute the agenda and background materials to all meeting participants at least 5 calendar days in advance of the meeting, and prepare and provide a summary of these meetings to the Project Officer within 7 calendar days of the conclusion of the meeting/teleconference, and include each summary in the Semi-Annual Technical Progress Reports.

d. Ad hoc Reports

Prepare and provide up to 3 ad hoc reports per year to the Project Officer and Contracting Officer, as requested, on topics that fall within the scope of the Statement of Work. Only with approval of the Project Officer, the information contained within the ad hoc reports may be provided to various branches of the Government and/or public health related agencies and collaborators. The Project Officer will specify the report format at the time of the request.

10. PUBLICATIONS AND PRESENTATIONS OF CONTRACT-GENERATED DATA AND FINDINGS

- a. Develop and implement policies and procedures for authorship, preparation, review, and final approval of publications, press releases, abstracts and oral presentations resulting from contract-sponsored studies, and for submission of manuscripts for publication in peer reviewed journals.
- b. The Contractor shall not publish, present or disseminate any information from work performed under this contract without submission of the materials to the Project Officer for review.
- c. The Project Officer will have 15 calendar days from receipt of materials to review and provide comments. If the Project Officer does not respond within this time frame, the Contractor may proceed with such publications or presentations. For press releases, the Project Officer will review advance copies of press releases not less than 7 calendar days prior to the issuance of the press release.

11. SAFETY OF RESEARCH FACILITIES

- a. Provide safe facilities and resources and conduct work in accordance with the Biosafety in Biomedical and Microbiological Laboratories guidelines, Centers for Disease Control and Prevention and the National Institutes of Health, fifth edition (<http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm>).
- b. Provide biocontainment facilities and staff with the required training and expertise to operate the facilities and conduct the contractual services at the appropriate Biosafety Level (BSL) (<http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm>)
- c. Provide training, protective garments, equipment, and monitoring to assure safe handling of potentially hazardous microorganisms and materials for all Contractor personnel involved in any activities provided under the contract. Safety and Health HHSAR 352.223-70 clauses shall apply.
- d. When appropriate, conduct work in accordance with the DHHS regulations regarding the transfer of select agents (42 CFR Part 72) (<http://www.cdc.gov/ncidod/srp/specimens/shipping-packing.html>).

12. FINAL TRANSITION

Plan and implement an orderly, safe and efficient transition to a subsequent contractor or to the Government, by the expiration date of the contract, including the transfer and movement of stored reagents and materials, data, web portals, databases, software applications and algorithms, protocols, technologies, purchased supplies and equipment, and any other resource generated under this contract.

- a. Prepare and submit, for review and approval by the Project Officer and the Contracting Officer, a draft written Final Transition Plan 12 months prior to the completion date of the contract. The Final Transition Plan shall detail how the resources generated under this contract shall be transferred in an orderly manner to a subsequent contractor or the Government. Within 14 calendar days after receipt of and agreement on comments from the Project Officer, modify the draft Final Transition Plan as necessary to incorporate Project Officer recommended revisions and provide the Final Transition Plan to the Project Officer for approval.
- b. Implement the Final Transition Plan as approved by the Project Officer and the Contracting Officer.

**ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS,
FORMAT FOR TECHNICAL PROPOSAL, and TABLE OF CONTENTS**

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

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

Offerors are advised to give careful consideration to the Statement of Work, all reference materials, and attachments, the Technical Evaluation Criteria in Section M, and the RFP as a whole in the development of their Technical Proposals.

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

Offerors are reminded that the total page limitation for the entire Technical Proposal is 200 pages including all appendices and attachments. Any pages in excess of this limit will be expunged from the proposal and will not be considered in the technical review.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1:

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

SECTION 2: TECHNICAL PROPOSAL OVERVIEW (suggested 3-page maximum)

Provide a brief overview of the proposed Center, including:

- A. A description of the activities to be performed by the offeror and those that shall be performed by all proposed subcontractors. This description should include the

identification of the proposed subcontractors and a list of key personnel of the offeror and the proposed subcontractors with degrees and titles.

- B. A description of the facilities, equipment, and other resources to be made available by the offeror and all proposed subcontractors.

