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

RFP-NIH-NIAID-DMID-06-10
Pathogen Functional Genomics Resource Center (PFGRC)

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:** September 15, 2005	4. **Due Date:** December 15, 2005 **Time:** 4:30PM Local Time Bethesda, MD	5. **Small Bus. Set-Aside:** [ ]Yes [x] No **8(a) Set-Aside:** [ ]Yes [x] No **NAICS #:** 541710 (See Part IV, Section L.)
6. **Just In Time:** [x] No [ ] Yes (See Part IV, Section L.)	7. **Number of Awards:** [x] Only 1 Award [ ] Multiple Awards	8. **Technical Proposal Page Limits:** See Section J, Attachment 4, Packaging and Delivery of Proposal (page 2).
9. **Issued By:** Robert Singman Contracting Officer Contract Management Program, DEA NIH, NIAID 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	[x] **NIAID reserves the right to make awards without discussion.** 10. **Options:** **[x] No** **[ ] Yes** (See Part IV, Section L.)	11. **Period of Performance:** **September 1, 2006 through August 31, 2011**
12. **Primary Point of Contact:** **Name :** Robert Singman **Phone:** 301-451-2607 **Fax:** 301-480-4675 E-Mail: rsingman@niaid.nih.gov	13. **Secondary Point of Contact:** **Name:** Paul McFarlane **Phone:** 301-496-0349 **Fax:** 301-402-0972 E-Mail: pm24v@nih.gov	14. **Protest Officer:** Program Director, CMP **Address (see Block 9.)**
15. COLLECT CALLS WILL NOT BE ACCEPTED. FACSIMILE SUBMISSIONS ARE NOT ACCEPTABLE.		
16. **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)**		
17. **DELIVERY ADDRESS INFORMATION**		
18. **Hand Delivery or Overnight Service:** Robert Singman Contract Management Program, DEA **NIAID, NIH** 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	19. **U.S. Postal Service or an Express Delivery Service** Robert Singman Contract Management Program, DEA NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612	
20. 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 SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.		

Updated thru FAC 2005-04 (05/08/2005)

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

The Division of Microbiology and Infectious Diseases (DMID) of The National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) supports a comprehensive extramural research program focused on all infectious agents (with the exception of the Human Immunodeficiency Virus) and includes basic research, such as studies of microbial biology and physiology; applied research, including the development of medical diagnostics; and clinical trials to evaluate experimental drugs and vaccines. NIAID has a requirement to provide the research community with needed functional genomic resources, data and reagents to study infectious diseases. These include gene expression analysis reagents, whole genome functional expression clones, microbial comparative genomics and genotyping, bioinformatics and computational software tools, proteomic analysis and purification, high quality protein arrays, and comparative microbial protein profiling. In addition, there is a requirement for providing reagents and resources for discovery of potential candidates for clinically useful pathogen or host protein biomarkers in well-defined clinical samples.

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.

1. Confidential Treatment of Sensitive Information

If the Government determines that some of the information/data that the contractor will or has generated, or that will be provided to the Contractor during the performance of the contract, is of a sensitive nature, the contractor shall guarantee strict confidentiality of the information/data during the performance of the contract. As specified in Appendix D of the "Automated Information Systems Security Program (AISSP) handbook", available at http://irm.cit.nih.gov/policy/aissp.html :

Sensitive information is defined as any information, the loss, misuse, or unauthorized access to or modification of which could adversely affect the national interest or the conduct of Federal programs, or the privacy to which individuals are entitled under section 552a of title 5, United States Code (the Privacy Act), but which has not been specifically authorized under criteria established by an Executive order or an Act of Congress to be kept secret in the interest of national defense or foreign policy. (Computer Security Act of 1987)

Sensitive data are defined as data that require protection due to the risk and magnitude of loss or harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the data. The term includes data whose improper use or disclosure could adversely affect the ability of an agency to accomplish its mission, proprietary data, records about individuals requiring protection under the Privacy Act, and data not releasable under the Freedom of Information Act. (OMB Circular A-130)

The parties understand and agree that the definition of sensitive information/data shall not include information which is in the public domain or which is ordinarily published in scholarly journals, including data and information generated by the Contractor under this contract. Similarly, the definition of sensitive information/data shall not include the information/data generated by the Contractor under this contract unless, by mutual agreement of the Contractor with the

Government, the information/data generated by the Contractor is derived from or is containing information/data that is given by the Government to the Contractor to perform work under this contract, and that is clearly marked by the Government as sensitive.

Disclosure of the sensitive information/data, in whole or in part, by the Contractor can only be made after the contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of the information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated August 17, 2005, attached hereto and made a part of this Solicitation (See Section J - List of Attachments - **ATTACHMENT 1**).

ARTICLE C.2. REPORTING REQUIREMENTS

a. Technical Report

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

1. Program Development Plan

The Contractor shall submit the original Program Development Plan (paper and electronic) to the NIAID Contracting Officer and one (1) copy (paper and electronic) to the NIAID Project Officer ninety (90) calendar days following the award of the contract. The Program Development Plan shall include the following:

a. 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;

b. Definition of a vision of the PFGRC during the initial inception phase (years 1-5), and the five years beyond the expiration date of this contract, and state the criteria which must be met to justify an ongoing effort;

c. Description of operational requirements of the PFGRC in a phase of rapid growth;

d. Identification of special or extraordinary facilities and resource requirements beyond the initial inception phase that would best allow it to meet the needs of the community; and

e. Establishment of performance metrics and utilization measures of the PFGRC as well as propose methods for gathering data to monitor them.

2. Plan for Providing Functional Genomics Data and other Resources to Scientific Community

The Contractor shall submit an original of the subject Plan (paper and electronic) to the NIAID Contracting Officer and one (1) copy (paper and electronic) to the NIAID Project Officer ninety (90) calendar days following the award of the contract and annually thereafter. The Plan shall include the following:

a. 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;

b. Description of how the Contractor will provide resources to the scientific community in a timely fashion, including reagents, bioinformatics tools, software and source codes, protocols, technologies, and functional genomics data and annotation developed under this protocol; and

c. Details on how functional genomics data will be released to publicly accessible, web-based database sites and a small number of other database sites, as specified by the NIAID Project Officer involved in long term management of the functional genomics data, including NIAID Bioinformatics Resource Centers. The plan shall include a timeline for releasing data to the scientific community and if appropriate, submitting a publication describing the data.

3. Final Transition Plan

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

a. 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;

b. A comprehensive list of all stored reagents, data, web sites, databases, bioinformatics software and tools, technologies, SOPs, unused supplies, Government-furnished equipment and any other resources generated under this contract; and

c. A plan for the transportation of these resources and deliverables to a subsequent contractor or the Government.

4. Quarterly Progress Reports

The Contractor shall submit Quarterly Progress Reports in an original (paper and electronic) to the NIAID Contracting Officer and one (1) copy (paper and electronic) to the NIAID Project Officer on the final day of the month following the end of each quarterly annual performance period.

The Quarterly Progress Report shall include the following:

a. 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.

b. Reports shall include the following information:

(1) An introduction covering the purpose and scope of the contract effort;
(2) A full description of overall progress on all projects during the reporting period, including reagents generated, produced, distributed, and acquired; websites and software developed; technologies developed and distributed; SOPs developed; and functional genomics data generated;
(3) Functional genomics data for each project should be displayed in graphs and tables as appropriate to present comprehensively significant results achieved, conclusions for analysis, scientific evaluation of the data, technologies developed, and reagents produced to date under the contract;
(4) A completed table as provided below listing each project with project-specific deliverables, the date they are due, and the percent completion of the deliverable;
(5) A description of problems encountered, difference between planned and actual progress, cause(s) of the difference, and proposed or completed corrective actions;
(6) A proposed work plan, timeline and description of the work proposed for the next reporting period;

(7) A summary of all meetings and conference calls, workshops, conferences, etc., that have taken place during the reporting period, including progress on administration and management issues;
(8) A full description of collaborators for each project, if appropriate and their role in the progress during the reporting period; and
(9) Disclosure of any and all patents and copyrights or patent and copyright applications of reagents, data, software, technologies or methods or procedures 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.

SAMPLE PROJECT TABLE [Insert Project Number]

Status of Project-specific Deliverables

Item	Deliverable	Date Due (MM/DD/YYYY)	Progress (% completion)
1.			
2.			
3.			
4.			

5. Ad hoc Reports

The Contractor shall submit an original and one (1) copy (paper and electronic) of 10 ad hoc reports per year to the NIAID Project Officer and the NIAID Contracting Officer as requested including data sets, progress on individual projects, list of reagents produced and software and technology developed. The information contained within the reports may be provided to various branches of the Government and/or public health related agencies and collaborators upon their request. The NIAID Project Officer will specify the report format at the time of the request.

