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

RFP-NIH-NIAID-DMID-07-19
"NIAID Structural Genomics Centers for Infectious Diseases"

OMB Control Number 0990-0115

1. **OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE FOLLOWING WEBSITE FOR ANY SOLICITATION AMENDMENTS. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.** http://www.fedbizopps.gov/

2. **SECTION A – SOLICITATION/CONTRACT FORM -- PURCHASE AUTHORITY: FAR 1.602-1**
NOTE: The issuance of this solicitation does not commit the government to an award.

3. **Issue Date:**	4. **Due Date:**	5. **Small Bus. Set-Aside:** [ ]Yes [X] No
September 14, 2006	**December 15, 2006**	**8(a) Set-Aside:** [ ]Yes [X] No
	Time: **4:00 P.M., Local Time**	**NAICS:** 541710 (See Part IV, Section L.)

6. **Just In Time:**	7. **Number of Awards:**	8. **Technical Proposal Page Limits:**
[X] No [ ] Yes (See Part IV, Section L.)	[ ] Only 1 Award [X] Multiple Awards	[ ] No [X] Yes (See Section J, Attachment 1, Packaging and Delivery of Proposal)

9. **Issued By:**

Robert J. Singman
Contracting Officer
Office of Acquisitions, DEA, NIH, NIAID
6700-B Rockledge Drive
Room 3214, MSC 7612
Bethesda, MD 20892-7612

10. [**X**] **NIAID reserves the right to make awards without discussion.**

11. **Options:**

[X] No
[ ] Yes (See Part IV, Section L.)

12. **Period of Performance:**

September 28, 2007 through September 27, 2012

13. **Primary Point of Contact:**	14. **Secondary Point of Contact:**	15. **Protest Officer:**
Name : Robert Singman **Phone:** 301- 451-2607 **Fax:** 301-480-4675 **E-Mail:** rs485j@nih.gov	**Name:** Sharon Kraft **Phone:** 301-496-0195 **Fax:** 301-480-4675 **E-Mail: skraft@niaid.nih.gov**	Branch Chief, MID RCB-A, OA Address (see Block 9.)

16. **COLLECT CALLS WILL NOT BE ACCEPTED. FACSIMILE SUBMISSIONS ARE NOT ACCEPTABLE.**

17. Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See Part III, SECTION J – Attachments)

18. **DELIVERY ADDRESS INFORMATION**

19. **Hand Delivery or Overnight Service:**	20. **U.S. Postal Service or an Express Delivery Service**
Robert Singman Contracting Officer Office of Acquisitions, DEA, NIH, NIAID 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	Robert Singman Contracting Officer Office of Acquisitions, DEA, NIH, NIAID 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612

21. The **Official Point of Receipt** for the purpose of determining timely delivery is the address provided in Block 19, above. The original paper copy with original signatures is the official copy for recording timely receipt. If the original paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with FAR 15.208 entitled "Submission, Modification, Revision, and Withdrawal of Proposals." FACSIMILE AND E-MAIL SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

DETAILED TABLE OF RFP CONTENTS

PART I - THE SCHEDULE

THE CONTRACT SCHEDULE SET FORTH IN SECTIONS B THROUGH H, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS NOT AN EXACT REPRESENTATION OF THE PROPOSED CONTRACT DOCUMENT. CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (I.E., THOSE RELATING TO THE ORGANIZATIONAL STRUCTURE [E.G., NON-PROFIT, COMMERCIAL] AND SPECIFIC COST AUTHORIZATIONS UNIQUE TO THE OFFEROR'S PROPOSAL AND REQUIRING CONTRACTING OFFICER PRIOR APPROVAL) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. HOWEVER, THE ENCLOSED CONTRACT SCHEDULE PROVIDES ALL THE NECESSARY INFORMATION FOR THE OFFEROR TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

To apply state-of-the-art structural genomics technologies to structurally characterize targeted proteins from NIAID Category A-C pathogens and organisms causing emerging or re-emerging infectious diseases. The goal is to create a collection of three dimensional protein structures that are widely available to the broad scientific community and serve as a blueprint for structure-based drug development for infectious diseases.

ARTICLE B.2. PRICES/COSTS

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

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

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

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

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 September 14, 2006, attached hereto and made a part of this Solicitation (See Section J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. Please refer to Attachment 5, Reporting Requirements and Deliverables under this solicitation.

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, TBD is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at 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 52.246-8, Inspection of Research and Development - Cost-Reimbursement (May 2001).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

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

a. The items specified below as described in SECTION C, ARTICLE C.2. will be required to be delivered F.O.B. Destination as set forth in FAR Clause 52.247-35, F.o.b. Destination, Within Consignees Premises (April 1984), and in accordance with and by the date(s) specified in Section C, Article C.2. and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of the contract.

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

This contract incorporates the following clause(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).

52.242-17, Government Delay of Work (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

Any contract awarded from this RFP will contain the following:

ARTICLE G.1. PROJECT OFFICER

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

[To be specified prior to award]

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

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

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL

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

The following individuals are considered to be essential to the work being performed hereunder:

NAME	TITLE

[To be specified prior to award]

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

a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

These instructions also provide for the submission of financial and personnel reporting required by HHSAR 342.7002.

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

(a) To be considered a "proper" invoice in accordance with FAR 32.9, Prompt Payment, each invoice shall clearly identify the two contract numbers that appear on the face page of the contract as follows:

Contract No. (This is the 17 digit number that appears in Block 2 of the SF-26, i.e. HHSN266200711000C.)

ADB Contract No. (This is the 10 digit number that appears in the upper left hand corner of the SF-26, i.e. N01-AI-41234.)

(b) An original and two (2) copies to the following designated billing office:

Contracting Officer
Office of Acquisitions
National Institute of Allergy & Infectious Diseases, NIH
Room 3214, MSC 7612
6700B Rockledge Drive
Bethesda, MD 20892-7612

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

b. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to the salary rate limitation provisions as specified in SECTION H. of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with the applicable Public Law Number for the applicable Fiscal Year as stated in SECTION H. of the above referenced contract."

ARTICLE G.4. INDIRECT COST RATES

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

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

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

ARTICLE G.5. 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 evaluations will be prepared annually to coincide with the bi-annually anniversary date of the contract.

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

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic

use involving humans without the prior written approval of the Contracting Officer.

ARTICLE H.2. 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.3. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

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

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

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

ARTICLE H.4. 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.5. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

(1) The Small Business Subcontracting Plan, dated TBD 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 Contract shall be included as a contact for notification purposes at the following e-mail address: asiller@niaid.nih.gov

ARTICLE H.6. 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 per year salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year

contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

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

[Applicable information to be included at award]

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

For the period 10/1/05 - 12/31/05, the Executive Level I rate is $180,100. Effective January 1, 2006, the Executive Level I rate increased to $183,500 and will remain at that rate until it is revised. See the web site listed below for the Executive Schedule rates of pay:

FOR FY-06 EXECUTIVE LEVEL SALARIES EFFECTIVE JANUARY 1, 2006:
http://www.opm.gov/oca/06tables/html/ex.asp

(Note: This site shows the FY-06 rates. For previous years, click on "salaries and wages" and then scroll down to the bottom of the page and click on the year to locate the desired Executive Level salary rates.)

ARTICLE H.7. ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) all Electronic and Information Technology (EIT) developed, procured, maintained and/or used under this contract shall be in compliance with the "Electronic and Information Technology Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR Part 1194. The complete text of Section 508 Final Standards can be accessed at http://www.access-board.gov/.

ARTICLE H.8. PUBLICATION AND PUBLICITY

The contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

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

ARTICLE H.9. PRESS RELEASES

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

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

[Applicable information to be included at award]

ARTICLE H.10. 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.11. 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.12. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

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

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

a. Sharing of Model Organisms for Biomedical Research

The plan for sharing model organisms submitted by the contractor is acceptable/The contractor'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.

ARTICLE H.13. SHARING RESEARCH DATA

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

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

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

ARTICLE H.14. 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.15. 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.16. 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.17. ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) all Electronic and Information Technology (EIT) developed, procured, maintained and/or used under this contract shall be in compliance with the “Electronic and Information Technology Accessibility Standards” set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the “Access Board”) in 36 CFR Part 1194. The complete text of Section 508 Final Standards can be accessed at http://www.access-board.gov/.

The standards applicable to this requirement are [identified in the Statement of Work/listed below]:

ARTICLE H.18. 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.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

TBD

(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

TBD

(End of Clause)

ARTICLE H.20. 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.21. CONSTITUTION DAY

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

ARTICLE H.22. CONFIDENTIALITY OF INFORMATION

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

ARTICLE H.23. 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.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses 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. Also, the full text of a clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html.

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

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Jul 2004	Definitions (Over $100,000)
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Sep 2005	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
52.204-7	Jul 2006	Central Contractor Registration
52.209-6	Jan 2005	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Oct 2004	Pension Adjustments and Asset Reversions
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Dec 2002	Allowable Cost and Payment

52.216-8	Mar 1997	Fixed Fee
52.219-8	May 2004	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Jul 2005	Small Business Subcontracting Plan (Over $500,000, $1,000,000 for Construction)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000, $1,000,000 for Construction)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor
52.222-21	Feb 1999	Prohibition of Segregated Facilities
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-50	Apr 2006	Combating Trafficking in Persons
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Aug 2003	Toxic Chemical Release Reporting (Over $100,000)
52.225-1	Jun 2003	Buy American Act - Supplies
52.225-13	Feb 2006	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data - General
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Oct 2003	Prompt Payment, Alternate I (Feb 2002)
52.232-33	Oct 2003	Payment by Electronic Funds Transfer--Central Contractor Registration

52.233-1	Jul 2002	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate I (January 2006)
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.244-6	Feb 2006	Subcontracts for Commercial Items
52.245-5	May 2004	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract)
52.245-9	Aug 2005	Use and Charges
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

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

HHSAR CLAUSE NO.	DATE	TITLE
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.216-72	Oct 1990	Additional Cost Principles
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publications and Publicity
352.270-7	Jan 2001	Paperwork Reduction Act

[End of GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT - Rev. 04/2006].

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

ARTICLE I.2 AUTHORIZED SUBSTITUTION OF CLAUSES

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

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

Alternate II (October 2001) of FAR Clause 52.219-9, Small Business Subcontracting Plan (July 2005) is added.

FAR Clause 52.232-20, Limitation Of Cost (April 1984), is deleted in its entirety and FAR Clause 52.232-22, Limitation Of Funds (April 1984) is substituted therefor. [NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]

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

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

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

(2) FAR Clause 52.217-2, Cancellation Under Multiyear Contracts (July 1996).

(3) FAR Clause 52.227-14, Rights in Data - General (June 1987).