SECTION 3: TECHNICAL APPROACH

1. CLINICAL PROTEOMICS FACILITIES AND SCIENTIFIC/TECHNICAL TEAM (SOW 1)

- a. Describe plans to establish, operate and maintain a high throughput, state-of-the art Clinical Proteomics Center for Infectious Diseases and Biodefense for discovery, qualification, and verification of candidate pathogen and host protein biomarkers useful for clinical research of infectious diseases. Include a discussion of the facilities, resources, technologies, equipment, methodologies, and scientific and technical expertise necessary to operate a clinical proteomics center to identify biomarkers to be made widely available to the scientific community. Provide a description of the bioinformatics and computational expertise and software tools required to track clinical samples and reagents, and to store, manage, analyze and release data to the scientific community.
- b. Describe technical approaches and strategies for the development, evaluation, and incorporation of improvements in existing proteomics technologies, platforms and resources and efficiency of production to maintain a high throughput, state-of-the-art proteomics facility.
- c. Describe experience and accomplishments in operating a state-of-the art proteomics facility during the last 5 years. Include a discussion of technical problems encountered in discovery, qualification, and verification of protein biomarkers and how they were overcome. Describe approaches used to update equipment, procedures, and technologies to keep pace with the state-of-the art, and the rationale for instituting changes.

2. CLINICAL PROTEOMICS PIPELINE (SOW 2)

A. Initial Clinical Proteomics Research Project

Describe in detail an Initial Clinical Proteomics Research Project for the discovery, qualification, and verification of a candidate biomarker(s) to be undertaken within 60 calendar days of contract award. The Project Plan (limited to 25 pages) should include detailed information regarding:

- i. **Significance:** Scientific rationale and justification for the proposed candidate biomarkers(s) chosen for the clinical proteomics research project. Address the relevance of the proposed protein biomarker(s) to be identified for use by the broad scientific community and the potential for clinical utility in the diagnosis and treatment of diseases caused by NIAID Category A-C priority pathogens and those causing emerging and re-emerging infectious diseases.
- ii. **Approach:**

- (1) Goals and objectives:
- (2) Study design; including but not limited to:
 - (a) How samples will be obtained (prospectively or retrospectively)
Include documentation of commitment of the collaborating clinical researchers and the assured availability of a sustained source(s) of the quantity of well characterized clinical samples from cases and controls necessary to obtain statistically significant results from the initial clinical proteomics research project.
 - (b) Information to be provided for each sample: diagnosis, gender, age, race, method of sample collection and handling, information on concurrent diseases, documentation of appropriate informed consent for the proposed use, documentation indicating that samples are anonymous in compliance with 45CFR46.102(f)(2), documentation that the clinical studies are being done in accordance with all Federal regulations and requirements, and NIAID Clinical Terms of Award (<http://www3.niaid.nih.gov/research/resources/DMIDClinRsrch/policies.htm>)
 - (c) Sample size and detailed Statistical Analysis Plan
 - (d) Clinical endpoints and their relevance to answering the question(s) being addressed
 - (e) Technical approach: Detail plans and procedures necessary to carry out the discovery, qualification, and verification of the candidate biomarker(s). Include a discussion of potential pitfalls and alternative approaches.
- iii. Plan for quality assurance and quality control, proposed timelines, milestones and deliverables.
- iv. **Investigators:** List the proposed scientific and technical personnel, including collaborators.

B. Source of Clinical Samples

- a. Describe the proposed procedures to obtain and ensure a sustained source of well-characterized clinical samples from cases and controls from clinical infectious disease research collaborators. Include plans for:
 - i. collecting and documenting minimum data elements for samples obtained detailing demographic characteristics (such as, gender, age, and race), diagnosis, information on concurrent diseases, and method of sample collection and handling;
 - ii. ensuring and documenting informed consent for the proposed use;
 - iii. ensuring that all collaborating institutions providing samples obtain the appropriate Health Insurance and Portability and Accountability Act of 1996

(HIPAA) authorization to collect and transmit data and samples; and IRB approval for protocols, informed consent forms, and processes for using previously collected samples or samples to be collected.