6. Project Plans

The Contractor shall submit an original and one (1) copy (paper and electronic) of Project Plans to the NIAID Project Officer and the NIAID Contracting Officer for carrying out the development and distribution of functional genomic reagents, resources, technologies and data as requested within 30 days of notification. The Project Plan shall include:

a. 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;

b. Specification of the reagents, resources, data, or technologies to be developed and provided;

c. Description of key goals and objectives;

d. Delineation of the project milestones and timelines to accomplish the milestones;

e. 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, including obtaining the necessary reagents such as DNA, RNA clones or microorganisms;

f. List of proposed scientific and technical personnel, including collaborators and a description of their qualifications, relevant experience and role in the project;

g. Plan for Quality Assurance and Quality Control of the project; and

h. Proposed budget.

7. Final Report

The Contractor shall submit the Final Report in an original (paper and electronic) to the NIAID Contracting Officer and one (1) copy (paper and electronic) to the NIAID Project Officer of the Final Report that documents and summarizes the results of the entire contract period of performance. A draft Final Report shall be submitted thirty (30) calendar days prior to the completion of the contract for review by the NIAID Project Officer and NIAID Contracting Officer. The Final Report shall be submitted on the completion of the contract. The Final Report shall include the following:

a. 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.

b. An introduction covering the purpose and scope of the contract effort including a summary, not to exceed 200 words, of salient results and deliverables accomplished during the performance of the contract.

c. A detailed description of work performed and results on all individual projects, including reagents generated, produced, distributed and acquired; websites and software developed; technologies developed and distributed; comparative genomics and proteomics projects and data generated; SOPs and methods developed; and genomic and functional genomics data generated. Functional genomics data should be displayed in graphs and tables as appropriate to present significant results achieved, conclusions for analysis and a scientific evaluation of the data, technologies developed, and reagents produced under the contract.

d. Copies of any abstracts, manuscripts and publications generated from this contract.

e. Disclosure of any and all patents and copyrights or patent and copyright applications of reagents, data, software, technologies or methods or procedures 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.

8. Invention Reporting Requirement

All reports and documentation required by FAR Clause 52.227-11 including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the 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
Contract Management Program
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.

SECTION D - PACKAGING, MARKING AND SHIPPING

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

SECTION E - INSPECTION AND ACCEPTANCE

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

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

c. Inspection and acceptance will be performed at the NIAID, DMID, OBRA, 6610 Rockledge Drive, Bethesda, MD 20892.

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

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

FAR Clause 52.246-8, 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 below [and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of the contract]:

Technical Report Distribution

	Deliverable	No. of Copies	Addressee/Distribution	Due Dates
a	Program Development Plan	Original (paper and electronic) 2 Copy (paper and electronic)	NIAID Contracting Officer NIAID Project Officer	90 calendar days from the contract award date
b	Plan for Functional Genomics Data and other Resources	Original (paper and electronic) 2 Copy (paper and electronic)	NIAID Contracting Officer NIAID Project Officer	90 calendar days from the contract award date and then on or before the 30th calendar day of the month following each anniversary date of the contract
		Original (paper and	NIAID Contracting Officer	On the 30th calendar

c	Quarterly Reports	electronic) 2 Copy (paper and electronic)	NIAID Project Officer	day of the month following the end of each quarterly annual performance period
d	Ad Hoc Reports	Original (paper and electronic) 2 Copy (paper and electronic)	NIAID Contracting Officer NIAID Project Officer	As required
e	Project Plans	Original (paper and electronic) 2 Copy (paper and electronic)	NIAID Contracting Officer NIAID Project Officer	As required
f	Final Transition Plan	Original (paper and electronic) 2 Copy (paper and electronic)	NIAID Contracting Officer NIAID Project Officer	12 months prior to the contract's completion date
g	Draft Final Report	Original (paper and electronic) 2 Copy (paper and electronic)	NIAID Contracting Officer NIAID Project Officer	30 calendar days prior to the contract's completion date
h	Final Report	Original (paper and electronic) 2 Copy (paper and electronic)	NIAID Contracting Officer NIAID Project Officer	On or before the contract's completion date
i	Invention Report	1	OPERA, NIH	As required by FAR Clause 52.227-11

Other Deliverables

Deliverables shall be delivered in a format that is compatible with sites or repositories involved in long-term management of the data, reagents, software tools and other materials generated under this contract, as specified by the NIAID Project Officer.

Other deliverables include:

All genomic, functional genomic, bioinformatics and proteomic data generated under this contract.

All reagents generated under this contact including DNA, RNA, clones, microarrays, genomic libraries, and proteins.

All genome sequencing data, sequence traces, and annotation data generated under this contract.

All web sites, software and source codes, and computational tools and databases developed and generated under this contract.

Copies (paper and electronic) of protocols, methods, and SOPs for reagent, reference data, and technology development generated under this contract.

All equipment procured under this contract.

A computerized list of accurate and updated information on reagent inventory generated, distributed and acquired including data files, databases, and any necessary information related thereto.

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

Addressee	**Deliverable Item**	**Quantity**
Project Officer	(a), (b), (c), (d), (e), (f),	Project Officer: 2 copies

DMID, NIAID, NIH 6610 Rockledge Dr., Room MSC 6605, Bethesda, MD 20892-6605	(g), (h)	(1 electronic PDF file on a CD and 1 paper copy)
Contracting Officer CMP, NIAID, NIH 6700-B Rockledge Drive, Room 3214 MSC 7612 Bethesda, MD 20892-7612	(a), (b), (c), (d), (e), (f), (g), (h)	Contracting Officer: (1 electronic PDF file on a CD and 1 original paper)
Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH 6705 Rockledge Drive, Room 1040A MSC 7980 Bethesda, MD 20892-7980	(i)	All reports and documentation required by FAR 52.227-11.

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

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. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

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

SECTION G - CONTRACT ADMINISTRATION DATA

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. HHSN266200411000C.)

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 copies to the following designated billing office:

Contracting Officer
Contract Management Program, DEA
National Institute of Allergy and Infectious Diseases, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
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 Contracts Management
National Institutes of Health
6100 Building, Room 6B05
6100 EXECUTIVE BLVD MSC 7540
BETHESDA MD 20892-7540

ARTICLE G.5. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the DHHS Publication (OS) 686, entitled, **Contractor's Guide for Control of Government Property**, (1990) which can be found at:
http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluations may be prepared annually to coincide with the 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://ocm.od.nih.gov/cdmp/cps_contractor.htm

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

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H. 1. HUMAN SUBJECTS

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

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

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. The information below is a summary of the NIH Policy Announcement:

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

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

ARTICLE H.3. HUMAN MATERIALS

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

ARTICLE H.4. 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.5. 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 46.208(a)(2) 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.6. 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.7. PRIVACY ACT

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

The Privacy Act System of Records applicable to this project is Number 09-25-0200. This document may be accessed at **http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm** .

ARTICLE H.8. 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

(1) **Subcontracting Report for Individual Contracts, SF-294**

The Contractor shall submit the original and one (1) copy of Subcontracting Report for Individual Contracts, SF-294 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. In addition to the information contained in the General Instructions on the back of this form for Block 17, "Remarks," the Contractor shall provide an explanation **for any category** of small business subcontracting for which there were no dollars reported since the last reporting period.

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

The Report shall be sent to the Contracting Officer at following address:

Contracting Officer
Contract Management Program, DEA
NIAID, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

(2) **Summary Subcontract Report, SF-295**

The Contractor shall submit two (2) copies of Summary Subcontract Report, SF-295 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. 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

One copy of this report shall be sent to the Contracting Officer at the address above. One copy of this Report shall be mailed to the Office of Small and Disadvantaged Business Utilization, DHHS at the following addresses:

Office of Small and Disadvantaged Business Utilization
Department of Health and Human Services
Hubert H. Humphrey Bldg., Room 360G
200 Independence Avenue, S.W.
Washington, D.C. 20201

(3) The contractor shall also send an "Information Copy" of the SF-295 to the Cognizant Commercial Representative (CMR) at the address provided by the SBA. The Contractor should call SBA Headquarters in Washington, DC at (202) 690-7235, for the correct address if unknown.

ARTICLE H.9. 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 10/1/04 - 12/30/04, the Executive Level I rate is $175,700. Effective January 1, 2005, the Executive Level I rate increased to $180,100 and will remain at that rate until it is revised. See the web site listed below for the Executive Schedule rates of pay:

FOR FY05 EXECUTIVE LEVEL SALARIES EFFECTIVE JANUARY 1, 2005:
http://www.opm.gov/oca/05tables/html/ex.asp

(NOTE: This site shows the CY 05 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.10. 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.11. 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.12. 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 and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. TBD .

ARTICLE H.13. PRESS RELEASES

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

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

[Applicable information to be included at award]

ARTICLE H.14. 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.15. 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.16. 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.