(4) Alternate II (June 1987), FAR Clause 52.227-14, Rights in Data--General (June 1987).

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

(5) Alternate III (June 1987), FAR Clause 52.227-14, Rights in Data--General (June 1987).

Additions to, or limitations on, the restricted rights set forth in the Restricted Rights Notice of subparagraph (g)(3) of the clause are expressly stated as follows:

(6) 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:

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

(8) FAR Clause 52.227-23, Rights to Proposal Data (Technical) (June 1987).

Excluded pages from the proposal dated , are identified as follows:

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

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

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

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

(13) FAR Clause 52.242-4, Certification of Final Indirect Costs (January 1997).

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

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

(1) HHSAR Clause 352.223-70, Safety and Health (January 2001). [This clause is provided in full text in Section J - Attachments.]

(2) HHSAR Clause 352.224-70, Confidentiality of Information (April 1984 - including revisions mandated by the 1/3/2005 Federal Register notice which was effective March 2005).

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

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

The following clauses are attached and made a part of this contract: None

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

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

This contract incorporates the following clauses in full text.

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

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

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

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

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

in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).

Notice to Employees

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

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

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

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

To locate the nearest NLRB office, see NLRB's website at http://www.nlrb.gov.

(c) The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR part 470, and orders of the Secretary of Labor.

(d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.

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

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

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

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

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

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

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

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

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 20210, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

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

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

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States.

b. FAR Clause 52.222-50, Combating Trafficking in Persons (April 2006)

(a) Definitions. As used in this clause-- Coercion means--

(1) Threats of serious harm to or physical restraint against any person;
(2) Any scheme, plan, or pattern intended to cause a person to believe that failure to perform an act would result in serious harm to or physical restraint against any person; or
(3) The abuse or threatened abuse of the legal process.
Commercial sex act means any sex act on account of which anything of value is given to or received by any person.

Debt bondage means the status or condition of a debtor arising from a pledge by the debtor of his or her personal services or of those of a person under his or her control as a security for debt, if the value of those services as reasonably assessed is not applied toward the liquidation of the debt or the length and nature of those services are not respectively limited and defined.

Employee means an employee of a Contractor directly engaged in the performance of work under a Government contract, including all direct cost employees and any other Contractor employee who has other than a minimal impact or involvement in contract performance.

Individual means a Contractor that has no more than one employee including the Contractor. Involuntary servitude includes a condition of servitude induced by means of--

(1) Any scheme, plan, or pattern intended to cause a person to believe that, if the person did not enter into or continue in such conditions, that person or another person would suffer serious harm or physical restraint; or
(2) The abuse or threatened abuse of the legal process.

Severe forms of trafficking in persons means--

(1) Sex trafficking in which a commercial sex act is induced by force, fraud, or coercion, or in which the person induced to perform such act has not attained 18 years of age; or
(2) The recruitment, harboring, transportation, provision, or obtaining of a person for labor or services, through the use of force, fraud, or coercion for the purpose of subjection to involuntary servitude, peonage, debt bondage, or slavery. Sex trafficking means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act.

(b) Policy. The United States Government has adopted a zero tolerance policy regarding Contractors and Contractor employees that engage in or support severe forms of trafficking in persons, procurement of commercial sex acts, or use of forced labor. During the performance of this contract, the Contractor shall ensure that its employees do not violate this policy.

(c) Contractor requirements. The Contractor, if other than an individual, shall establish policies and procedures for ensuring that its employees do not engage in or support severe forms of trafficking in persons, procure commercial sex acts, or use forced labor in the performance of this contract. At a minimum, the Contractor shall--

(1) Publish a statement notifying its employees of the United States Government's zero tolerance policy described in paragraph (b) of this clause and specifying the actions that will be taken against employees for violations of this policy. Such actions may include, but are not limited to, removal from the contract, reduction in benefits, or termination of employment;

(2) Establish an awareness program to inform employees about--

(i) The Contractor's policy of ensuring that employees do not engage in severe forms of trafficking in persons, procure commercial sex acts, or use forced labor;
(ii) The actions that will be taken against employees for violation of such policy;
(iii) Regulations applying to conduct if performance of the contract is outside the U.S., including--

(A) All host country Government laws and regulations relating to severe forms of trafficking in persons, procurement of commercial sex acts, and use of forced labor; and
(B) All United States laws and regulations on severe forms of trafficking in persons, procurement of commercial sex acts, and use of forced labor which may apply to its employees' conduct in the host nation, including those laws for which jurisdiction is established by the Military Extraterritorial Jurisdiction Act of 2000 (18 U.S.C. 3261-3267), and 18 U.S.C 3271, Trafficking in Persons Offenses Committed by Persons Employed by or Accompanying the Federal Government Outside the United States;

(3) Provide all employees directly engaged in performance of the contract with a copy of the statement required by paragraph (c)(1) of this clause and obtain written agreement from the employee that the employee shall abide by the terms of the statement; and

(4) Take appropriate action, up to and including termination, against employees or subcontractors that violate the policy in paragraph (b) of this clause.

(d) Notification. The Contractor shall inform the contracting officer immediately of--

(1) Any information it receives from any source (including host country law enforcement) that alleges a contract employee has engaged in conduct that violates this policy; and
(2) Any actions taken against employees pursuant to this clause.

(e) Remedies. In addition to other remedies available to the Government, the Contractor's failure to comply with the requirements of paragraphs (c) or (d) of this clause may render the Contractor subject to--

(1) Required removal of a Contractor employee or employees from the performance of the contract;
(2) Required subcontractor termination;
(3) Suspension of contract payments;
(4) Loss of award fee for the performance period in which the Government determined Contractor non-compliance;
(5) Termination of the contract for default, in accordance with the termination clause of this contract; or
(6) Suspension or debarment.

(f) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (f), in all subcontracts for the acquisition of services.

c. FAR Clause 52.223-9, Estimate Of Percentage Of Recovered Material Content For EPA Designated Products (August 2000)

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

Postconsumer material means a material or finished product that has served its intended use and has been discarded for disposal or recovery, having completed its life as a consumer item. Postconsumer material is a part of the broader category of "recovered material."

Recovered material means waste materials and by-products recovered or diverted from solid waste, but the term does not include those materials and by-products generated from, and commonly reused within, an original manufacturing process.

(b) The Contractor, on completion of this contract, shall--

(1) Estimate the percentage of the total recovered material used in contract performance, including, if applicable, the percentage of postconsumer material content; and

(2) Submit this estimate to ___TBD_____ [Contracting Officer complete in accordance with agency procedures].

(End of clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP and can be found in the Attachments at the end of this document:

SOLICITATION ATTACHMENTS:

Attachment No.	Title	Location
Attachment 1	Packaging and Delivery of Proposal	See Attachment Section at the end of this RFP
Attachment 2	Proposal Intent Response Sheet	See Attachment Section at the end of this RFP
Attachment 3	Statement of Work	See Attachment Section at the end of this RFP
Attachment 4	Reporting Requirements and Deliverables	See Attachment Section at the end of this RFP
Attachment 5	Appendix A - Additional Technical Proposal Instructions and Format for Technical Proposal Table of Contents	See Attachment Section at the end of this RFP
Attachment 6	Appendix B - Additional Business Proposal Instructions and Uniform Cost Assumptions	See Attachment Section at the end of this RFP

TECHNICAL PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable, and submitted with the Technical Proposal. They may be accessed at: http://www.niaid.nih.gov/contract/forms.htm.)

Title	Location
Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf

BUSINESS PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable, and submitted with the Business Proposal. They may be accessed at: http://www.niaid.nih.gov/contract/forms.htm.)

Title	Location
Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Small Business Subcontracting Plan	http://rcb.cancer.gov/rcb-internet/forms/sb-subplan-nci.pdf
Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet	http://www.niaid.nih.gov/contract/forms.htm http://ocm.od.nih.gov/contracts/spsh/spshexcl.xls
Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf

INFORMATIONAL ATTACHMENTS: (The following Attachments and Reports will become part of any contract resulting from this RFP and will be required during contract performance. They may be accessed at: http://www.niaid.nih.gov/contract/forms.htm.)

Title	Location
Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Safety and Health, HHSAR Clause 352.223-70	http://www.niaid.nih.gov/contract/forms/form10.pdf
Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf
Commitment To Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

SECTION K can be accessed electronically from the INTERNET at the following address:

http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

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

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE SECTION K AND SUBMIT IT AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

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

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

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

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

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

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

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

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

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

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

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

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

that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or
(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
(3) It is the only proposal received.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(End of Provision)

(2) NAICS CODE AND SIZE STANDARD

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

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.

(2) The small business size standard is 500 employees.

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

(3) TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that two (2) awards will be made from this solicitation and that the award(s) will be made on/about September 28, 2007.

It is anticipated that the award from this solicitation will be a cost-reimbursement, completion type contract with a period of performance of five (5) years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

(4) 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 29.7 Full-Time Equivalents (FTEs) per year for the entire five (5) years. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

(5) 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.

(6) 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.

(7) 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.

(8) COMPARATIVE IMPORTANCE OF PROPOSALS

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

(9) PREPARATION COSTS

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

(10) SERVICE OF PROTEST (AUGUST 1996) - FAR 52.233-2

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

Branch Chief,
Microbiology and Infectious Diseases Research Contracts Branch-A
Office of Acquisitions, DEA
National Institute of Allergy & Infectious Diseases
6700B Rockledge Drive
Room 3214, MSC-7612
Bethesda, MD 20892-7612

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

(End of Provision)

(11) LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70

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

(End of provision)

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

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

(1) Contract Type and General Clauses

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

(2) Authorized Official and Submission of Proposal

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

I. COVER 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. (See Attachment 6, Appendix A - Additional Technical Proposal Instructions and Format for Technical Proposal Table of Contents.)

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. (See Attachment 7, Appendix B - Additional Business Proposal Instructions and Uniform Cost Assumptions.)

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

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

(4) Separation of Technical and Business Proposals

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

(5) Alternate Proposals

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

(6) Evaluation of Proposals

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

(7) Potential Award Without Discussions

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

(8) Use of the Metric System of Measurement

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

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

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

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

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

(9) Specific Copyright Provisions Applicable to Software Development and/or Enhancement(s)

Under the provisions of the Rights in Data General clause (52.227-14), contractors must seek permission to establish a copyright for software and associated data generated under a contract. As a general rule, permission is normally granted provided, a paid-up, world-wide, irrevocable, nonexclusive license to the government is provided. This is to advise offerors that for this project, the government intends to assert additional copyright permissions under this contract. The scope of the Government's interest in the copyright will be determined during negotiations.