- iv. ensuring all protocols for IRB approved clinical studies are conducted ethically and safely
- v. ensuring and documenting that clinical samples are anonymous in compliance with 45CFR46.102(f)(2),
- vi. ensuring that all clinical studies undertaken to collect samples, including those conducted by collaborators, are conducted in accordance with all Federal regulations and requirements, and NIAID Clinical Terms of Award <http://www3.niaid.nih.gov/research/resources/DMIDClinRsrch/policies.htm>.

b. Describe previous experience in obtaining well-characterized clinical samples from cases and controls necessary to conduct a proteomics research project. Discuss, to the extent applicable, instances in which the samples that were used had been previously accumulated for other purposes, and those in which clinical studies were undertaken to collect clinical samples specifically for use in the clinical proteomics research projects. Detail experience in:

- i. Thoroughly annotating the samples with respect to demographic characteristics (such as gender, age, and race) diagnosis and information on concurrent diseases, and method of sample collection and handling.
- ii. Documenting appropriate informed consent for the proposed use.
- iii. Documenting that samples are anonymous in compliance with 45CFR46.102(f)(2).
- iv. Assuring a sustained source(s) of the quality and quantity of well-characterized clinical samples needed to complete the study.

C. Discovery, Qualification and Verification of Candidate Biomarkers

- 1. Describe approaches for conducting clinical proteomics research projects to discover, qualify, and verify protein biomarkers using high-throughput proteomic and genomic technologies and platforms. Include a discussion of methods and protocols including optimization strategies, as well as a description of the rationale for augmenting methods for:
 - i. Preparation of human clinical samples for proteomic analysis.
 - ii. Preparation and initial protein purification for clinical samples for use in protein profiling assays.
 - iii. High-throughput comparative and qualitative protein profiling assays to discover and qualify protein biomarkers in human samples by means of, but not limited to, protein solubilization, fractionation and separation and analytical techniques such as isoelectric focusing, 2-dimensional gel electrophoresis, and high-performance liquid chromatography, mass spectrometry platforms such as LC-MALDI-TOF-MS and LC-MS/MS, protein arrays, and immunoassays and bioinformatics and biostatistical tools.
 - iv. Verification studies by means of, but not limited to, cloning and protein expression and purification to generate high quality DNA and/or protein

arrays, and immunoassays to achieve sensitivity and specificity measurements sufficient to achieve the statistical significance of protein biomarkers.

2. Describe experience in conducting proteomics research projects to discover, qualify, and verify protein candidate biomarkers using high-throughput proteomic technologies and platforms. Include a discussion of collaborations established for the successful implementation and completion of clinical proteomics research projects, and of the pitfalls/obstacles encountered and the mid-course modifications and corrections applied. Provide a list of protein biomarkers identified and their potential relevance to diagnosis and treatment of infectious diseases.

3. QUALITY ASSURANCE/QUALITY CONTROL (SOW 5)

Describe a plan to standardize contract processes and ensure the conduct of all proteomics activities meets the requirements of the contract. Describe quality control procedures that will be used throughout the discovery, qualification, and verification steps including quality control of reagents and tools generated during the contract.

4. RECEIPT, STORAGE, SHIPPING, AND INVENTORY (SOW 8)

Describe procedures for receiving and storing samples, materials, and reagents; and distributing and shipping samples, materials and reagents in accordance with applicable safety and other regulatory guidelines.

SECTION 4. CLINICAL PROTEOMICS SERVICES TO THE SCIENTIFIC COMMUNITY

1. REQUEST AND REVIEW OF PRE-PROPOSALS (SOW 3)

- a. Describe plans to address: i) the approach the broad scientific community will use to submit pre-proposals for clinical proteomics research projects to be undertaken at the Center for identifying candidate protein biomarkers and ii) the review process the Center will use to approve the pre-proposals. Include information on:
 - i. the outreach activities to promote awareness of the clinical proteomics services provided to the broad scientific community
 - ii. web-based receipt of pre-proposals
 - iii. pre-proposal design and information to be completed by requestors
 - iv. process for acceptance and review of pre-proposals
 - v. evaluation criteria for selecting pre-proposals
 - vi. timeline for the process from receipt of pre-proposals to review
 - vii. process to ensure confidentiality

2. CLINICAL PROTEOMICS RESEARCH PROJECT PLANS (SOW 3)

- a. Describe plans for working with members of the broad scientific community to develop Clinical Proteomics Research Project Plans for clinical proteomics research projects to be undertaken by the Center. Discuss how the process will be made objective. For example, how will the most promising requests be selected for further development if the number of requests exceeds the capacity of the Center staff to

respond and how will requests that are not worthy of further consideration be managed?