ARTICLE H.17 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.18. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

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

ARTICLE H.19. 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.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

General Clauses for a Cost-Reimbursement Research and Development Contract

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

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

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 IV (October 1997) of FAR Clause **52.215-21, Requirements For Cost Or Pricing Data Or Information Other Than Cost Or Pricing Data--Modifications** (October 1997) is added.

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

"(c) Waiver of evaluation preference.....

[ ] Offeror elects to waive the evaluation preference."

(2) FAR Clause 52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting (October 1999).

(3) FAR Clause 52.223-3, Hazardous Material Identification and Material Safety Data (January 1997), with Alternate I (July 1995).

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

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

(8) FAR Clause 52-227-15, Representation of Limited Rights Data and Restricted Software (May 1999).

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

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 (March 2005).

(3) HHSAR Clause 352.270-8, Protection of Human Subjects (March 2005).

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

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

(1) NIH (RC)-7, Procurement of Certain Equipment (April 1984) (OMB Bulletin 81-16).

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:

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

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

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

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

Notice to Employees

Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an

employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

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

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

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

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

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

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

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

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

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

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

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

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

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

(f) The Department of Labor publishes the official employee notice in two variations; one for contractors covered by the

Railway Labor Act and a second for all other contractors. The Contractor shall--

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

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

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

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

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS: (The following are attached at the back of the solicitation package in full text.)

Attachment No.	Title	Location
Attachment 1:	Statement of Work	Linked to the Attachment Title
Attachment 2:	Appendix A and B to Section L.	Linked to the Attachment Title
Attachment 3:	Proposal Intent Response Sheet	Linked to the Attachment Title
Attachment 4:	Packaging and Delivery of Proposal	Linked to the Attachment Title
Attachment 5:	Government Property To be Provided	Linked to the Attachment Title

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

Attachment No.	Title	Location
Attachment 6:	Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Attachment 7:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Attachment 8:	Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
Attachment 9:	Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (formerly Optional Form 310	http://rcb.cancer.gov/rcb-internet/forms/of310.pdf
Attachment 10:	Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf

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

Attachment No.	Title	Location
Attachment 11:	Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Attachment 12:	Small Business Subcontracting Plan	http://rcb.cancer.gov/rcb-internet/forms/sb-subplan-nci.pdf
Attachment 13:	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

Attachment 14:	Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Attachment 15:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf

INFORMATIONAL ATTACHMENTS: (The following Attachments and Reports will become part of any contract resulting from this RFP and will be required during contract performance.)

Attachment No.	Title	Location
Attachment 16:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 17:	Privacy Act System of Records *System of Records No. 09-25-0200 is applicable to this RFP.*	http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm
Attachment 18:	Safety and Health, HHSAR Clause 352.223-70	http://www.niaid.nih.gov/contract/forms/form10.pdf
Attachment 19:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.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

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

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

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting 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)

b. NAICS CODE AND SIZE STANDARD

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

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

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

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

c. **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that One Award will be made from this solicitation and that the award will be made on or about August 31, 2006.

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

d. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be as follows:

Performance Period (5 Years) 93,600 total direct labor hours [equivalent to 45 FTE's]

This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

e. **COMMITMENT OF PUBLIC FUNDS**

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

f. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

g. **RELEASE OF INFORMATION**

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

h. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors 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.

i. **PREPARATION COSTS**

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

j. **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 General Accounting Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Program Director
Contract Management Program, DEA
NIH, NIAID
6700-B Rockledge Drive
Room 3214, MSC 7612
BETHESDA MD 20892-7612

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

(End of Provision)

k. **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70

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.

(1) **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 and Appendix A - Additional Technical Proposal Instructions..

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 and Appendix B - Additional Business Proposal Instructions and Uniform Cost Assumptions

(2) **Proposal Summary and Data Record (NIH-2043)**

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

(3) **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 INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS). 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.

(4) **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.

(5) **Evaluation of Proposals**

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

(6) **Potential Award Without Discussions**

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

(7) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all 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.

(8) **Standards for Privacy of Individually Identifiable Health Information**

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

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

(9) 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.

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

Notice to Offerors of Requirements of: 42 CFR Part 73, Possession , Use, and Transfer of Select Agents and Toxins (relating to public health and safety): (http://www.cdc.gov/od/sap/42_cfr_73_final_rule.pdf);
7 CFR Part 331, Possession, Use, and Transfer of Select Agents and Toxins (relating to plant health or plant products) (http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf); and,
9 CFR Part 121, Possession, Use, and Transfer of Select Agents and Toxins (relating to human and animal health, animal health or animal products) (http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) - March 18, 2005.

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

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

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

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

Domestic Institutions

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

- include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.

- comply with 42 CFR part 73, 7 CFR part 331 and/or 9 CFR part 121 at: http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf, as required, before using NIH funds for research involving Select Agents. No NIH funds can be used for research involving Select Agents if the final registration certificate is denied.

Foreign Institutions

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

- include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.

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

An NIAID-chaired committee of U.S. federal employees (including representatives of NIH grants/contracts and scientific program management, CDC , Department of Justice and other federal intelligence agencies, and Department of State) will ultimately assess the results of the facility inspection, the regulations, policies, and procedures of the foreign institution for equivalence to the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at:
http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf.
The committee will provide recommendations to the DEA Director, NIAID. The DEA Director will make the approval decision and notify the Contracting Officer. The Contracting Officer will inform the prime contractor of the approval status of the foreign institution. No NIH funds can be used for research involving Select Agents at a foreign institution until NIAID grants this approval.

The following notice is applicable when contract performance is expected to involve possession, use and/or transfer

of select biological agents or toxins:

Notice to Offerors of Requirements of: 42 CFR Part 73, Select Agents and Toxins (relating to public health and safety)**; Agricultural Bioterrorism Protection Act of 2002,** which consists of **7 CFR Part 331, Possession, Use, and Transfer of Biological Agents and Toxins** (relating to plant health or plant products)**; and 9 CFR Part 121, Possession, Use, and Transfer of Biological Agents and Toxins** (relating to human and animal health, animal health or animal products) - **December 13, 2002**

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, 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 who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the NIH that a process equivalent to that described in 42 CFR 73 (http://www.cdc.gov/od/sap/docs/42cfr73.pdf) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. In the technical proposal, the offeror must include details about the select agent and the quantity proposed to be used during contract performance. When requested by the contracting officer during negotiations, potential awardees must provide information addressing the following key elements for the foreign institutions: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to 42 CFR 73. 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 assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. Toward this end, when requested during negotiations, potential awardees will be asked to provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes concise summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, foreign institutions must provide the names of all individuals who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the resulting contract.

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

Listings of HHS Select Agents and Toxins, biologic agents and toxins, and Overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap/

(11) **Obtaining and Disseminating Biomedical Research Resources**

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

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

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://ott.od.nih.gov/NewPages/64FR72090.pdf.

(a) **Sharing Research Data**

[Note: The NIH Guide announcement referenced below states that this policy is applicable to "all investigator-initiated applications with direct costs greater than $500,000 in any single year." This is an overall grant policy which requires that an applicant must seek agreement by NIH to accept assignment of their application in advance of the submission date. As such, this policy has not correlation to the contract process, therefore, the threshold is not applicable to contracts. Thus, this article applies to ***any*** *contract that may generate research data.]*

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan 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

(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 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.

(12) **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.

(13) **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.

(14) **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, see Section J to this RFP for an example of such a plan.

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

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

c) The offeror understands that:

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

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

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

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

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small

Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

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

d) Each plan must contain the following:

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

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

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

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

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

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

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

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

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $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; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

(15) **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.

(16) **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). The NAICS codes can be found at:
http://www.sba.gov/size

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

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

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS 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 (Includes joint venture partners and team arrangements)*	10%	$100,000
SDB Participation by subcontractors	15%	$150,000

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

(17) **Salary Rate Limitation in Fiscal Year 2005**

Offerors are advised that pursuant to P.L. 108-447, no NIH Fiscal Year 2005 (October 1, 2004 - September 30, 2005) 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. 108-447 applies only to Fiscal Year 2005 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. 108-447 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 extramural mechanism at a rate in excess of Executive Level I*."

LINK TO EXECUTIVE SCHEDULE SALARIES: http://www.opm.gov/oca/05tables/html/ex.asp

***Note to Offerors:** The current Fiscal Year Executive Level I Salary Rate should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award will be required to be in compliance with the current Fiscal Year 2005 Executive Level I Salary rates.*

(18) **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.

(19) **ROTC Access and Federal Military Recruiting on Campus**

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

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

(20) **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 3 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.

(21) **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.

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

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

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

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

f) 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 (See Appendix A). 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 Section M, Evaluation Factors for Award, herein.

(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.

<u>IMPORTANT NOTE TO OFFERORS</u>: The following 12 paragraphs [(5) through (16)] shall be addressed in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

(5) **Human Subjects**

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (MARCH 2005)

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

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

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

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The OpDiv will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consultation with OHRP, (telephone: 301-496-7005), is recommended.