(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) Past Performance Information

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

A list of the last five (5) contracts completed during the past three (3) years and the last contracts awarded currently in process that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

Include the following information for each contract or subcontract:

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

The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort. For the purpose of this solicitation, a "major subcontract" is defined as any subcontract over $550,000.

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

b) Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

(14) Electronic and Information Technology Accessibility

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

all EIT acquired must ensure that:

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

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

This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards.

Further information about Section 508 is available via the Internet at http://www.section508.gov .

(15) 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.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

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

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

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

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

b. TECHNICAL PROPOSAL INSTRUCTIONS

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

(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) Principal Investigator/Project Director

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

responsible.

(2) Other Investigators

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

(3) Additional Personnel

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

-The specific items or expertise they will provide.

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

-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) Resumes

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

(2) Technical Evaluation

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

(3) Additional Technical Proposal Information

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

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

(4) Other Considerations

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

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

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

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

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

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

(5) 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 (Revised 1986, Reprinted 2000)

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, 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 PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER, OLAW. 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 OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are 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 offeror’s 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.

(6) 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

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan in its technical proposal for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

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

(b) Sharing of Model Organisms for Biomedical Research

The NIH Research Tools Policy, also referred to as Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, December 1999, supports the concept of timely sharing and distribution of research resources. In accordance with NIH Guide Notice NOT-OD-04-042, dated May 7, 2004, and the September 10, 2004 extension of this policy NOT-OD-04-066,the NIH provides further sharing guidance with particular attention on model organisms for biomedical research. Such organisms include, but are not limited to: mammalian models such as the mouse and rat, and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

Offerors must include in their technical proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, OR provide appropriate reasons why such sharing is restricted or not possible. A reasonable time frame for periodic disposition of material and associated

data must be specified in the proposal. In addition, the plan must address if, or how, offerors will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. At a minimum, the plan should address the following:

- Will material transfers be made with no more restrictive terms than in a Simple Letter Agreement (SLA) (http://ott.od.nih.gov/NewPages/Rtguide_final.html#sla)for the transfer of materials or the Uniform Biological Material Transfer Agreement (UBMTA) (http://ott/od/nh/gov/NewPages/UMTA.pdf)?

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

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

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

(i) References

(1) Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); http://csrc.nist.gov/policies/FISMA-final.pdf
(2) DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf
(3) NIH Computer Security Awareness Training Course: http://irtsectraining.nih.gov/
(4) NIST Special Publication 800-16, Information Technology Security Training Requirements: http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf Appendix A-D: http://csrc.nist.gov/publications/nistpubs/800-16/AppendixA-D.pdf
(5) NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems: http://csrc.ni
(6) NIST SP 800-26, Revision 1, Computer Security: http://csrc.nist.gov/publications/drafts/Draft-sp800-26Rev1.pdf
(7) NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems: http://www.csrc.nist.gov/publications/drafts/800-53-rev1-ipd-clean.pdf
(8) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories,
Volume I: http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V1-final.pdf;
Volume II, Appendices to Guide For Mapping Types of Information and Information Systems To Security Categories, Appendix C at: http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V2-final.pdf and Appendix D at: http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V2-final.pdf.
(9) NIST SP 800-64, Security Considerations in the Information System Development Life Cycle: http://csrc.nist.gov/publications/nistpubs/800-64/NIST-SP800-64.pdf
(10) FIPS PUB 199, Standards for Security Categorization of Federal Information and Information Systems: http://csrc.nist.gov/publications/fips/fips199/FIPS-PUB-199-final.pdf
(11) FIPS PUB 200, Minimum Security Requirements for Federal Information and Information Systems: http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf

(7) T**echnical Questions**

Offerors should submit all technical questions concerning this solicitation in writing to the contract specialist. NIIAID 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.

(8) **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.

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 rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

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

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

1. Direct Labor

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

2. Materials

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

3. Subcontracted Items

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

4. Raw Materials

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

5. Purchased Parts

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

6. Fringe Benefits

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

7. Indirect Costs

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

8. Special Equipment

If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. Travel

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

10. Other Costs

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

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

(a) Exceptions from cost or pricing data.

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

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

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

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

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

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

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify

any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

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

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

Alternate I (October 1997). As prescribed in 15.408(l), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

(b)(1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

(5) Salary Rate Limitation in Fiscal Year 2006

Offerors are advised that pursuant to P.L. 109-149, no NIH Fiscal Year 2006 (October 1, 2005 - September 30, 2006) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 109-149 applies only to Fiscal Year 2006 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 109-149 states in pertinent part:

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

LINK TO EXECUTIVE SCHEDULE SALARIES: http://www.opm.gov/oca/06tables/indexSES.asp

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

with the current Fiscal Year 2006 Executive Level I Salary rates.

(6) Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the apparent successful 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, Section J - List of Attachments, Business Proposal Attachments, is an example of such a plan.

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

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

c) The offeror understands that:

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

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

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

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

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

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

d) Each plan must contain the following:

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

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be

subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

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

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

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

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

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

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

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

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

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

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

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

23% for Small Business
5% for Small Disadvantaged Business
5% for Women-Owned Small Business
3% for HUBZone Small Business
3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

(7) HUBZone Small Business Concerns

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

(8) Extent of Small Disadvantaged Business Participation

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

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

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) code, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). TheNAICS 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 Subsector(s). The applicable authorized NAICS Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team 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 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	15%	$150,000

subcontractors

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

(9) Qualifications of the Offeror

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

a) General Experience

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

b) Organizational Experience Related to the RFP

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

c) Performance History

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

d) Pertinent Contracts

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

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

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

(10) Other Administrative Data

a) Property

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the

offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

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

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

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

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

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

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

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

c) Financial Capacity

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

d) Incremental Funding

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

HHSAR 352.232-75, Incremental Funding (January 2001)

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

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

(End of provision)

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

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

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

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

(End of Provision)

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

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

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

(11) Subcontractors

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

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

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

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

d) Information on their cognizant field audit offices.

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

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

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

(12) Proposer's Annual Financial Report

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

(13) Representations and Certifications

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(14) Travel Costs/Travel Policy

a) Travel Costs - Commercial

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

b) Travel Policy

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

SECTION M - EVALUATION FACTORS FOR AWARD

a. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against four (4) factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

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

b. 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, 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.

c. 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 or if the plan in your proposal is considered unacceptable, and the Government includes your proposal in the competitive range, 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 by the Government after discussions, your proposal may not be considered further for award.

d. 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. The Subcriteria for each criteria are of equal weight.

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

CRITERIA	WEIGHT
CRITERION 1: Scientific and Technical Approach	40

Scientific and technical merit, adequacy, appropriateness, and feasibility of proposed plans and procedures for establishing, operating, and maintaining a high-throughput (HTP) Structural Genomics Center for Infectious Diseases that generates a collection of high-quality experimental structures of targets of biomedical relevance for research in infectious diseases.

(1) Adequacy and appropriateness of the documented experience in experimental protein structure determination using existing state-of-the-art facilities, equipment, and other resources including HTP methodologies.

(2) Adequacy and soundness of the scientific rationale and technical approach described in the three sample proposals for selecting targets (ref. Appendix A Additional Technical Proposal Instructions Section 3.A.2) of biomedical relevance belonging to organisms in the NIAID Category A-C biodefense priority list and organisms causing emerging and re-emerging infectious diseases.

(3) Adequacy and soundness of the scientific and technical approach to structure determination by X-ray crystallography and NMR spectroscopy, from target expression to structure solution, including testing for biophysical properties of the samples, protein purification and production, sample preparation, refinement and validation of the structure models, and quality control procedures.

(4) Adequacy and feasibility of the approach to ensure selected targets are not already targets whose three dimensional structure will be made publicly available.

(5) Adequacy and appropriateness of the proposed data management system architecture and computational infrastructure including the LIMS and other database systems to support the data management, data analysis, algorithms and software applications development, data dissemination, data and communication exchange within the Center, and other computational needs of the proposed Center.

(6) Appropriateness and adequacy of the plan for sharing and disseminating to the scientific community information about the targets, their structural data, reagents, and data analysis software tools generated under this contract.

(7) Adequacy and appropriateness of procedures for receipt, storage, shipping, and inventory of materials and reagents in compliance with applicable safety and other regulatory guidelines.

CRITERION 2: Collaboration and Consultation with the Scientific Community 15

Adequacy and appropriateness of plans to collaborate and provide structural genomics services and resources to the broad scientific community.

(1) Adequacy and feasibility of the proposed plans to provide a structure determination service for targets requested by the broad scientific community and to increase public awareness of the resources provided by the Center.

(2) Soundness of the plan to safeguard confidentiality and intellectual property of data and materials provided by third parties or the Government.

(3) Adequacy and appropriateness of plans for establishing and maintaining close interaction with the scientific community, including the establishment and use of a Scientific Working Group, coordination with other structural genomics centers and collaboration with users of protein structures for drug, vaccine and diagnostics development.

CRITERION 3: Project Management and Administration 15

Adequacy, thoroughness and appropriateness of the plans and procedures for overseeing, monitoring, coordinating and managing a state-of-the art Structural Genomics Center for Infectious Diseases.

(1) Adequacy and appropriateness of the proposed overall project organization and staffing; and plans and procedures for the close monitoring, tracking, coordination and management of all contract activities, including interacting with the Project Officer and Contracting Officer to ensure the efficient planning, initiation, implementation, monitoring, and management of all projects carried out under the contract, including projects carried out by subcontractors and consultants.

(2) Appropriateness and feasibility of the proposed draft Program Development Plan for the Center that defines the scientific vision, describes the operational and resource requirements, and provides a schedule with goals and

milestones.

(3) Adequacy and appropriateness of the plan to monitor, maintain and increase the Center's efficiency and quality of the molecular structures.

CRITERION 4: Scientific and Technical Personnel 15

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.

(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 Structural Genomics Center for Infectious Diseases, including experience with other structural genomics centers or structural biology laboratories, coordination with other structural genomics centers and collaborations with users of the structure information for the development of vaccines, diagnostics and therapeutics; and provision of software and data to public resources. Appropriateness of the proposed time commitment.

(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 scientific and technical staff, including subcontractors and consultants, their documented capacity to perform their proposed responsibilities and their prior experience with similar projects. Previous experience with NIAID Category A-C pathogens and organisms causing emerging and re-emerging diseases; coordination with other structural genomics centers and collaborations with users of the structure information for the development of vaccines, diagnostics and therapeutics; provision of software and data to public resources and development of publicly accessible web sites.

CRITERION 5: Facilities, Equipment, Safety and Training 15

Availability, adequacy, and suitability of facilities, equipment, network and computational resources to carry out all phases of the proposed project, including the facilities, equipment, network and computational resources of subcontractors and consultants.