- b. Describe plans for working with collaborators to develop ethical, safe and implementation-ready clinical plans for all approved clinical proteomics research projects.

3. RECEIPT AND REVIEW OF CLINICAL PROTEOMICS RESEARCH PROJECT PLANS (SOW 3)

Describe plans to manage receipt and review of Clinical Proteomics Research Project Plans to conduct clinical proteomics research projects, including the following aspects of the process:

- i. Development of criteria, in collaboration with the other Center(s) to evaluate proposed Clinical Proteomics Research Project Plans.
- ii. Development of a process, in collaboration with the other Center(s), to manage receipt and review of Clinical Proteomics Research Project Plans to conduct clinical proteomics research projects in collaboration with the Center. The plan shall outline processes and the information technology systems required to support them for:
 - (a) Web-based receipt of Clinical Proteomics Research Project Plans
 - (b) Tracking the receipt and review of Clinical Proteomics Research Project Plans, and reporting results to applicants.
 - (c) Review by the Scientific Working Group (SWG) for scientific and technical merit including turnaround time and how confidentiality will be maintained.
 - (d) Reporting SWG recommendations to the Project Officer for approval of Clinical Proteomics Research Project Plans to be undertaken by the Center.
 - (e) Reporting feedback to requestors regarding the status of their Clinical Proteomics Research Project Plans.

Describe previous experience in conducting outreach, working with members of the community to develop collaborations, and in managing web-based systems.

4. SCIENTIFIC WORKING GROUP (SOW 4)

Describe in detail plans to establish a Scientific Working Group (SWG), in conjunction with the Project Officer, composed of approximately seven (7) investigators drawn from academia, government, and industry. These individuals shall be independent of the Center and possess expertise and experience in discovery, qualification, and verification aspects of the clinical proteomics pipeline, biostatistics, bioinformatics, clinical microbiology, and infectious diseases related to diverse organisms and pathogens. Outline how the SWG will interact with the Contractor to provide advice to the Contractor on the needs of the scientific community regarding clinical proteomics reagents and resources and on the management, operations and planning of future directions of the Center. Outline also how the SWG will review applications and make recommendations based on scientific and technical merit to the Project Officer for collaborative clinical proteomics research projects to be undertaken by the Center.

Do not identify in the Technical Proposal the names of any individual proposed for SWG membership nor contact any specific individual regarding service on the SWG.

5. INFORMATION DISSEMINATION AND PROVISION OF CONTRACT-GENERATED RESOURCES (SOW 7)

Provide a detailed plan for sharing resources such as proteomic data, protocols, technologies, reagents, technologies, and bioinformatics and computational software tools and source codes generated under this contract, with the scientific community, including:

- a. **Public Databases:** A plan to disseminate data related to sample preparation, protein expression, cloning, purification, biochemical and biophysical characterization, mass spectroscopy, liquid chromatography, 2D gel electrophoresis, and protein array analysis
- b. **Public Web portal:** A description of the proposed public web portal, including methods for design and maintenance, to disseminate general information about the Center, its activities, results and publications to the public; to provide relevant information about the biomarkers and their status in the protein biomarker pipeline; to distribute open source software tools and algorithms; and to provide web links to the data released by the Center into other database resources.
- c. **Public Repositories:** Procedures for distribution of physical materials and reagents to the scientific community through existing repositories.

SECTION 5: 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 key scientific and technical personnel, including scientific and technical personnel of all collaborators and proposed subcontractors. Limit CVs to 2-3 pages and provide selected references for publications relevant to the scope of the RFP, and include experience with projects of similar scope, size and complexity carried out by the offeror and any proposed collaborators and subcontractors over the past 5 years.