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

http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html

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

(End of provision)

(6) **Instructions to Offerors Regarding Protection of Human Subjects**

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

(a) Risks to the subjects

Human Subjects Involvement and Characteristics:

- Describe the proposed involvement of human subjects in response to the solicitation.

- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.

- Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.

Sources of Materials:

- Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks:

- Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.

- Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

- Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

Protection Against Risk:

- Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.

- Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.

- In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

(c) Potential Benefits of the Proposed Research to the Subjects and Others

- Discuss the potential benefits of the research to the subjects and others.

- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

(d) Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.

- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

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

Collaborating Site(s)

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

(7) **Required Education in the Protection of Human Research Participants**

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

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

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

http://www.centerwatch.com/order/pubs_profs_protect.html.

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

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

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

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

(8) **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is NIH policy that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an Institute/Center Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data

from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43), ***and applies to research subjects of all ages***.

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

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

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research," at:
(http://www.nih.gov/news/crp/97report/execsum.htm).

Information Required for ALL Clinical Research Proposals

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

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

The proposal must include the following information:

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

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

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

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

selected only one category, for each of the five racial categories. If you collapse data on multiple responses, you shall make available, at a minimum, the total number of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

In addition to the above requirements, solicitations for **NIH defined Phase III clinical trials**[1] require that*:* a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide:
http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm,
Definitions - Significant Difference), by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences.

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

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

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

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

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

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

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

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

(9) **Inclusion of Children in Research Involving Human Subjects**

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

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

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

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1 See NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, for the Definition of an "NIH-Defined Phase III clinical trial.

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

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

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

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

Justifications for Exclusion of Children

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

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

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

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

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

Definition of a Child

For the purpose of this solicitation, a child is defined as an individual under the age of 21 years.
The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to

participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

(10) **Data and Safety Monitoring in Clinical Trials**

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

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

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

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

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

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

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

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

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

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

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

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

(11) **Research Involving Human Fetal Tissue**

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

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

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

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

(12) **Research Involving Prisoners as Subjects**

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

b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

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

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

1. The sole purposes are:

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

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

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

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

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

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

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

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

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

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

(14) Human Embryonic Germ Cell (HEGC) Research

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

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

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

2. Procedure for Required Review by Human Pluripotent Stem Cell Review Group (HPSCRG) **This section is not applicable to this action.**

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

   If the offeror's proposal includes research using human embryonic germ cells and it receives a contract award,

the contractor may not perform any research using these human embryonic germ cells until the Human Pluripotent Stem Cell Review Group (HPSCRG) has reviewed and approved the documentation furnished as prescribed in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html) and the contracting officer has notified the contractor of the approval in writing.

The resultant contract will be divided into discrete phases or option period(s). During Option Period(s)/Phase(s)_____ of the contract, the contractor shall submit the original and two copies of the required documentation and assurances that address the areas covered in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells," at:

(http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html)

to the contracting officer. This documentation will be forwarded for review and approval to the HPSCRG.

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

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

(15) **Human Embryonic Stem Cell (HESC) Research**

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

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

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

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

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

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) **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.

(6) **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.

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

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

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.

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

d) **Financial Capacity**

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

e) **Incremental Funding**

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

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

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

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

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

(End of Provision)

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

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

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

(7) **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

(8) **Proposer's Annual Financial Report**

All offerors included in the competitive range will be required to submit a copy of the organization's most recent annual financial report.

(9) **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.

(10) **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**

All offerors included within the competitive range will be required to submit one copy of their written travel policy. A written travel policy for any proposed subcontractors shall also be submitted at that time. If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

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.

(11) **Certification of Visas for Non-U.S. Citizens**

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

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost/price, past performance, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, cost/price, past performance, and SDB Participation are also important to the overall contract award decision. All evaluation factors other than cost/price, when combined, are significantly more important than cost or price. The trade-off process described in FAR 15.101-1 may be employed. This process permits tradeoffs among cost/price and non-cost factors and allows the Government to consider award to other than the lowest priced or highest technically rated Offeror. In any event, the Government reserves the right to make an award to that Offeror whose proposal provides the best overall value to the Government.

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

2. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing technical proposals. Proposals will be judged solely on the written material provided by the Offeror. The criteria listed below are in the order of relative importance with weights assigned for evaluation purposes.

Offerors and reviewers are advised to refer to Appendix A – Additional Technical Proposal Instructions of this solicitation package for guidance and information related to the preparation and format of technical proposals**.**

CRITERIA	WEIGHT
A. Scientific and Technical Approach	**35**

Scientific and technical merit, adequacy, appropriateness, and feasibility of proposed plans and procedures for producing high quality functional genomics data, technologies, resources and reagents to the scientific community.

1. Adequacy and feasibility of the plan for establishing a state-of-the-art, high throughput, efficient, cost-effective PFGRC for infectious diseases to provide high quality functional genomics data, technologies, resources and reagents to the scientific community.

2. Soundness and practicality of the technical approach for generating and constructing functional genomic reagents, resources, technology and data; and adequacy of the proposed plans for identifying, evaluating and implementing continued improvements in functional genomics technology for:

    a. gene expression analysis including DNA microarrays for viruses, bacteria, fungi, larger eukaryotic protozoan parasites, and multi-organisms; and genome annotation;
    b. producing whole genome microbial functional expression clones using recombinational cloning technology or other appropriate technologies; and
    c. conducting state-of-the-art microbial comparative genomics and genotyping.

3. Soundness of the technical approach for developing and generating proteomic reagents, resources, technology and proteomic data for protein expression, comparative protein profiling and clinical biomarker discovery.

4. Soundness of the technical approach for conducting all aspects of computational and bioinformatics activities required for a state-of-the-art functional genomics facility.

5. 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, in order to identify needs of the research community.

B. Provision of Resources and Training for the Scientific Community 20

Adequacy and appropriateness of plans and procedures for receipt, storage, distribution, and dissemination of functional genomics reagents, resources, data, and technology to the scientific community.

1. Adequacy and appropriateness of procedures for identifying, acquiring, and producing reagents; receiving and storing reagents in compliance with all safety regulations; providing for quality control of reagents; and distributing and shipping reagents in compliance with all Local, State, and Federal laws and regulations.

2. Adequacy and feasibility of the proposed plan to provide functional genomics data and resources to the scientific community.

3. Adequacy and feasibility of proposed training for, and technical support to, the scientific community in the use of functional genomics reagents and technologies.

4. Adequacy and appropriateness of plans for disseminating information on functional genomic reagents, data, and resource availability.

C. Project Management 15

Adequacy, thoroughness and appropriateness of the plans and procedures for overseeing, monitoring, and managing a state-of-the art functional genomics facility.

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

2. Adequacy and feasibility of plans for the development, implementation, and maintenance of a proposed project database management system to monitor and coordinate the activities of the PFGRC.

3. Soundness and feasibility of the proposed Program Development Plan for the PFGRC over a ten-year period.

D. Experience and Qualifications of Personnel 15

Appropriateness and relevance of the documented training, experience, expertise and availability of proposed scientific, technical and administrative staff in relation to their specific duties and responsibilities.

1. Principal Investigator: Documented training, related expertise and experience, leadership skills, and availability of a Principal Investigator with scientific, technical and managerial competence to successfully plan, manage, conduct and direct a project of a comparable size and complexity, including the appropriateness of the proposed time commitment of the Principal Investigator.

2. Project Managers: Documented training, related expertise and experience, leadership and availability of Project Managers with 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 of the staff.

3. 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.

E. Facilities, Resources and Information Technology Support 15

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

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

2. Adequacy of the information regarding ownership/lease of the facility which demonstrates availability for the duration of the proposed contract.

3. Adequacy of the documented availability and suitability of the computational facilities, and support to conduct work described in the Statement of Work, including hardware, software and other necessary equipment.

TOTAL POSSIBLE POINTS: 100

3. PAST PERFORMANCE FACTOR

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

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

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

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an Offeror's performance on a list of contracts, but rather the product of subjective judgment by the Government after consideration of 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.

4. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

Small Disadvantage Business (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) Complexity and variety of the work SDB concerns are to perform; and
(b) Extent of participation of SDB concerns in terms of the value of the total acquisition.

5. HUMAN SUBJECT EVALUATION

This research project involves human subjects. NIH Policy requires:

(a) Protection of Human Subjects from Research Risks

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

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

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

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

(b) Data and Safety Monitoring

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

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

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

(c) Women and Minorities

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

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

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

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

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

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

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

- For NIH-defined Phase III clinical trials, reviewers will also consider whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is expected in the primary analyses.

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

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

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

(d) Children

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

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

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

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

6. EVALUATION OF DATA SHARING PLAN

The Offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy. If your proposal does not include a plan or if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award. The following web site provides guidance on data sharing and additional information on the implementation of this policy: http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm.