(1) Facilities, equipment and resources, including the synchrotron and NMR facilities, dedicated to the project, as demonstrated in the detailed floor plan of the proposed facilities showing the location of the equipment and resources and any facility modifications that would be accomplished prior to initiation of the contract.

(2) Computational facilities and support to conduct work described in the Statement of Work, including hardware, software and other necessary equipment.

(3) Information regarding ownership/lease of the facility which demonstrates availability for the duration of the proposed contract.

(4) Plan for compliance with all safety guidelines and regulations, including training and monitoring of personnel for exposure to infectious and hazardous reagents.

TOTAL POSSIBLE POINTS: 100 Maximum Points

(1) 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 mechnaical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgement 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.

(2) 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; and
(c) Extent of participation of SDB concerns in terms of the value of the total acquisition.

SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP

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

PACKAGING AND DELIVERY OF THE PROPOSAL

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

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

A. EXTERNAL PACKAGE MARKING:

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

"**RFP NO. NIH-NIAID-DMID-07-19**
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. PAPER COPIES and CD-Rom to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Robert Singman Contracting Officer Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20817	Robert Singman Contracting Officer Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612

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

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

C. NUMBER OF COPIES:

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

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

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

- Type size must be 10 to 12 points.
- Type spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
- Print margins must be at least one inch on each edge of the paper.
- Print setup should be single-sided on standard letter size paper (8.5 x 11" in the U.S., A4 in Europe).

CREATING AND NAMING ELECTRONIC FILES:

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

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

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

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

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

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

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

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

PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE PROVIDED TO THE REVIEWERS TO BE READ OR EVALUATED. OFFERORS MUST CERTIFY THAT THE INFORMATION IN THE PAPER AND ELECTRONIC COPIES IS THE SAME.

Document	Number of Copies	Page Limits
Technical Proposal and all Appendices	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** Twenty (20) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices) in a Portable Document Format (PDF)	**Not to Exceed 175 pages**
Business Proposal	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** Three (3) Compact Disks containing an electronic copy of the Business Proposal in a Portable Document Form (PDF).	N/A
Breakdown of Proposed Estimated Cost using Electronic Cost Proposal EXCEL Workbook	This Attachment to the Business Proposal should be submitted as a separate EXCEL file on the Business Proposal Compact Disk. **See Section J, Attachment entitled Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet to access the Excel Workbook.**	N/A

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DMID-07-19
RFP Title: NIAID Structural Genomic Centers for Infectious Diseases

Please review the attached Request for Proposal. Furnish the information requested below and return this page by no later than **November 15, 2006**. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

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

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

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

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

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

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

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

Attn: Robert Singman
RFP-NIH-NIAID-DMID-07-19
FAX# (301) 480-4675
Email: rs485j@nih.gov

STATEMENT OF WORK

NIAID Structural Genomics Centers for Infectious Diseases
RFP NIH-NIAID-DMID-07-19

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 recognized the incredible potential of microbial genomic research and, in the last few years, has made a significant investment in genomic-related activities that provide comprehensive genomic, functional genomic, bioinformatics, and proteomic resources to the scientific community for basic and applied research 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* – provide 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 of genomic and related data in a user-friendly format, and include databases to host microbial genomic data and analysis centers to develop and provide software tools;
- *Proteomics Research Centers* – provide the characterization of 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.

To build upon the objectives of the NIAID Genomics programs and address the Institute's need to further expand the knowledge of the proteome, NIAID is launching a five-year initiative to establish two large scale NIAID Structural Genomics Centers for Infectious Diseases that will apply state-of-the-art high-throughput (HTP) structural biology technologies to experimentally characterize the three dimensional atomic structure of targeted proteins from pathogens in the NIAID Category A-C priority lists (http://www3.niaid.nih.gov/biodefense/bandc_priority.htm) and organisms causing emerging and re-emerging infectious diseases. The three dimensional structure of proteins can assist drug design and development by yielding direct insights into the target molecular mechanisms, in interaction with other biological molecules, or with synthetic

compounds, in order to improve selectivity, specificity and optimize drug development in a rational way.

NIAID recognizes that a single organization or institution may not have the expertise and facilities required to perform all of the activities of a Structural Genomics Center for Infectious Diseases (hereinafter also referred to as "Center") set forth in the Statement of Work and, consequently, that the Contractor may need to be supported to a certain extent by the expertise and resources of subcontractors to perform some of the tasks required. However, the Contractor shall be responsible for ALL work performed under this contract including that performed by any subcontractor(s).

SCOPE:

The scope of the Structural Genomics Centers for Infectious Diseases is to create a collection of high quality, experimentally determined three-dimensional structures that is widely available to the scientific community and serves as a blueprint for development of structure-based drugs, vaccines and diagnostics for infectious diseases.

The primary focus of the Structural Genomics Centers for Infectious Diseases shall be pathogen targets that are expected to have an important biological role and a potential impact on biomedical research, such as:

- Proteins involved in pathogenesis, such as invasins, adhesins, toxins;
- Proteins essential to the pathogen's life and reproductive cycle;
- Proteins involved in antimicrobial/drug resistance;
- Protein markers of acute or chronic infection;
- Complexes with natural substrates, cofactors, receptors, drug candidates;
- Protein splice variants, post-translational modifications and other functionally characterized variants.

Pathogen targets shall be proposed by external investigators, NIH, other Government agencies, and the Contractor; however, target selection must be approved by the Project Officer prior to the initiation of any structural determination activity.

The Contractor shall provide NIAID and the broad scientific community with established facilities, equipment, technologies, and scientific and technical expertise to perform in a HTP manner, every component of the protein structure determination pipeline. The HTP protein structure determination pipeline is a complex scientific and technical process that includes target selection, cloning, expression and purification, sample preparation for X-ray crystallography and NMR spectroscopy, X-ray and NMR data collection, structure solution and validation. The Contractor shall deposit the protein structure information generated under this contract into the public domain.

The Contractor shall use state-of-the-art techniques and technologies in determining the three dimensional structure of proteins and shall incorporate new and improved techniques and technologies into the contract activities.

Throughout the contract's period of performance, the Center must maintain productivity, quality and costs for structure determination that are competitive with those of similar HTP structural

genomics centers, such as the Large-Scale Centers funded by the NIH National Institute of General Medical Sciences (NIGMS) under the second phase of the Protein Structure Initiative (PSI-2) http://www.nigms.nih.gov/Initiatives/PSI/.

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:

A. Structure Determination Pipeline

Provide established facilities, equipment, other resources, and scientific and technical personnel with expertise to operate and manage a HTP structure determination pipeline to generate a collection of high-quality experimental protein structures.

1. Target Selection:

   a. Prepare and submit to the Project Officer and Contracting Officer written proposals for targets for structural determination from organisms in the NIAID Category A-C priority pathogens list (http://www3.niaid.nih.gov/biodefense/bandc_priority.htm) as well as organisms causing emerging and re-emerging diseases. Proposed targets should have an important role in biomedical research in infectious diseases, such as the examples provided in the Scope section of this Statement of Work. The proposals shall describe the target selection process, its scientific rational, whether the X-ray crystallography or NMR spectroscopy approach would be used and why, and how the knowledge of the three dimensional structure may facilitate basic biomedical research in infectious diseases, in particular the development of anti-microbial or anti-viral therapeutics, vaccines or diagnostics. The first proposal for targets shall be submitted to the Project Officer and Contracting Officer within one (1) month after the effective date of the contract.

   b. Ensure that the targets proposed by the Contractor are not already under consideration, in progress or completed by other structural genomics centers, such as those in the Protein Data Bank (PDB) listed at http://sg.pdb.org/target_centers.html, which will then make the structure available in public databases.

   c. Written Project Officer and Contracting Officer approval of the proposed targets shall be required prior to initiating any structure determination project. The Government will review and approve the proposed targets within one (1) month from proposal submission.

2. Target Cloning, Expression and Purification:

a. Generate target clones and screen their expression and solubility properties using HTP technologies and standard protocols. Produce high yields of the expression clones using a variety of approaches, including multiple expression systems, cleavage systems, optimization of codon usage and changes to the encoded amino acid sequence. Establish and conduct quality control procedures of the expression products.

b. Using HTP technologies, generate highly purified target proteins or protein fragments and produce them in sufficient quantity for structure determination through standardization and automation of protocols; screen for purity and concentration; evaluate biophysical properties of the purified samples to enhance the effectiveness for X-ray or NMR structural studies (e.g. protein folding, aggregation). Establish and conduct quality control procedures.

3. Crystallization Studies: Prepare samples for X-ray crystallography structure determination studies. Conduct HTP crystallization experiments, in which crystallization trials, optimization and data collection and interpretation must be highly automated, with limited human intervention. If necessary, conduct crystallization studies and screens of the target in complex with inhibitors, cofactors, and substrate analogs. Identify and harvest crystals that are suitable for diffraction screening. Conduct large scale crystal diffraction screenings, collect diffraction data and quality metrics of suitable crystals.

4. NMR Studies: Prepare samples for NMR spectroscopy structure determination studies. Conduct rapid NMR data collection and automated resonance assignments.

5. Final Structure Validation: Perform structure solution, model refinement and validation for both X-ray crystallography and NMR studies. A structure determination project will be considered complete when the refinement and validation of the final structure models do not provide any clear signal of where the model can be improved. The Project Officer will make the final structure validation based upon the data submitted by the Contractor.

6. Incorporation of New Technologies: Evaluate, incorporate and integrate new technological developments in protein structure determination in order to maintain a state-of-the-art HTP structure determination pipeline that uses both X-ray crystallography and NMR spectroscopy during the course of this contract and to salvage targets for which previous attempts to solve the structure failed.

7. Research and Development: Prepare and submit to the Project Officer and Contracting Officer, project plans for any type of Research and Development effort, such as the development of new or enhancements of existing laboratory protocols (SOPs), quality control procedures, technologies, or algorithms considered to be necessary to increase the protein structure determination productivity of the Center, to improve the quality of the structures or to reduce the costs of the center. A project plan shall include a description of the research goals and justifications; a delineation of the project's milestones and timelines to accomplish the milestones; a description of the technical approach to carry out the project and the physical facilities, equipment and other resources to be made available to the project; details on how to incorporate and integrate the new developments into the structure determination pipeline; a list of proposed scientific and technical personnel, including collaborators, and a description of their qualifications, relevant experience and role in the project; and the proposed budget broken down into total costs for labor, materials, subcontracts, and other line items, as appropriate for the project.

Written Project Officer and Contracting Officer approval of each project plan shall be required prior to initiating any Research and Development project.