1. **Principal Investigator (PI):** Describe the experience, training, expertise, education, qualifications and percentage of effort of the proposed Principal Investigator to lead and direct the activities to be carried out under this contract, including:
 - a. Record of strong scientific leadership
 - b. Experience in the design, management, and operation of a high throughput, state-of-the art proteomics center
 - c. Experience and demonstrated competence in designing methodology for and discovering, qualifying, validating, and optimizing assays for protein biomarkers
 - d. Demonstration of having engaged clinical collaborators to provide a sustained source of samples from which to develop protein biomarkers
2. **Project Manager (PM):** Describe the experience, training, expertise, education, qualifications, and percentage of effort of the proposed Project Manager who will assume responsibility for overall management of the Center's activities, including:

- a. Ensuring quality assessment/quality control
- b. Fostering internal/external communications
- c. Tracking of proteomics research projects in the proteomics pipeline
- d. Preparing progress reports and other deliverable documentation
- e. Monitoring the budget and providing required financial reports to the Contracting Officer and Project Officer
- f. Monitoring Center activities and progress and make recommendations for changes as necessary

3. Other Key Scientific and Technical Personnel: Describe the experience, training, expertise, qualifications, and level of effort for all proposed key scientific and technical personnel, including subcontractors. The list shall include, but is not limited to, individuals with expertise in:

- a. Molecular biology
- b. Clinical infectious diseases
- c. Preparation of samples for proteomic analysis
- d. Proteomics technologies and platforms
- e. Bioinformatics (computational biology and computer science)
- f. Software engineering
- g. Biostatistics
- h. IT administration
- i. Project management

SECTION 6: FACILITIES, EQUIPMENT, SAFETY AND TRAINING

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 (including lease or ownership information), should be provided.
2. Identification and description of ALL support services (including Information Technology systems) that will be required to effectively complete the SOW.

The Technical Proposal should further document how the Contractor shall (SOW 11):

3. Provide safe facilities and resources and conduct work in accordance with the Biosafety in Biomedical and Microbiological Laboratories guidelines, Centers for Disease Control and Prevention and the National Institutes of Health, fifth edition.
(<http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm>).
4. Provide biocontainment facilities and staff with the required training and expertise to operate the facilities and conduct the contractual services at the appropriate Biosafety Level (BSL).
(<http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm>).
5. Provide training, protective garments, equipment, and monitoring to assure safe handling of potentially hazardous microorganisms and materials for all Contractor personnel involved in any activities provided under the contract. Safety and Health HHSAR 352.223-70 clauses shall apply.

6. When appropriate, conduct work in accordance with the DHHS regulations regarding the transfer of select agents (42 CFR Part 72) (<http://www.cdc.gov/ncidod/srp/specimens/shipping-packing.html>).

SECTION 7: PROJECT PLANNING, INITIATION, AND MANAGEMENT

1. OVERALL PROJECT MANAGEMENT (SOW 9)

- a. Describe in detail how the project will be staffed, organized and managed in relation to the planning, initiation, implementation, conduct, and completion of tasks identified in the Statement of Work. Describe in detail the responsibilities for all proposed personnel who will be assigned to the contract, including proposed subcontractors and consultants, and provide an administrative framework indicating clear lines of authority and responsibility for the personnel. Include a diagram of the proposed organizational/management structure for the Center.
- b. Describe in detail 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.
- c. Outline how the Principal Investigator will communicate and interact with the Project Officer and Contracting Officer, how the Principal Investigator will communicate, monitor, and manage the Center both internally and externally (at subcontractor facilities), and how the Principal Investigator will communicate with the other Center PI(s).

2. INFORMATION TECHNOLOGY AND DATA MANAGEMENT SYSTEMS (SOW 6)

- a. Identify and describe the internal data management system architecture and computational infrastructure to support the data management, data analysis and other computational needs of the proposed Center.
- b. Describe the network infrastructure that will allow the Center's investigators access to the computational and database resources and software applications, to facilitate data sharing and communication exchange within the Center, and to support the data dissemination goals of the Center.
- c. Describe the Laboratory Information Management System (LIMS) and any other database systems that will be utilized and maintained to track, receive, process, store, and access data generated by, or related to, all proteomics activities, the Center's data analysis needs and data dissemination activities delineated in the Statement of Work.

SECTION 8: OTHER CONSIDERATIONS

Section L of the RFP provides minimum documentation requirements for the following items. The required information described in Section L should be assembled together, in the following clearly marked sections of the Technical Proposal. Refer to Section L of the RFP for specific

requirements. Read each section below carefully. In some cases, offerors may be asked to provide documentation which is in addition to the minimum requirements identified in Section L.

1. Human Subjects

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

2. Obtaining and Disseminating Biomedical Research Resources

Section L of the RFP specifies the minimum documentation requirements for this element. The Technical Proposal should document all information necessary to evaluate this issue.