7. EVALUATION OF PLAN FOR SHARING MODEL ORGANISMS FOR BIOMEDICAL RESEARCH

The Offeror's proposal must address the plans for sharing model organisms, OR state appropriate reasons why such sharing is

restricted or not possible. Offerors must also address as part of the sharing plan if, or how, they will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. The discussion areas regarding intellectual property outlined in Section L should be addressed.

If your proposal does not include a plan, appropriate reasons for restricting sharing, or, if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your plan for sharing model organisms during discussions and in your Final Proposal Revision (FPR). If your plan for sharing model organisms is still considered "unacceptable," or your justification for restricting sharing is still considered inappropriate by the Government after discussions, your proposal may not be considered further for award. The following web site provides guidance on sharing model organisms and additional information about this policy: http://grants.nih.gov/grants/policy/model_organism/index.htm.

SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP

The following pages include Attachments 1 through 5 applicable to this RFP as specified in SECTION J - List of Attachments

Attachment 1

Introduction/Background
Pathogen Functional Genomics Resource Center

The National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) supports research related to the basic understanding of microbiology and immunology leading to the development of vaccines, therapeutics, and medical diagnostics for the prevention, treatment, and diagnosis of infectious diseases. 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; and clinical trials to evaluate experimental drugs and vaccines.

The NIAID 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, 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 research programs, which build upon, and take advantage of, the genome sequence of microbes and humans available in the public domain, include:

Microbial Genome Sequencing Centers - provide rapid and cost-efficient production of high-quality genome sequences of human pathogens and invertebrate vectors of diseases;

Bioinformatics Resource Centers - provide the scientific community with 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 - focus on characterizing the pathogen and/or host cell proteome; identifying proteins associated with the biology of microbes, mechanisms of microbial pathogenesis, and host response to infection; discovering targets for potential candidates for the next generation of vaccines, therapeutics, and diagnostics; and developing proteomic technology; and

Population Genetic Analysis Programs - characterize genetic polymorphisms in human immune response genes after infection with, or vaccination against, pathogens, and to examine the functional significance of these responses.

The NIAID-supported Pathogen Functional Genomics Resource Center (PFGRC) contract was awarded in FY 2001 (contract N01-AI-15447) to The Institute for Genomic Research (TIGR) in Rockville, MD to provide the research community with the needed functional genomic resources, data and reagents to study infectious diseases including DNA microarrays, protein expression clones, genotyping and comparative genomics, and comparative protein profiling.

Statement of Work
Pathogen Functional Genomics Resource Center (PFGRC)

Independently, and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional and technical personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, as needed, to perform the work set forth in the Statement of Work.

For the purpose of this contract, functional genomics is defined as functional analysis of the genome and includes proteomics and bioinformatics.

Specifically, the Contractor shall carry out the tasks specified below.

1. Initial Transition

If assuming this requirement from a predecessor contractor, the Contractor shall:

a. Provide for the safe and efficient assumption of activities from the incumbent contractor to ensure a seamless transition without loss of time, loss of resources, or that would not pose obstacles to the conduct of on-going functional genomics research.

b. Complete the transition within the first ninety (90) calendar days following the effective date of the contract. The functions of the PFGRC must be maintained during the transition period and distribution of functional genomics resources and technologies to the scientific community must not be interrupted at any time.

c. Implement the Final Transition Plan of the incumbent contractor which will be provided by the NIAID Project Officer, and will specify the approved transition requirements, as well as methods and time frame for implementing the transition.

2. Facilities and Scientific/Technical Infrastructure

a. Provide a state-of-the-art large scale functional genomics facility, infrastructure and necessary equipment, methods, and technologies required to develop, generate, produce, receive, and distribute to the scientific community reference functional genomics data, technologies, bioinformatics tools and software, resources and reagents for infectious disease research.

b. Provide a scientific/technical infrastructure that includes expertise in microbial biology and pathogenesis, and functional genomics to: develop and generate reagents; conduct research; and develop technology that is designed to produce reference functional genomics data for understanding microbial pathogenesis and host response and to provide potential target information for vaccines, drugs, and medical diagnostics.

c. Provide facilities and bioinformatics and computational expertise to support, develop, and distribute bioinformatics and computational software and tools required for a state-of-the-art functional genomics facility. This includes tracking samples, reagents, and data; assessing

quality of data; analyzing functional genomics data produced; storing, visualizing, and releasing functional genomic data and annotation for the Internet; and transferring functional genomic data to other publicly accessible web sites and databases.

3. Gene Expression Analysis

a. Produce and provide gene expression analysis reagents, functional genomic data, and other resources, including high quality, high density cDNA or oligonucleotide-based microarrays, and standard operating procedures (SOPs) and validation of the reagents that are high throughput and cost-efficient. This includes producing DNA microarrays for viruses, bacteria, fungi, and larger eukaryotic protozoan parasites and invertebrate vectors of infectious diseases, multi-organisms and host response genes, and, RNA or DNA as controls for hybridization assays.

b. Conduct and provide automated and manual annotation of the genome of microorganisms selected for gene expression analysis as requested by the NIAID Project Officer, in conjunction and collaboration with NIAID Bioinformatics Resource Centers (http://www.niaid.nih.gov/dmid/genomes/brc/default.htm) or other facilities designated by the NIAID Project Officer.

c. Develop, evaluate, and incorporate new or continued improvements in existing technologies and resources and efficiency of production to provide state-of-the art gene expression reagents, functional genomic data, technologies and resources during the course of this contract, including genome-wide analysis of essential genes, predicting functions, and determination of relevant phenotypes.

4. Whole Genome Functional Expression Clones

a. Provide high throughput resources and reagents for large-scale clone production for open reading frames derived from microorganisms and invertebrate vectors of diseases, specified by the NIAID Project Officer, using recombinational cloning technology or other appropriate technologies.

b. Provide an automated pipeline for the cost-efficient and effective construction and production of complete clone sets and individual clones.

c. Provide clone validation procedures for the clones produced including, but not limited to, nucleic acid sequence verification.

d. Develop, evaluate and incorporate new or continued improvements in existing technologies and resources and efficiency of production for high throughput construction and production of functional expression clone sets during the course of this contract.

5. Microbial Comparative Genomics and Genotyping

a. Provide and conduct state-of-the-art comparative genomics and microbial genotyping for producing, cost efficient, robust, high quality and with high levels of accuracy, genotyping of microbial genomes.

b. Provide, conduct, and maintain platforms for microbial comparative genomics, resequencing and genotyping of microorganisms. These platforms shall be used to generate reference functional genomics data for the scientific community including at the genome wide scale to identify and validate SNPs and other genetic variations or polymorphisms in a diversity of strains and/or closely related species at the DNA sequence level. The identification of the genetic variations may be related to phenotypic characteristics, such as disease severity, pathogenesis, infectivity, and others. This work shall include nucleic acid amplification, labeling and hybridization methods, microarray based resequencing (with greater than 90% base calling and quality score greater than 30), comparative functional genomic hybridization, and SNP discovery and validation assays.

c. Develop, evaluate, and incorporate new or continued improvements in existing technologies and resources and efficiency of production to provide state-of-the art comparative genomics and genotyping.

6. Proteomics Analysis

a. Provide state-of-the-art proteomics resources required for a proteomics production scale pipeline that is focused on cloning, protein expression, protein purification, and generating high quality protein arrays for studying infectious diseases.

b. Provide and conduct comparative protein profiling of microorganisms to generate reference data for the scientific community including protein fractionation and separation, and analytical techniques such as protein solubilization, two-dimensional gel electrophoresis, high performance liquid chromatography, and liquid chromatography/mass spectroscopy platforms as LC-MS/MS matrix-assisted laser desorption and ionization time-of-flight (LC-MALDI-TOF MS). The PFGRC shall not conduct analyses to identify and characterize the complete proteome of the microbe.

c. Develop reagents for discovery of potential candidates for clinically useful pathogen or host protein biomarkers in well-defined clinical samples that have the potential to be used for clinical proteomics platforms for differential diagnosis and staging of infectious diseases, strategies for therapeutic interventions and monitoring therapeutic responses.

(1) Develop procedures and methods for sample preparation for proteomic analysis of clinical samples.

(2) Apply existing technologies, augment existing technologies, and/or develop proteomic technologies and platforms for comparative and quantitative protein profiling of biofluids for discovering pathogen and host protein candidates for protein biomarkers in clinical samples such as serum, urine, sputum, and stool. This may include protein fractionation and separation and analytical techniques such as protein solubilization, two-dimensional gel electrophoresis, high performance liquid chromatography, and liquid chromatography/mass spectroscopy platforms as LC-MALDI-TOF MS.

(3) Discover clinically useful pathogen and host protein candidates biomarkers from

well-defined human clinical samples using high-throughput protein purification and proteomic technologies platforms developed for comparative and quantitative protein profiling.

(4) Identify potential collaborators with sources of well-defined clinical samples for discovery of potential biomarkers. The Contractor shall not rely on obtaining all samples from the NIAID Project Officer.