B. Structural Genomics Services to the Scientific Community

Provide a structural genomics resource that offers the Center's technologies, resources and staff expertise to outside investigators, NIH and other Government agencies, who will propose to the Center targets for structure determination that have a potential impact on biomedical research in infectious diseases. The Project Officer will review and ultimately approve and prioritize all proposals for targets to be entered in the structure determination pipeline.

1. Target Proposal Request and Review: Within (3) three months from contract award, and in collaboration with the other Center, provide and submit to the Project Officer and Contracting Officer, a Plan for Structural Genomics Services to the Scientific Community, describing the request process the broad scientific community should use to propose targets to the Centers. The Plan shall delineate the information required by the Centers to accept and review proposals, the evaluation criteria for selecting targets, turnaround time to review those proposals, the information technology (IT) systems to support the request and review process, how potential confidentiality and intellectual property issues regarding data and materials provided by the requestor shall be managed, and outreach activities to promote awareness of the structural genomics services provided to the broad scientific community. Implement the plan within two (2) months of receipt of written approval by the Contracting Officer and Project Officer.

2. Confidentiality: Ensure that the scientific information about the targets (e.g. their experimental functional characterization, validated binding sites or epitopes) and any biological reagent provided by the requestor to the Center shall be treated in a confidential manner. It is anticipated that some reagents and data about the targets provided to the Center will be proprietary in nature. NIAID's experience has shown that third parties are reluctant to provide their proprietary materials or ideas without complete assurance that their intellectual property rights are protected. Therefore, the NIAID requires the Contractor and its subcontractors to safeguard the proprietary materials, data and other information of the Third Party Suppliers. The Contractor shall also establish Material Transfer Agreements (MTAs) with the Third Party Suppliers, as needed. All such MTAs will allow the Contractor to deliver data and other deliverables specified under the contract and will not conflict with the contract. For an example MTA see **Federal Register**, Dec. 23, 1999, Vol. 64, No. 246 [Notices] pp. 72090-72096 If the Contractor is uncertain if terms of an MTA conflict with the contract, the Contractor shall consult with the Contracting Officer.

3. Target Status: Provide quarterly updates to the requestor about the status of the target in the structure determination pipeline.

4. Outreach: Promote awareness of the structural genomics 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.

C. Information Technology and Data Management Systems

1. Provide and maintain a secure, internal IT system architecture and computational infrastructure to support the data management, data analysis, algorithms and software applications development, and other computational needs of the Center. The Contractor's institution's security policies and guidelines must be followed.

2. Utilize and maintain a relational database and a Laboratory Information Management System (LIMS), in support of the data types and experimental results generated by or related to all the steps of the protein structure determination pipeline, the Center's analysis needs and data dissemination activities delineated in this Statement of Work. Utilize and update software applications for populating and updating the database; provide query capabilities, web and graphical user interfaces to the database; develop software applications to export data in a variety of formats and to submit structural and other experimental data, clones and reagents to public repositories.

3. 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.

4. Provide a plan for developing and maintaining the information technology and data management systems: Within two (2) months of contract award, submit to the Project Officer and Contracting Officer a plan for developing and maintaining the information technology and data management systems of the Center. The minimum areas to be addressed by the plan include security awareness training for the Contractor and subcontractors staff; logical access control to networks, systems, remote access, monitoring, etc.; protection against data loss; malicious code protection (ex: antivirus, filtering of e-mail attachments, etc) ; physical security, such as access control (ex: locks, guards), power conditioning, air conditioning, fire protection. Provide similar information for any subcontractor developing or accessing the Center's information technology infrastructure and network.

D. Information Dissemination and Provision of Contract-Generated Resources

1. Information Dissemination to Public Databases and Repositories:

    a. Within four (4) weeks from completion of a structure determination project and following the guidelines established by the NIGMS-PSI large scale Centers for Structural Genomics (http://www.nigms.nih.gov/Initiatives/PSI/), or as directed by the Project Officer, disseminate and deposit into public databases, such as the PDB (http://www.rcsb.org/pdb/Welcome.do) and other databases as directed by the Project Officer, the atomic coordinates of the targets' three-dimensional structure and associated data, such as the structure factors, NMR constraints and chemical shift lists. In addition to the atomic coordinates, the Contractor shall make publicly available measures to interpret the validation criteria of the structural model and to allow the evaluation of its quality.

    b. Deliver into the public domain experimental outcome data related to cloning, expression and solubility, purification, protein biochemical and biophysical characterization, crystallization screening, experimental protocols and quality control procedures of both complete and interrupted projects. Such information

shall either be made available on the Center's public web portal described below, or be submitted for dissemination into a public database resource, as directed by the Project Officer.

c. Deposit materials and reagents (e.g. physical clones, expression constructs) into public repositories, such as the NIAID Biodefense and Emerging Infections Research Resources Repository (http://www.beiresources.org/), as directed by the Project Officer, for distribution to the broad scientific community.

2. Public Web Portal:

Within three (3) months of contract award establish, maintain and make publicly available a Section 508-compliant (www.section508.gov) web portal, to provide the following:

a. information of general interest about the Center and its activities, staff members, Center's publications, news and events;

b. summary statistics as well as detailed information about each selected target's status in the structure determination pipeline;

c. relevant protein and genomic data retrieved from public resources (e.g. from NCBI's databases http://www.ncbi.nih.gov/Database/ or the NIAID Bioinformatics Resource Centers http://www.brc-central.org/), or computationally generated by the Center. Examples of data types include: molecular weight, signal peptide prediction, target species, the gene locus, protein sequence region targeted for structure determination, protein functional annotation and domain structure, the literature information, and similar proteins of known structure;

d. links to other public database resources hosting information about the atomic structure of the targets generated by the Center, and their related experimental information and reagents; and

e. source codes and executables of all software applications and algorithms newly developed or enhanced under the contract.

Information provided in the public web portal will be discussed, reviewed and approved by the Project Officer.

E. Receipt, Storage, Shipping, and Inventory

1. Develop and maintain efficient and effective procedures sufficient to support contract activities for receiving, storing, shipping, archiving and retrieving compounds of pathogenic organisms including, for example, DNA samples, protein expression constructs and crystals.

2. Obtain appropriate licenses and permits required by local, State, and Federal authorities for the safe transport, storage and distribution of compounds.

3. Provide for safe packing, labeling, and shipping of materials and reagents to public repositories so that shipments are coordinated for timely receipt.

4. 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.

5. 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:
    a. Provide facilities with aseptic and/or sterile conditions, as well as biosafety containment, as appropriate.

    b. Provide suitable air-conditioned floor space sufficient for the installation, storage and maintenance of equipment.

    c. 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.

    d. Supply uninterruptible power to accommodate the refrigerators/freezers and other equipment.

    e. House the units in an air-conditioned facility with the capacity to maintain a room temperature of 66 to 72 degrees F.

    f. 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, security system and 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.

    g. Provide an automated temperature monitoring system composed of individual temperature probes for 24 hours per day, seven 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.

    h. Maintain 24-hour per day security that provides an appropriately secure environment for employees and materials within the facility.

6. Establish and maintain an electronic inventory of all materials and reagents received, produced, stored, and shipped, such as in a LIMS or a relational database, that includes searchable information, such as compound identifiers, amounts available, storage locations, shipping data and other biological and chemical characteristics of the compound.

F. Collaboration and Consultation with the Scientific Community

Establish and maintain continuous, close interaction with the scientific community through carrying out the following activities:

1. Scientific Working Group

    a. Establish a Scientific Working Group (SWG) in conjunction with the Project Officer, composed of approximately seven (7) investigators that are independent from the Center. Those scientists should be knowledgeable in a broad range of structural biology areas, including, for example, development of technologies, expertise in microbiology and infectious diseases, structure-to-function inferences and structure-based drug, vaccine and diagnostics development. The SWG will provide advice to the Contractor on the structural genomics needs of the scientific community and make recommendations on how to efficiently generate protein structures or other experimental results and resources and make them available to the scientific community.

    b. Within two (2) months 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 at least one SWG meeting to be held at the Contractor's site, and one SWG meeting via teleconference per year for soliciting advice from the SWG. Seven (7) calendar days prior to the SWG meeting, provide a draft meeting agenda to the Project Officer for review. Upon approval by the Project Officer, distribute the meeting agenda to all meeting participants. Provide a summary of all meetings and conference calls in the Semi-Annual Progress Reports. The Project Officer will be permitted to participate in the SWG meetings and conference calls as an external member of the group.

2. Users of the Protein Structure Information: Interact and consult with the scientific community on an ongoing basis to solicit feedback from users of the protein structure information, in particular from those that perform structure-based studies for the development of therapeutics, diagnostics and vaccines.

3. Other Structural Genomics Centers: Interact and collaborate with the investigators of other national or international Structural Genomics projects, including the other Structural Genomics Center for Infectious Diseases, NIGMS-PSI Centers and those listed at http://sg.pdb.org/target_centers.html. Establish coordination with other Structural genomics projects, for example by registering the Center's targets at public resources that monitor the progress of the production and solution of the structures (e.g. http://targetdb.pdb.org/), as directed by the Project Officer, or by adopting any community standards for release of experimental data and materials or, when appropriate, by utilizing new promising structural biology technologies arising from those Centers.

G. Project Management and Administration

1. Overall Project Management

   Provide a technical and administrative management infrastructure to ensure the efficient planning, implementation, oversight, and completion of all projects carried out under this contract. This infrastructure shall include:

   a. 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.

   b. A Project Manager (PM) with overall responsibilities for project management, including assisting in fostering internal/external communications, reporting on the number of proposals by the community, tracking of targets in the pipeline, preparing progress reports and other deliverable documentation, monitoring the budget, and making recommendations for changes to the Center activities and their timelines.

2. Evaluation of Efficiency and Cost

   Define, monitor and report to NIAID on a semi-annual basis, metrics for efficiency and evaluation of costs of the protein structure determination pipeline, for both X-ray crystallography and NMR spectroscopy approaches. Quality metrics of the generated protein structures shall also be provided. The metrics will be used as the basis for evaluating the need to improve existing high-throughput protocols and technologies to increase the efficiency, improve the quality and decrease the costs of the protein structure determination pipeline.