3. Sharing Research Data (Plan)

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

4. Sharing of Model Organisms for Biomedical Research (Plan)

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

5. Information Technology (IT) Systems Security

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

ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS

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

Offerors are advised to give careful consideration to the Statement of Work, all reference material provided as attachments, the Technical Evaluation Criteria, and, the RFP as a whole, in the development of your proposal. The information requested in these instructions should be used as a guide for the development and formatting of your Business Proposal. Offerors should consider and include the information requested here, as well as **any other** information which will benefit the proposal.

BUSINESS PROPOSAL – TABLE OF CONTENTS

SECTION 1 – PROPOSAL COVERSHEET (Use form NIH 2043 identified in section J)

SECTION 2 – COST OR PRICE SUPPORT

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

SECTION 3 – UNIFORM COST ASSUMPTIONS

1. **Technical Cost Assumptions.** For budget estimating purposes, Offerors should assume the following:
 - a. One clinical proteomics research project will involve the prospective collection of human samples.
 - b. Completion of 5 clinical proteomics research projects (from discovery through qualification, and verification) over the 5 years of the contract award.
 - c. Conduct of 3 ongoing clinical proteomics research projects each year of the contract.
 - d. Receipt and review of 25 pre-proposals from the scientific community per year.
 - e. Establishment of 15 potential collaborations with members of the scientific community per year to develop Project Plans to conduct clinical proteomics research projects.
 - f. Receipt and review of 10 Project Plans from the scientific community per year to conduct clinical proteomics research projects.
 - g. Inclusion of up to 5% of the total annual budget for research and development efforts to improve existing proteomics technologies and resources.

2. **Travel and Teleconferences**

- a. *Monthly Meetings/Teleconferences:* Assume one meeting per month of the Contractor's Principal Investigator and Project Manager with the Project Officer and Contracting Officer, either in person or via teleconference. Budget travel costs for the first meeting and a subsequent meeting 6 months later to be held in Bethesda, MD for 1 half-day to discuss progress, problems, proposed solutions and any matter that is relevant to the scientific and financial administration of the Center and future activities. Budget for the remaining monthly meetings to be held via teleconference.
- b. *Annual Meetings:*
 - 1) *Annual Site Visits:* Assume annual 2-day site visits at the Contractor's facilities to be attended by the Principal Investigator, Program Manager, and key personnel of the Contractor, 5 Government personnel and 6 collaborators and/or key personnel of subcontractors. Travel and per diem costs for the Government personnel shall not be provided by the contract. Assume that each Annual Site Visit Report will be 10 pages in length.
 - 2) *Annual Programmatic Meetings:* Assume annual 1 and ½ day programmatic meetings, to be held in conjunction with the other Center(s) in Bethesda, MD. Include travel costs (transportation, meals, hotel, etc.) for 5 Contractor staff members, including the Principal Investigator, the Project Manager, key co-investigators, collaborators and subcontractors.
- c. *Scientific Working Group Meetings:* Assume annual 1-day Scientific Working Group (SWG) meetings to be held at the Contractor's site. Include travel costs (transportation, meals, hotel, etc.) for 7 SWG members and 3 others who may be staff members of the Contractor, collaborators or proposed subcontractors. In addition, include costs for two (2), 3-hour teleconferences per year to be attended by the 7 SWG members and 3 staff members of the Contractor, collaborators, or proposed subcontractors.
- d. *Scientific Meetings:* Budget travel costs (transportation, meals, hotel, etc) for 3 scientific meetings for up to 3 personnel to travel to present scientific findings generated under this contract as well as to promote outreach and awareness of the clinical proteomic services provided by the Center to the scientific community.
- e. *Visits to Academic Institutions and Industry:* Budget travel costs (transportation, meals, hotels, etc.) for 2 trips per year for 1 person per trip for 5 days to visit academic institutions or industry to learn about new proteomics technologies and platforms.

3. Outreach to the Scientific Community

Assume \$50,000 per year for promoting awareness of the clinical proteomics services provided to the broad scientific community through electronic and print media, posters and oral presentations at scientific meetings, symposia and workshops, brochures or advertisement in relevant scientific journals.

4. Storage of Data and Materials

Assume \$10,000 annually for storage of data and materials, receipt of samples to the Center, and shipping of materials and reagents to public repositories with a 3% annual escalation in years 2 through 5 of the contract period of performance.