(5) Receive well-defined clinical samples from sources identified by the Contractor, such as a collaborator, or identified by the NIAID Project Officer.

(6) Perform early validation to confirm the candidate biomarkers and clinical utility of these discovered protein biomarkers as related to specific infectious diseases in well-characterized populations of human clinical samples to assess the predictive value, sensitivity, and specificity of these protein markers/signatures in infectious diseases.

7. Quality Control of Reagents and Tools

Provide for quality control of reagents. Quality control includes assays and evaluation of reagents, as directed by the NIAID Project Officer. Assays shall include the following:

a. For microorganisms – purity, culture viability, genotyping
b. For nucleic acids – concentration, purity, restriction enzyme analysis, sequence verification
c. For PCR primers – amplification to predicted size fragment
d. For PCR amplified products – sequence verification
e. For DNA or protein microarrays - validation of content for each lot
f. For protein/DNA expression vectors and clones - sequence verification and protein expression (where applicable)
g. For bioinformatics and computational tools and software - confirm proposed functionality

8. Storage and Processing Facilities and Equipment

Provide facilities and equipment to receive and store reagents, including those that are potentially hazardous, in a way that will maintain their activity or viability. Storage facilities for all reagents must 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. In addition, the Contractor shall house the units in an air-conditioned facility with the capacity to maintain a room temperature of 66 to 72 degrees F, when all equipment is

operational.

e. Provide freezers connected to a central alarm system that is monitored 24 hours per day, seven days per week. 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.

f. Provide protective garments, equipment, and sufficient training and monitoring to Contractor staff to assure safe handling of potentially toxic, biohazardous, and radioactive materials. Comply with all applicable health and safety regulations as outlined in http://www.cdc.gov/od/ohs/biosfty/biosfty.htm while conducting the work set forth herein.

g. Comply with Federal Guidelines for Research involving Recombinant DNA molecules as outlined in http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html, when appropriate.

h. Provide facilities to measure or dispense solid and liquid reagents into aliquots and labeled vials. Because of the nature of some of the reagents, facilities should be available for the appropriate handling of infectious agents and for hazardous materials.

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

j. Provide an automated temperature monitoring system composed of individual temperature probes for 24 hours per day monitoring. Identify measures to ensure that necessary personnel are notified in the event of a refrigerator/freezer malfunction. The Contractor shall be responsible for promptly repairing malfunctioning equipment or for arranging for the prompt repair.

k. Provide appropriate storage for radioactive material in accordance with all Local, State, and Federal regulations.

9. Identification, Acquisition and Production/Expansion of Reagents

a. Actively and independently, identify and acquire reagents that are not readily available and produced at the PFGRC. Prioritize acquisition based on the needs of the projects supported by the contract, the needs of the scientific community, availability, and cost.

b. Acquire reagents after receiving approval by the NIAID Project Officer. The acquisition of reagents, either by purchase or donation, shall be an ongoing activity of the PFGRC.

c. Develop and use standard correspondence for acquiring and accepting reagents, including the use of uniform Material Transfer Agreements, which shall conform to the Simple Letter Agreement provided in http://www.nih.gov/od/ott/Rtguide_final.htm or another document approved by the NIAID Project Officer with no more restrictive terms.

d. Produce reagents as needed after receiving approval by the NIAID Project Officer.

Production of reagents may include expansion of renewable reagents including microbial cultures and recombinant DNA.

For the purposes of this contract, reagents include the following biological materials:

- Microbial strains, clones or isolates;
- Functional genomic DNA or RNA prepared from a specific organism, including viruses;
- Libraries (cDNA, functional genomic DNA, whole genome shotgun libraries) used in large-scale genome sequencing projects;
- Sets of plasmids or other vectors covering part or the entire genome or chromosome or expressing biomarkers/proteins; and
- Sets of oligonucleotide PCR primers and/or amplicons corresponding to open reading frames identified in genome sequencing and annotation of organisms or to cDNA clones.

10. Receipt and Distribution of Functional Genomic Reagents

a. Distribute reagents to approved investigators and institutions in accordance with operating procedures that are in compliance with all Federal and State regulations and approved by the NIAID Project Officer. The Contractor shall consult with NIAID Project Officer in questionable cases.

b. In consultation with the NIAID Project Officer, develop standard correspondence to be used for acceptance and distribution, or refusal of reagent requests, including uniform Material Transfer Agreements that are substantially similar to the Simple Letter Agreement (Published in the Federal Register Vol. 64 No 246. December, 1996) http://ott.od.nih.gov/pdfs/64FR72090.pdf.

c. Notify the recipient electronically of the status of the reagent request within 7 days of approval or refusal by NIAID Project Officer.

d. Ship and receive reagents, ensuring the assumption of the shipping costs by the recipient whenever possible. Assumption of shipping costs for reagent distribution by the Contractor shall require prior approval by the NIAID Project Officer.

e. Ship available reagents within 7 working days from the date requests are received, using the most economical method of transport appropriate for maintaining stability/viability of the reagent.

f. Provide, packaged with outgoing reagents, data sheets containing technical information, references and citations of the relevant information for safe handling and use of the reagents, and applicable safety standards. The Contractor shall specify safety standards for the safe handling and use of specific reagents in compliance with Local, State and Federal regulations.

g. Provide for safe packaging, shipping and distribution of reagents approved by the NIAID Project Officer to eligible research investigators within and outside of the U.S. All shipments shall be tracked and coordinated to ensure timely receipt. A secure package

tracking system shall be utilized to insure that all materials are delivered to the intended recipient.

h. Implement any necessary changes in airport shipping/receiving procedures and requirements to remain in continuous compliance with all applicable U.S. Department of Transportation Regulations.

i. Obtain the appropriate licenses and permits required by Local, State and Federal authorities for the safe import, storage and distribution of reagents. Additionally, the Contractor shall obtain the appropriate interstate, intrastate and foreign import/export shipping licenses and permits for transporting biohazardous reagents.

j. Provide 24-hour, seven days per week, if necessary, the availability of trained personnel to pick up and store incoming shipments of reagents from a specified airport or other site in a timely manner to assure that the reagents are maintained at necessary temperature until placed in the PFGRC. Because the incoming shipments usually represent a substantial financial investment, it is essential that the Contractor coordinates shipments so that trained personnel will be available to receive the arriving package whenever delivered and transport the shipment to the PFGRC for storage at the required temperature. All shipments when received shall be maintained for stability and viability by providing the necessary temperature in transit from the pick-up site to the PFGRC.

k. Manage and coordinate all shipments so that viability, biological activity or purity of the reagents will not be adversely affected. Send notification by Internet, facsimile, or telegram to all foreign investigators to coordinate shipping and receiving of frozen or refrigerated reagents. Advise domestic investigators in the most suitable manner, of shipments and projected arrival dates. Establish a mechanism for being notified by the requester of the date reagents were received and the condition of reagents upon receipt.

l. Use shipping containers for reagents that comply with current domestic and international transport regulations and pertinent International Air Transport Association/International Civil Aviation Organization Dangerous Goods Regulations (http://www.iata.org/whatwedo/dangerous_goods1).

m. 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.

11. Provision of Functional Genomics Data and Other Resources to the Scientific Community

a. Develop, submit to the NIAID Project Officer, and implement upon acceptance of the NIAID Project Officer, a plan to provide resources to the scientific community in a timely fashion, including reagents, bioinformatics tools, software and source codes, protocols, technologies, and functional genomics data and genome annotation developed under this contract. Towards this goal, the Contractor shall establish acceptable standards for usability and interoperability.

The plan also shall detail how functional genomic data will be released to a publicly, web-accessible database site and a small number of other database sites, as specified by the

NIAID Project Officer, involved in long-term management of functional genomics data, including NIAID Bioinformatics Resource Centers. The plan shall also include a timeline for releasing data to these sites and if appropriate, submitting a publication describing the data.

The plan is subject to modification prior to approval and will be reviewed annually by the NIAID Project Officer.

b. With the approval of the NIAID Project Officer, make the reagents, bioinformatics tools, software and source codes, protocols, functional genomics data generated under the contract, and technologies of proven utility, widely available to the scientific community.

12. Consultation with and Training for the Scientific Community

Develop and maintain continuous, close interaction with the scientific community associated with infectious diseases, microbiology, immunology, molecular biology and functional genomics.

a. Interact and consult with the scientific community on an ongoing basis to solicit feedback from potential users and recipients of functional genomic resources, reagents, and technologies. Ensure that domain experts in microbiology, immunology, molecular biology, infectious diseases, functional genomics and related technologies work closely with the Contractor's personnel to foster this strong collaboration.

b. Develop, conduct, and provide facilities for training for the scientific community on the use of functional genomics reagents and technologies including workshops on a variety of aspects of technologies and computational tools, on-line technical help desk support on array technologies and assays, web-based tutorials for users with a wide-range of functional genomics expertise, and on-site facility support for processing client samples and microarrays.

c. Disseminate public information concerning functional genomic reagents, data, and resources availability.