3. Contract Meetings and Teleconferences

   a. Monthly Meetings/Teleconferences:
      I. Plan and conduct meetings at a minimum of monthly intervals, either in person or via teleconference, with the Contractor's key personnel to review the overall progress of the Center.
      II. Plan and conduct meetings of the Contractor's PI and PM with the Project Officer and Contracting Officer at a minimum of monthly intervals, either in person or via teleconference, to review the proposals for structure determination from the research community and from the Center, the status of the approved projects, and to discuss 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. Prepare and distribute the agenda and meeting/teleconference materials to all meeting participants. Provide a summary of all meetings and teleconferences in the Semi-Annual Progress Reports.

b. Annual site visits: Arrange for site visits on a yearly basis, as requested by the Project Officer or the Contracting Officer.

c. Annual Program Meetings: Organize and conduct, in conjunction with the PI of the other Center, an annual programmatic meeting of the Centers' investigators to share methodologies and findings. The meeting location and logistical arrangements shall be the responsibility of the Contractor's staff. The preparation and distribution of the agenda, meeting materials, and meeting summary shall be the responsibility of the Contractors' PIs and PMs, with final approval by the Project Officer. The meeting shall be attended by a maximum of five (5) individuals from each Center, including subcontractor personnel, as well as by the Project Officer, the Contracting Officer and other key NIAID and NIH staff.

4. Program Development Plan

Prepare and submit two (2) Program Development Plans (PDPs) for the Center: the first plan to cover the initial two (2) years of the contract and to be submitted three (3) months after contract award; and the second plan to cover the final three years of the contract period and to be submitted two (2) years and three (3) months from contract award. The PDPs shall:

a. define the vision and goals of the Center;

b. describe the facilities, technology and personnel 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 the needs of the community ;

c. provide a dissemination plan for the targets' structure data, the physical reagents and all their related data;

d. provide other information pertinent to the development of the Center as requested by the Project Officer or the Contracting Officer; and

e. provide project implementation schedules and milestones.

5. Ad hoc Reports: Prepare and provide up to three (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 the 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.

H. Scientific and Technical Team

Provide a scientific and technical team with the expertise required to implement the HTP structure determination studies, including, at a minimum, expertise in protein expression, purification and high-yield production, crystallization, X-ray crystallography and NMR spectroscopy, biophysics, computational biology and computer science, software engineering and IT administration. The Contractor's team must include strong scientific leadership, as

well as significant experience and experience in the management, design, and execution of a state-of-the art structural biology center.

I. Research Facilities, Equipment, Safety and Training

1. Provide all the facilities, state-of-the-art laboratory equipment, and standard operating protocols to manage such facilities and equipment in support of the Center to generate a collection of high-quality experimental structures of targets of biomedical importance.

2. Provide adequate access to state-of-the-art synchrotron beamlines and NMR spectroscopy facilities that can process samples from pathogenic organisms at the appropriate biosafety level.

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, fourth edition. (http://bmbl.od.nih.gov/index.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://bmbl.od.nih.gov/index.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).

J. 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, data, web portals, databases, software applications and algorithms, SOPs, technologies, purchased supplies and equipment, and any other resource generated under this contract.

1. Prepare and submit, for review and approval by the Project Officer and the Contracting Officer, a written Final Transition Plan twelve (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.

2. Implement the Final Transition Plan as approved by the Project Officer and the Contracting Officer.

REPORTING REQUIREMENTS AND DELIVERABLES

NIAID Structural Genomics Centers for Infectious Diseases
RFP NIH-NIAID-DMID-07-19

A. Technical Reports

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

Semi-Annual Progress Reports

The Contractor shall submit Semi-Annual Progress Reports in an original (paper and electronic) to the Contracting Officer and one (1) copy (paper and electronic) to the Project Officer on the final day of the month following the end of each semi-annual performance period. The document shall report on the activities performed by both the Contractor and all subcontractors and shall include the following information:

1. A cover page containing the contract number and title; the period of performance being reported; the Contractor's name, address, telephone, fax, and e-mail; the author(s); and date of submission;
2. An introduction covering the purpose and scope of the contract effort;
3. A detailed description of the progress made on all targets selected for structure determination, including those proposed by the broad scientific community, targets' selection rationale and any issue encountered through the structure determination pipeline, public dissemination status of the target structure coordinates # of structures in Protein Data Bank (PDB), experimental data and physical reagents;
4. A detailed description of the progress made on the establishment and maintenance of the IT infrastructure, data management systems, public web portal, algorithms and other software applications;
5. Metrics for efficiency and evaluation of costs of the protein structure determination pipeline, for both X-ray crystallography and NMR spectroscopy approaches. Quality metrics of the generated protein structures must also be provided;
6. A detailed description of the status of all the Research & Development (R&D) projects that have been approved by the Project Officer and performed during the reporting period, addressing the project deliverables and due dates, achievement of significant results, and names of collaborators;
7. A description of all the outreach activities performed, including advertising the structural biology services provided by the Center to the broad scientific community, collaborations established with external investigators, coordination with the other Structural Genomics Center for Infectious Diseases and other large scale structural genomics centers;
8. A description of problems encountered, difference between planned and actual progress, cause(s) of the difference, and proposed or completed corrective actions;
9. A summary of all meetings or conference calls with the Project Officer, Contracting Officer and Scientific Working Group, that took place during the reporting period;

10. A description of progress on administration and management issues (i.e. establishment of subcontracts; confidentiality issues related to requests for structure determination by external collaborators, personnel issues that seriously impair the Centers' activities, etc.);
11. A proposed work plan, timeline and description of the work proposed for the next reporting period;
12. 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;
13. Preprints and reprints of papers, abstracts, book chapters and any other type of publication;
14. A list 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 the project and their percent effort committed to the project;
15. Other pertinent contract information as requested by the Project Officer or the Contracting Officer.

Final Report

The Contractor shall submit the Draft and the Final Report in an original (paper and electronic) to the Contracting Officer and one (1) copy (paper and electronic) to the Project Officer to document and summarize the results of the entire contract period of performance. The Draft shall be submitted two (2) months prior to the completion date of the contract and the Final Report shall be submitted on the completion date of the contract. The Draft and Final Reports shall include the following:

1. A cover page containing the contract number and title; the period of performance being reported; the Contractor's name, address, telephone, fax, and e-mail; the author(s); and date of submission;
2. An introduction covering the purpose and scope of the contract effort;
3. An executive summary, not to exceed 250 words, of salient results and deliverables accomplished during the performance of the contract;
4. A detailed description of work performed and results on all Center's activities, including a list of all target structures determined and submitted to PDB; unsolved target structures; targets determined as a service to the scientific community; clones and reagents generated and/or deposited in public resources; new technologies, methodologies and standard protocols developed;
5. A list of all the R&D projects performed and their accomplished results;
6. Final summary of the overall costs, productivity and quality of the structure determination pipeline;
7. Copies of abstracts, manuscripts and publications generated from this contract;
8. Disclosure of all patents and copyrights or patent and copyright applications filed in or outside the United States by the Contractor and/or listed personnel or collaborators for activities derived from, or established by work supported by the contract.

B. Technical Reports Delivery Schedule

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

Progress Reports

Item	Type of Report	Initial Report Due	Recipient & Number of Hard & Electronic Copies	Subsequent Reports Due
1.	Semi-Annual Progress Report	7 months after the effective date of the contract	1 paper and e-Copy to PO 1 paper and e-Copy to CO	Semi-annually; due on or before 30 days following the end of each 6 month period beginning with the start of the contract. Semi-Annual Progress Report shall not be due when the Final Report is due.
2.	Final Report	Draft due 2 months prior to completion date of the contract	1 paper and e-Copy to PO 1 paper and e-Copy to CO	Final due at the completion date of the contract.

C. Other Reports/Deliverables

Proposals for Targets for Structure Determination

The Contractor shall submit an original (paper and electronic) to the Contracting Officer and one (1) copy (paper and electronic) to the Project Officer of the proposals for targets for structural determination from organisms in the NIAID Category A-C priority pathogens list (http://www3.niaid.nih.gov/biodefense/bandc_priority.htm) as well as organisms causing emerging and re-emerging diseases. Proposed targets should have an important role in biomedical research in infectious diseases, such as the examples provided in the Scope section of the Statement of Work. The first proposal for targets shall be submitted to the Project Officer and Contracting Officer within one (1) month after the effective date of the contract. Each proposal must be reviewed and approved by the Project Officer and Contracting Officer. The proposals shall include:

1. A cover page containing the contract number and title; the Contractor's name, address, telephone, fax, and e-mail; the author(s); and date of submission;

2. the target selection process and its scientific rational;

3. whether the X-ray crystallography or NMR spectroscopy approach will be used and why;

4. how the knowledge of the three dimensional structure may facilitate basic biomedical research in infectious diseases, in particular the development of anti-microbial or anti-viral therapeutics, vaccines or diagnostics; and

5. the description of the approach used to determine whether the target is already under consideration, in progress or completed by other structural genomics centers which will then make the structure publicly available.

Project Plan for Research and Development Efforts

The Contractor shall submit an original (paper and electronic) to the Contracting Officer and one (1) copy (paper and electronic) to the Project Officer of the project plan for any type of Research and Development effort, such as the development of new or enhancements of existing laboratory protocols (SOPs), quality control procedures, technologies, or algorithms, considered to be necessary to increase the protein structure determination productivity of the Center, to improve the quality of the structures or to reduce the costs of the Center. Each project plan must be reviewed and approved by the Project Officer and Contracting Officer. The project plan shall include:

1. A cover page containing the contract number and title; the Contractor's name, address, telephone, fax, and e-mail; the author(s); and date of submission;
2. Description of key goals, objectives and justifications;
3. Delineation of the project milestones and timelines to accomplish the milestones;
4. Description of the technical approach to carry out the project and the physical facilities, equipment, and other resources to be made available to the project;
5. Details on how to incorporate and integrate the new developments into the structure determination pipeline;
6. List of proposed scientific and technical personnel, including collaborators and a description of their qualifications, relevant experience and role in the project;
7. Proposed budget, broken down into total costs for labor, materials, subcontracts, and other line items, as appropriate.

Plan for Structural Genomics Services to the Scientific Community

The Contractor shall submit to the Project Officer and the Contracting Officer within 3 months from contract award an electronic copy of a plan describing a process for the broad scientific community to propose protein targets. The plan must be developed in collaboration with the other Structural Genomics Center for Infectious Diseases and shall include the following:

1. A cover page containing the contract numbers of the Structural Genomics Center for Infectious Diseases which contributed to the plan; plan title; the authors and their contact information; and date of submission;
2. The request process the broad scientific community should use to propose protein targets to the Centers, including the information required by the Centers to accept and review proposals, the evaluation criteria for selecting targets, and turnaround time to review those proposals;
3. The IT systems to support the request and review process;
4. Potential confidentiality and Intellectual Property issues regarding data and materials provided by the requestor and how the Contractor shall manage those issues;
5. How the Contractor will promote awareness of the structural genomics services provided to the broad scientific community.

Material Transfer Agreements

To safeguard the proprietary materials, data and other information provided to the Structural Genomics Center for Infectious Diseases by Third Party Suppliers who utilize the structure determination services of the Center, the Contractor shall develop and utilize Material Transfer Agreements (MTAs) with the Third Party Suppliers, as needed. All such MTAs will allow the Contractor to deliver data and other deliverables specified under the contract and will not conflict with the contract. The Contractor shall submit one (1) electronic copy to both the Project Officer and the Contracting Officer of any MTA the Contractor, or its subcontractors, and the Third Party have agreed upon.

Publications, Press Releases and Advertising Materials

The Contractor shall submit to the Project Officer and Contracting Officer for reviewing purposes one (1) electronic copy of any manuscript, abstract, or book chapter containing data generated under this contract authored by the Contractor's staff members, including subcontractors, 30 calendar days before submission for public presentation or for consideration for publication.

Similarly, one (1) electronic copy of any press release document, brochure, newsletter or any printed material describing the Center's accomplishments and activities must be submitted for reviewing purposes to the Project Officer and Contracting Officer. Brochures and newsletters and other types of printed materials must be submitted 30 calendar days before distribution to the broad scientific community. As for press releases:

- Review the requirements of the contract in Section H.
- As soon as possible but not less than four (4) calendar days prior to issuing a news release, send the Project Officer and Contracting Officer a copy of the news release.
- Include the following legend on all news releases: "The information contained in this release relates to contract (Provide contract number and contractor name)_which is funded by the National Institute of Allergy and Infectious Diseases, NIH, DHHS. This release is the product of (Provide contractor name). Information contained in this release does not necessarily represent the views of NIAID, NIH, DHHS."

Plan for Developing and Maintaining the Information Technology and Data Management Systems

The Contractor shall submit to the Contracting Officer and Project Officer a plan for developing and maintaining the information technology and data management systems 2 months following award. The Contractor shall submit a revised Plan incorporating any requested modifications within 1 month of being notified of the review.

The Contractor must include a plan commensurate with the size and complexity of the requirements of the Statement of Work. The minimum areas to be addressed include:

1. Security awareness training for the Contractor and subcontractors staff;
2. Logical access control to networks, systems, remote access, monitoring, etc.;
3. Protection against data loss;
4. Malicious code protection (ex: antivirus, filtering of e-mail attachments, etc) ;
5. Physical security, such as access control (ex: locks, guards), power conditioning, air conditioning, fire protection.

Provide similar information for any subcontractor developing or accessing the Center's information technology infrastructure and network.

Program Development Plan

The Contractor shall submit two (2) Program Development Plans (PDPs) in an original (paper and electronic) to the Contracting Officer and one (1) copy (paper and electronic) to the Project Officer. The first plan shall cover the initial 2 years of the contract period and be submitted three (3) months following the contract award; the second plan shall cover the final three years of the contract period and be submitted 2 years and 3 months from contract award.

The PDP for the initial phase (years 1-2) and the intermediate/final phases of the contract (years 3-5) shall include the following:

1. A cover page containing the contract number and title; the period of performance being addressed; the Contractor's name, address, telephone, fax, and e-mail; the author(s); and date of submission;
2. Definition of the vision and goals for the Center;
3. Description of facilities, technology and personnel 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 the needs of the community;
4. A dissemination plan for targets' experimental structure data, the reagents and all their related data;
5. Other information pertinent to the development of the Center activities as requested by the Project Officer or the Contracting Officer.
6. Project's implementation schedules and milestones.

Ad Hoc Reports

The Contractor shall submit as requested by the Project Officer and the Contracting Officer, an original (paper and electronic) and one (1) copy (paper and electronic) of up to three (3) ad hoc reports per year about topics that fall within the scope of the Statement of Work. Only with the approval of the Project Officer the information contained within the 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.

Final Transition Plan

The Contractor shall submit an original (paper and electronic) to the Contracting Officer and one (1) copy (paper and electronic) to the Project Officer of the Final Transition Plan twelve (12) months prior to the contract expiration date. The Final Transition Plan shall include the following:

1. A cover page containing the contract number and title; the period of performance being reported; the Contractor's name, address, telephone, fax, and e-mail; the author(s); and date of submission;
2. A comprehensive list of all deliverables listed under the Reporting Requirements and Deliverables section of the contract, including stored reagents, data, web portals, databases, software applications and algorithms, SOPs, technologies, purchased supplies and equipment, and any other resource generated under this contract;
3. A plan for the transportation of these resources and deliverables to a subsequent contractor or the Government, including timelines.

Invention Report 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 Office of 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 on the completion date of the contract to the Contracting Officer.

The annual utilization report shall be submitted in accordance with ARTICLE F.1. DELIVERIES of this contract. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on/before the completion date of the contract to the following address:

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

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 Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH.

D. Deliveries

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in Article C 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:

Item	**Type of Report**	**Initial Report Due**	**Recipient & Number of Hard & Electronic Copies**	**Subsequent Reports Due**
1.	Proposals for Targets for Structure Determination	1 month after the effective date of the contract	1 paper and e-Copy to PO 1 paper and e-Copy to CO	As needed
2.	Project Plan for Research and Development Efforts		1 paper and e-Copy to PO 1 paper and e-Copy to CO	As needed
3.	Plan for Structural Genomics Services to the Scientific Community	3 months after the effective date of contract	1 paper and e-Copy to PO 1 paper and e-Copy to CO	
4.	Material Transfer Agreements		1 e-Copy to PO 1 e-copy to CO	As needed
5.	Publications, Press Releases and Advertising Materials		1 e-Copy to PO 1 e-Copy to CO	4 calendar days prior to issuing a press release;30 calendar days for the other materials
6.	Plan for Developing and Maintaining the Information	2 months after the effective date of contract	1 paper and e-Copy to PO	1 month after NIAID review

	Technology and Data Management Systems		1 paper and e-Copy to CO	
7.	Program Development Plan	3 months after the effective date of contract	1 paper and e-Copy to PO 1 paper and e-Copy to CO	2 years and 3 months after the effective date of the contract.
8.	Ad hoc reports		1 paper and e-Copy to PO 1 paper and e-Copy to CO	As requested
9.	Final Transition Plan		1 paper and e-Copy to PO 1 paper and e-Copy to CO	12 months prior to the contract's completion date
10.	Invention Report		OPERA	As required by FAR clause 52.227-11

The items specified in the subsection Other Deliverables of SECTION C, 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 F, PACKAGING, MARKING AND SHIPPING, of the contract.

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

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

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

OPERA
Office of Extramural Inventions and Technology Resources Branch
OPERA, NIH
6705 Rockledge Drive, Room 1040 A, MSC 7980
Bethesda, Maryland 20892-7980

F. 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.

NIAID Structural Genomics Centers for Infectious Diseases
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APPENDIX A - ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS FORMAT FOR TECHNICAL PROPOSAL

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

These additional Technical Proposal instructions reflect the requirements of the RFP and provide specific instructions and formatting for the Technical Proposal. 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 in this Appendix.

Offerors are advised to give careful consideration to the Statement of Work, all reference materials, appendices 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 175 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

1. 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.
2. PROJECT OBJECTIVES (NIH FORM 1688-1)
3. GOVERNMENT NOTICE FOR HANDLING PROPOSALS
4. PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)
5. TABLE OF CONTENTS

SECTION 2: TECHNICAL PROPOSAL OVERVIEW (2-3 pages)

Provide a brief description of the proposed Structural Genomics Center for Infectious Diseases, including:

1. A description of the HTP structure determination pipeline activities to be performed by the Offeror and those that shall be provided by all proposed subcontractors, including the identification of the proposed subcontractors;
2. A list of key personnel of the Offeror and the proposed subcontractors with degrees and titles;
3. A brief description of the facilities, equipment, and other resources to be made available by the Offeror and all proposed subcontractors; and
4. The period of contract funding requested and the total budget for each year.

SECTION 3: TECHNICAL PLAN/APPROACH

A. Structure Determination Pipeline

1. Describe previous experience in experimental protein structure determination projects that utilized existing high-throughput technologies, state-of-the-art facilities, equipment, other resources, and expertise that will be used by the proposed Structural Genomics Center for Infectious Diseases. Provide information about the methodologies used and the projects' throughput. Provide examples of problems encountered while running the different steps of the structural determination pipeline and the approaches that were used to address those problems.

2. Provide three sample proposals of multiple targets of biomedical relevance from three different genomes of organisms in the NIAID Category A-C biodefense priority lists (http://www3.niaid.nih.gov/biodefense/bandc_priority.htm) or of organisms causing emerging and re-emerging diseases. Describe the target selection process, the scientific rationale for the proposed target, whether the X-ray crystallography or NMR spectroscopy approach would be used and why, and how the three dimensional structure may facilitate basic research in the development of anti-microbial or anti-viral therapeutics, vaccines or diagnostics. The page limit for each sample proposal is six (6) pages.

NOTE: These three sample proposals of targets are only meant to be illustrative of the types of projects that may be entered into the structure determination pipeline of the Center and will be used in the evaluation of scientific and technical merit, appropriateness and feasibility. All targets for experimental structure determination shall be subject to review and approval by the Project Officer post-award.

3. Describe the activities that will be performed to ensure the selected targets are not already targets whose three dimensional structure will be made publicly available by other structural genomics centers established world-wide, such as those listed at http://sg.pdb.org/target_centers.html.

4. Describe the decision strategy for assigning targets to either the X-ray crystallography or NMR spectroscopy approaches.

5. Describe the scientific and technical approaches that will be used for generating proteins and other biological molecules using high-throughput cloning, expression and purification systems to perform X-ray crystallography and NMR spectroscopy structural studies, including testing for biophysical properties of the samples and sample preparation. Demonstrate the ability to crystallize proteins for X-ray crystallography

studies, or label protein samples for NMR studies. Describe quality control procedure that will be used throughout the cloning, expression, purification, crystallization and protein sample labeling steps.

6. Describe the scientific and technical approaches that will be used to solve the target structure, including the collection and analysis of diffraction or NMR data, the generation and refinement of structural models and the structure validation.

B. Information Technology and Data Management

1. Identify and describe the internal data management system architecture and computational infrastructure to support the data management, data analysis, algorithms and software applications development, and other computational needs of the proposed Structural Genomics Center for Infectious Diseases.
2. Describe the Laboratory Information Management System (LIMS) and any other database system that will be utilized and maintained to store, retrieve, track and access the data generated by or related to all the steps of the protein structure determination pipeline, the Center's analysis needs and data dissemination activities delineated in the Statement of Work. Describe the software interfaces to the LIMS and other databases.
3. Describe the network infrastructure that will allow the Center's investigators access to the computational and database resources and software applications, to facilitate data and communication exchange across the Center's laboratories and to support the data dissemination goals of the Center.