(1) Promote awareness of the PFGRC services throughout the scientific community using electronic and print media and, as approved by the NIAID Project Officer, through leased booths and poster presentations at scientific meetings, symposia and workshops, and advertisements in relevant scientific journals.

(2) Provide HTML copy to publish and periodically update the PFGRC information on the NIAID Internet PFGRC site.

(3) Develop and maintain an Internet site for the PFGRC, describing the goals, summarizing the reagents and services available, and providing an electronic Internet-based reagent request system for the scientific community to request reagents such as microarrays and clones, and services such as microbial genotyping on a continuous basis.

d. Establish a Scientific Working Group (SWG), in conjunction with the NIAID Project

Officer, composed of approximately ten (10) scientists knowledgeable in a broad range of functional genomics areas including technology development and research areas such as infectious diseases and microbiology. The SWG shall provide advice to the Contractor on the needs of the scientific community regarding functional genomic resources such as reagents, technologies, bioinformatics software and computational tools, and reference functional genomics data.

(1) Recommend to the NIAID Project Officer selection criteria for SWG members, including information on the distribution of membership by area of expertise and other relevant selection factors. The Contractor shall NOT identify by name, or contact specific individuals regarding service on the SWG, until final approval by the NIAID Project Officer.

(2) Develop a plan, including a timeline for meetings and conference calls, for soliciting advice from the SWG. It is anticipated that the SWG will meet annually.

(3) Organize meetings and conference calls of the SWG and provide summary reports of all meetings and conference calls to the NIAID Project Officer.

13. Project Planning, Initiation, Management and Oversight

a. Provide a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation and management of all projects carried out under this contract, including effective communications with the NIAID Project Officer and the NIAID Contracting Officer. This infrastructure shall include a Principal Investigator (PI) with responsibility for overall project management and communications, tracking, monitoring, and reporting project status and progress, and recommending modifications to project requirements and timelines, including projects undertaken by subcontractors and/or collaborators. The infrastructure shall also include an overall Production Manager to coordinate the development of specific reagents and technologies conducted under this contract; and bioinformatics and computational staff.

b. Develop, implement, and maintain an electronic project database management system to monitor and assist in coordinating the activities under this contract. The project database management system shall compile, store, track and retrieve data, reagents, projects, protocols, and SOPs. The project database management system shall ensure maximum productivity, be cost efficient, and assist the PFGRC in meeting deadlines for production and distribution, as specified by the NIAID Project Officer.

c. Prepare plans for carrying out the development and distribution of functional genomic reagents, resources, technologies and data. Upon written notification by the NIAID Project Officer for reagents, resources, data and technologies to be developed and provided, develop a Project Plan to carry out the project. This Project Plan shall be submitted for review to the NIAID Project Officer and the NIAID Contracting Officer within 30 days of notification. Project initiation shall proceed only upon written approval from the NIAID Contracting Officer with the advice of the NIAID Project Officer.

The Project Plan shall include:

(1) Specification of the reagents, resources, data, or technologies to be developed and provided;
(2) Description of key goals and objectives;
(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, including obtaining the necessary reagents such as DNA, RNA clones or microorganisms;
(5) List of proposed scientific and technical personnel, including collaborators and a description of their qualifications, relevant experience, and role in the project;
(6) Plan for Quality Assurance and Quality Control of the project; and
(7) Proposed budget.

Timelines, milestones and deliverables for projects carried out by the Contractor shall be commensurate with the complexity of the requirements and shall be discussed with and approved by the NIAID Project Officer and the NIAID Contracting Officer.

14. Program Development Plan

NIAID envisions the PFGRC to be an ongoing effort serving a rapidly growing and diverse research community. In order to accommodate growth and diversity, the Contractor shall prepare and submit a Program Development Plan that anticipates the development of the PFGRC over its initial five-year period and five years beyond the expiration date of this contract. The Program Development Plan shall:

a. define a vision of the PFGRC during the initial inception phase (years 1-5), and the five years beyond the expiration date of this contract, and state the criteria which must be met to justify an ongoing effort;

b. describe operational requirements of the PFGRC in a phase of rapid growth;

c. identify special or extraordinary facilities and resource requirements beyond the initial inception phase that would best allow it to meet the needs of the community; and

d. establish performance metrics and utilization measures of the PFGRC as well as propose methods for gathering data to monitor them.

15. Meetings and Conference Calls with NIAID Project Officer, NIAID Contracting Officer and Collaborators

The Contractor's key personnel, including the PI and the Project Managers and collaborators, when appropriate, shall meet in person or by telephone conference call with the NIAID Project Officer and the NIAID Contracting Officer at periodic intervals to review the projects and discuss the work to be performed. The schedule for the meetings will be established by the NIAID Project Officer after contract award.

16. Final Transition Plan

a. Coordinate an orderly and safe transition to a subsequent successor contractor or the Government including the transfer and movement of stored reagents, data, web sites, databases, bioinformatics software and tools, technologies, SOPs, unused supplies, purchased equipment, and any other resources generated under this contract.

b. Prepare and submit a written Final Transition Plan to NIAID twelve (12) months prior to the contract's expiration date detailing how the resources generated under this contract will be transferred in an orderly manner to a subsequent contractor or the Government.

The Final Transition Plan shall include:

(1) A comprehensive list of all stored reagents, data, web sites, databases, bioinformatics software and tools, technologies, SOPs unused supplies, Government-furnished equipment and any other resources generated under this contract.
(2) A plan for the transportation of these resources and all deliverables listed under Reporting Requirements and Other Deliverables section of this RFP to a subsequent contractor or the Government.

Attachment 2
APPENDIX A
Pathogen Functional Genomics Resource Center (PFGRC)
RFP NIH-NIAID-DMID 06-10

APPENDIX A – ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS

THE ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS PROVIDED BELOW REFLECT THE REQUIREMENTS OF THE RFP AND ARE MEANT TO PROVIDE A CLEAR UNDERSTANDING OF THE INTENT OF THIS SOLICITATION.

OFFERORS ARE ADVISED TO GIVE CAREFUL CONSIDERATION TO THE STATEMENT OF WORK AND THE TECHNICAL EVALUATION CRITERIA IN THE DEVELOPMENT OF THE TECHNICAL PROPOSAL.

OFFERORS ARE REMINDED THAT THE TOTAL PAGE LIMIT FOR THE TECHNICAL PROPOSAL PACKAGE IS 150 PAGES, INCLUDING APPENDICES. PLEASE REFER TO THE FOLLOWING LINK FOR SPECIFIC PROPOSAL PREPRATION INSTRUCTIONS WITH REGARD TO PAGE LIMITATIONS: **http://www.niaid.nih.gov/contract/eproposal.htm#electronic**

SECTION 1: Reagents and Resources for Functional Genomics, Proteomics, and Bioinformatics

1. Propose a plan to establish a state-of-the art, high throughput, efficient, cost-effective functional genomics facility to provide high quality functional genomics data, technologies, resources and reagents to the scientific community.

2. Describe the scientific and technical approach for generating and constructing functional genomic reagents, resources, technology and data, including validation procedures and SOPs, for the following:

   a. Gene expression analysis reagents including microarrays and annotation of the genome;
   b. Production of whole genome microbial functional expression clones; and
   c. Platforms for microbial comparative genomics and genotyping.

3. Describe plans for identifying, evaluating and incorporating new or continued improvements in technologies and resources, and efficiency of production to provide state-of-the art functional genomics reagents, data, technologies, and resources.

4. Describe the scientific and technical approach for developing and generating proteomic reagents, resources, technology, and data for protein expression, comparative protein profiling and clinical biomarker discovery.

5. Describe potential sources of well-defined clinical samples, including those received from collaborators, for discovery of potential biomarkers of infectious diseases.

6. Describe the scientific and technical approach for conducting bioinformatics and computational activities necessary to support microbial functional genomics research. Include a description of applicable tools and technologies.

SECTION 2: Distribution of Resources to the Scientific Community

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

2. Provide a draft plan for the provision of resources and data developed under this contract to the scientific community for further research and development. The plan must describe proposed approaches/methods for providing contract resources and data, in a timely and efficient manner, including: reagents, software and source codes, technologies, and functional genomics data and genome annotation. It is anticipated that, if available, international databases, such as GenBank or dbSNP, will be the first choice for depositing data for public access and, if not available, the Offeror should describe other appropriate publicly accessible web sites. In some cases, long-term management of the data may be specified by the NIAID Project Officer to include the NIAID Bioinformatics Resource Center or other sites, when appropriate.