C. Information Dissemination and Provision of Contract-Generated Resources

Provide a detailed plan for sharing information, structural data, reagents, and data analysis software tools generated under this contract, with the scientific community, including:

1. Protein Data Bank (PDB): A data sharing plan to release to PDB the targets' three-dimensional structure coordinates, structure factors and NMR constraints, adopted models' validation criteria and quality evaluation data. The plan shall follow the data release guidelines identified in the Statement of Work.
2. Other Public Databases: A plan to disseminate to other database resources data related to the experimental conditions and outcomes of cloning, expression and solubility purification, protein biochemical and biophysical characterizations, crystallization screening, experimental protocols and quality control procedures.
3. Public Repositories: Procedures for distribution of physical materials and reagents to the scientific community through appropriate existing repositories.
4. 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 publicly provide relevant information about the targets and track the targets' status in the structure determination 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. Describe procedures to ensure the web portal is Section 508 compliant.

D. Receipt, Storage, Shipping, and Inventory

1. Describe procedures for receiving and storing compounds, materials, and reagents; and distributing and shipping compounds, materials, and reagents in accordance with applicable safety and other regulatory guidelines. Include appropriate quality control/quality assurance procedures.

2. Describe the electronic inventory system for the management of associated records and documents.

SECTION 4: COLLABORATION AND CONSULTATION WITH THE SCIENTIFIC COMMUNITY

A. Structural Genomics Services to the Scientific Community

Provide a draft plan that offers the Center's technologies, resources and staff expertise to the broad scientific community, NIH or other Government agencies, who will propose to the Center targets for structure determination. The draft plan shall address:

1. The request process the broad scientific community shall use to propose protein targets to the Center, including the information required by the Center to accept and review proposals, the evaluation criteria for selecting targets, and turnaround time to review those proposals;
2. Information technology systems to support the request and review process;
3. Potential confidentiality and intellectual property issues regarding data and materials provided by the requestor and how the Offeror proposes to manage those issues; and
4. Proposed approaches/methods to promote awareness of the structural genomics services provided to the broad scientific community.

B. Scientific Working Group

Provide a plan to establish the Scientific Working Group (SWG) and describe the ideal composition and expertise of its members to provide advice on the management and performance of the Structural Genomics Center for Infectious Diseases. 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.

C. Collaboration with the Scientific Community

Provide a plan to establish and maintain strong and effective interactions with the scientific community, in particular those that perform structure-based studies for the development of therapeutics, diagnostics and vaccines, as well as with investigators who develop new and promising technologies for protein structure determination. The plan should also describe coordination efforts with the other Structural Genomics Center for Infectious Diseases, and other national or international structural genomics centers; and propose collaboration channels with users of protein structures for drug, vaccine and diagnostics development.

SECTION 5: PROJECT MANAGEMENT AND ADMINISTRATION

A. Overall Project Management

1. Provide a plan for project organization, staffing, and management in relation to the implementation, conduct, monitoring and completion of the tasks identified in the Statement of Work.

    a. Describe in detail the responsibilities and level of effort for all proposed key scientific, technical and administrative personnel who will be assigned to the contract, including proposed subcontractors and consultants.

    b. Provide an organizational chart indicating clear lines of authority and responsibility for the Center's personnel.

    c. Include a diagram of the proposed organizational/management structure for the project.

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

2. Outline how the PI will communicate and interact with the Contracting Officer and the Project Officer and how the PI will communicate, monitor, and manage the project both internally and at subcontractor facilities, if any.

B. Program Development Plan

1. Provide a draft Program Development Plan for the five (5) years of the contract. The plan will define the scientific vision of the Structural Genomics Center for Infectious Diseases; describe operational and resource requirements and provide a schedule with goals and milestones for the Center.

C. Evaluation of Efficiency

1. Provide a plan to monitor, maintain and increase the Center's production rate and quality of the molecular structures.

SECTION 6: SCIENTIFIC AND TECHNICAL PERSONNEL

1. Principal Investigator (PI) and Project Manager (PM): Describe the training, education, experience and qualifications of the PI and PM as well as the percentage of the total time each will be committed to the project. Provide the following documentation:

    a. CVs (limit to 2 pages).
    b. Qualifications and relevant training.
    c. Previous experience with projects having goals, size and complexity similar to those of the proposed Structural Genomics Center for Infectious Diseases (limited to the past 5 years), including experience with other structural genomics centers or structural biology laboratories, (limited to the past 5 years). Include information about the role played in those centers or laboratories; coordination with other structural genomics centers and

collaborations with users of the structure information for the development of vaccines, diagnostics and therapeutics; provision of software and data to public resources.

d. Previous experience with project management and other leadership roles. Include details such as achieving milestones and deadlines; tracking, monitoring, and reporting project status and progress; monitoring costs; and solving critical process integration issues which may arise as target structure production increases in scale.
e. References to relevant publications.
f. Availability for the proposed project.

2. Other Scientific and Technical Staff: Describe the training, education, experience and qualifications of the senior scientific and technical personnel proposed, as well as the percentage of the total time each will be committed to the project. This includes staff of the Offeror and all proposed subcontractors. Provide the following documentation:

   a. CVs (limit to 2 pages).
   b. Qualifications and relevant training.
   c. Previous experience with projects having goals, size and complexity similar to those of the proposed Structural Genomics Center for Infectious Diseases (limited to the past 5 years). Include information about the role played in those projects; describe the experience with NIAID Category A-C pathogens and organisms causing emerging and re-emerging diseases; coordination with other structural genomics centers and collaborations with users of the structure information for the development of vaccines, diagnostics and therapeutics; provision of software and data to public resources and development of publicly accessible web sites.
   d. References to relevant publications.
   e. Availability for the proposed project.

SECTION 7: FACILITIES, EQUIPMENT, SAFETY AND TRAINING

Document the availability and adequacy of facilities, equipment, space and other resources necessary to carry out the Statement of Work, including:

1. A list of equipment and other resources dedicated to the project; a detailed floor plan of the proposed facility showing the location of the equipment and other resources; and a description of any facility modifications that would be accomplished prior to initiation and during the performance of the contract. It should be noted that NIAID will not fund any facility modification/renovations.
2. Information regarding the ownership/lease of the facility that demonstrates availability for the duration of the contract.
3. Identification and description of the synchrotron beamlines and NMR spectroscopy facilities and their availability to the Contractor and subcontractor staff.
4. A description of the IT hardware and network systems architecture. Provide a plan for IT systems security and administration in support of all the informatics activities of the Center.
5. A thorough summary of safe practices and facilities that will be available to assure a safe working environment for all personnel handling or in contact with pathogenic microorganism. Describe the plans and procedures to be utilized to ensure compliance with all safety guidelines and regulations, including training and monitoring of personnel.

6. A description of the level of training for proposed staff working with pathogenic microorganisms.
7. A letter signed by the appropriate authority allowing for pre-award site visits to the Contractor's facility and proposed subcontractor's facilities.

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APPENDIX B -- ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS

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

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

BUSINESS PROPOSAL – 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

(a) Number of three-dimensional structures determined
It is anticipated that the number of atomic structures generated and deposited into the Protein Data Bank by the Structural Genomics Center for Infectious Diseases will be approximately 100 per contract year. The estimate should be used for budget estimating purposes.

(b) Estimated Level of Effort
Assume approximately twenty-nine (29.75) Full-Time Equivalents (FTE's) per year, including subcontractor personnel. This information is furnished to Offerors for information purposes only and is not to be considered restrictive for proposal purposes.

(c) Research and Development Projects
Include up to 5% of the total annual budget for budget estimating purposes.

(d) Facility Modifications/Renovations
Do not include costs for facility modifications or renovations that would be accomplished prior to the initiation and during the performance of the contract.

2) **Monthly teleconferences**

For budget estimating purposes, include the cost of monthly teleconferences with the Project Officer and Contracting Officer, as well as with the Contractor's key personnel.

3) Travel

(a) Annual Programmatic Meeting
The cost estimate for annual programmatic meetings of the Structural Genomics Center for Infectious Diseases should include travel costs (transportation, meals, hotel, etc.) for five (5) Contractor staff members, including the Principal Investigator, the Project Manager, Co-Investigators and selected subcontractors. The Contractor is responsible for all costs incurred for conducting the logistical tasks associated with the meeting including: preparing meeting agendas; collecting, organizing, and disseminating meeting materials; preparing and disseminating the summary of the meeting to participants; securing conference rooms; organizing coffee breaks; luncheons; and the coordination of audiovisual and other relevant equipment.

All cost estimates for the annual programmatic meeting should be based on Government per diem rates. Assume the meetings will alternate between the Contractor site and Bethesda, Maryland and will last for two (2) days.

(b) Scientific Working Group
The annual Scientific Working Group (SWG) meeting cost estimate should include travel costs (transportation, meals, hotel, etc.) for the seven (7) SWG members and three (3) staff members of the Contractor or proposed subcontractors. The Contractor is responsible for all costs incurred for conducting the logistical tasks associated with the meeting including: preparing meeting agendas; collecting, organizing, and disseminating meeting materials; preparing and disseminating the summary of the meeting to participants; securing conference rooms; organizing coffee breaks; luncheons; and the coordination of audiovisual and other relevant equipment.

All cost estimates for the annual SWG meeting should be based on Government per diem rates. Assume the meetings will be held at the Contractor site for one (1) day. The Contractor should also include cost estimates for one (1) teleconference per year with the SWG.

(c) Scientific Meetings
Budget travel costs (transportation, meals, hotel, etc.) for one (1) scientific meeting for up to five (5) personnel for a maximum of 4 days per year to present scientific findings generated under this contract as well as to promote awareness of the structural genomics services provided by the Center to the scientific community.

(d) Visits to Academic Institutions or Industry
Budget travel costs (transportation, meals, hotels, etc.) for (2) trips per year for up to one (1) personnel per trip for a maximum of 5 days to visit academic institutions or industry to learn about new structural genomics technologies, equipment and protocols.

(e) Travel to subcontractor sites

Budget travel costs (transportation, meals, hotels, etc.) for two (2) trips per year for up to two (2) personnel per trip for a maximum of 2 days to perform subcontractor oversight.

4) Outreach to the Scientific Community

Budget for informing through electronic and print media, the broad scientific community of the structural genomics services provided by the Center, based on advertising once a year on the following venues: scientific journals, a booth or workshops at meetings and through Professional Societies such as the American Society of Microbiologists (ASM).

5) Shipping, receiving and storage

Assume resources to support storage, receipt and domestic shipping of approximately 300 compounds per year, including DNA samples, protein samples, crystals and clones of pathogenic organisms, including select agents that may require BSL-2 or -3 facilities.

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

1) Small Business Subcontracting Plan

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

2) Extent of Small Disadvantaged Business Participation

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

3) Past Performance Data, including references

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