   For data, the plan must provide details to assure that the data release and usage will support the principle that data should be rapidly and freely released to the broad scientific community without restriction and, in most cases, prior to publication, and reconcile the interests of the scientific community for early data release and those produced at the PFGRC. The plan must recognize the widely accepted ethic in the scientific community that investigators/organizations that generate data should have the priority to publish the work in a peer-reviewed journal in a timely manner. The plan also shall detail how the Offeror will comply with the principles and guidelines for recipients of NIH research grants and contracts on obtaining and disseminating biomedical research resources. The guidelines are found at the following site: http://ott.od.nih.gov/NewPages/RTguide_final.html.

SECTION 3: Consultation with and Training for the Scientific Community

1. Provide a proposed plan for establishing and maintaining strong and effective interactions with the scientific community, including proposed approaches to soliciting advice and keeping investigators informed and educated.

2. Propose appropriate training and approaches for providing technical support to the scientific community.

3. Describe plans for dissemination of information on functional genomic reagents, data, and resource availability**.**

4. Describe the types of expertise required for the Scientific Working Group (SWG) and provide a plan for establishing the SWG and utilizing the expertise of its members to provide advice on the conduct of the PFGRC functions. Do not identify in the Technical Proposal the names of any individuals proposed for SWG membership.

SECTION 4: Project Planning, Initiation, Management and Oversight

1. Propose 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. Describe in detail the responsibilities and level of effort for all proposed personnel who will be assigned to the contract, including proposed subcontractors and consultants, and an administrative and technical framework indicating clear lines of authority and responsibility for personnel. Document past success with project management for a large-scale production functional genomics facility for generating, producing, acquiring, and distributing reagents and other resources. Include details such as achieving milestones and deadlines for production and distribution; tracking, monitoring, and reporting project status and progress; monitoring costs; and solving critical process integration issues which may arise as production increases in scale.

2. Program Development Plan: Propose a draft plan for the development of the PFGRC during the five-year award period of this contract and five years beyond the expiration date. The plan must define a vision for the PFGRC; describe operational, facility, and resource requirements in a phase of rapid growth; and propose methods to monitor and evaluate performance, efficiency and PFGRC utilization.

3. Describe the database management system that will be used to monitor and coordinate the activities of this contract.

4. Outline how the Principal Investigator will communicate and interact with the NIAID Contracting Officer and the NIAID Project Officer and how the Principal Investigator will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).

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SECTION 5: Facilities and Equipment (includes the Offeror and any proposed subcontractors)

1. Provide 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 of the contract.

2. Provide information regarding the ownership/lease of the facility that demonstrates availability for the duration of the contract.

3. Provide documentation of the availability and suitability of the computational facilities and other resources to carry out the contract requirements, including hardware and software.

SECTION 6: Personnel

CVs must be limited to 2-3 pages in length.

1. Document past success in providing a state-of-the-art high throughput, efficient, and cost-effective functional genomics facility and producing and distributing microbial functional genomics reagents, technologies, data, and resources to the scientific community, including

microbial gene expression reagents, whole genome functional expression clones, microbial comparative genomics and genotyping, and proteomics technologies and resources. Include details to describe the reagents and resources, the number distributed to the scientific community, and microbial comparative genomics and proteomic technologies and data produced.

2. Document training, expertise, related experience, leadership skills and availability of key personnel with scientific, technical and managerial competence in microbial functional genomics, proteomics, bioinformatics, and project management to successfully plan, manage, conduct and direct a project of a comparable size and complexity.

3. Document experience in developing, implementing, and distributing to the scientific community, bioinformatics and computational software and tools.

4. Document experience in developing technologies for microbial proteomics and generating microbial proteomics data, including protein expression and purification and microbial comparative protein profiling.

5. Document experience in developing technologies for microbial functional genomics and generating gene expression analysis reagents, whole genome microbial functional expression clones, and platforms for microbial comparative genomics and genotyping.

6. Describe experience in collaborating with the microbial scientific community for active involvement with generating microbial functional genomic resources, reagents, and technologies, including domain experts in microbiology, infectious diseases, functional genomics and related technologies.

7. Document experience and expertise to produce, acquire, store, ship, receive, and distribute reagents and resources to the scientific community efficiently and cost-effectively.

8. Document experience in making functional genomics data widely available in a timely manner to the scientific community through international databases (such as GenBank, dbSNP or other appropriate publicly accessible web sites).

APPENDIX B
Pathogen Functional Genomics Resource Center (PFGRC)
RFP NIH-NIAID-DMID 06-10

APPENDIX B-ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS
UNIFORM 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, AND 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.

Uniform Budget Assumptions
For purposes of the budget preparation, the Offeror shall assume the following activities will occur in each year, unless otherwise stated.

Annual Capacity
It is anticipated that the annual capacity of the facility will be the following and is to be used for budget estimating purposes. The NIAID Project Officer will specify the final selection and number of functional genomic reagents, comparative genomics and proteomic projects to be initiated and generated each year after consultation with the scientific community, the Contractor, and the Scientific Working Group.

Reagent/Resource	Number/Year
Gene Expression Reagents/DNA Microarrays	15,000
Functional Expression Clones	25,000
Microbial Proteins Expressed and Purified	1,000
Microbial Comparative Genomics Project	4
Microbial Comparative Protein Profiling Project	1
Clinical Protein Profiling Project	1 (Years 2-5)
Protein Arrays	1000 (Years 2-5)

Scientific Working Group

The annual Scientific Working Group (SWG) meeting cost estimate should include travel costs (transportation, meals, hotel, etc.) for the ten (10) SWG members and three (3) staff members of the Contractor and one (1) member of each of the proposed subcontractors/consultants. The Contractor is responsible for all costs accrued 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 in Bethesda, MD for one (1) day. The Contractor should also include cost estimates for two (2) conference calls a year with the SWG.

Scientific Meetings, Training, and Informing the Scientific Community

- Budget travel costs (transportation, meals, hotel, etc.) for one (1) scientific meeting for up to 5 personnel per year to present scientific findings generated under this contract.
- Budget travel costs (transportation, meals, hotel, etc.) and logistical costs for two (2) scientific meetings or workshops per year for up to 3 personnel per meeting/workshop to inform and train the scientific community at external sites and promote the availability of reagents and resources generated under this contract.
- Budget travel costs (transportation, meals, hotels, etc.) for three (3) trips per year for up to 2 personnel per trip to visit academic institutions or industry to learn about new functional genomics technologies and new equipment.
- Budget travel costs (transportation, meals, hotel, etc.) and logistical costs for three (3) training sessions for the scientific community to be held at the Contractor's site for 10 participants per training session.
- Budget for informing the scientific community of the reagents and resources available based on advertising once per year in the following venues: a scientific journal, a booth at meetings or workshops and through Professional Societies such as American Association of Immunologist (AAI) and the American Society of Microbiologists (ASM).

Ad Hoc Report Cost Estimates:

Budget for ten (10) ad hoc reports per year as requested by the NIAID Project Officer. Estimate 8 pages for each ad hoc report.

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DMID-06-10
RFP Title: "DEVELOPMENT OF A TRIVALENT (ABE) RECOMBINANT BOTULINUM VACCINE"

Please review the attached Request for Proposal. Furnish the information requested below and return this page by November 15, 2005. 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:
CMP, NIAID, NIH
Room 3214
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Ross Kelley
RFP-NIH-NIAID-DMID-06-22
FAX# (301) 480-4675
Email : RKelley@niaid.nih.gov

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 IS NOT ACCEPTABLE.

A. EXTERNAL PACKAGE MARKING:

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

"**RFP NO. NIH-NIAID-DAIDS-06-10**
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 Signman Contracting Officer Contract Management Program, DEA **NIAID, NIH** 6700-B Rockledge Drive, Room 3214 Bethesda, Maryland 20817	Robert Singman Contracting Officer Contract Management Program, 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:

TECHNICAL PROPOSAL PAGE LIMITS [See Below]

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

TOTAL PAGE COUNT DOES NOT INCLUDE: 1 Cover and Back Page; 1 Table of Contents; Section Dividers that do not contain information other than title of Section.

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.

The number of copies required of each part of your proposal are as specified below.

Document	Number of Copies	Page Limits
Technical Proposal	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** Fifteen (15) Compact Disks containing an electronic copy of the Technical Proposal in a Portable Document Format (PDF) 1 file on each disk.	**Limited to not-to-exceed 150 pages**
Technical Proposal Appendices **All materials not available electronically (i.e. SOPs, Pertinent Manuals, Nonscannable Figures or Data, and Letters of Collaboration/Intent).**	**One (1) unbound SIGNED ORIGINAL.** Twenty (20) bound COPIES	**Limited to not-to-exceed 150 pages**
Business Proposal	PAPER **One (1) unbound SIGNED ORIGINAL.** **Five (5) unbound COPIES** **ELECTRONIC FILES ON CD** Ten (10) Compact Disks containing an electronic copies of the Business Proposal in a Portable Document Form **(PDF). 1 PDF file on each disk.**	**N/A**
Breakdown of Proposed Estimated Cost	Attachment 13 of SECTION J should be submitted also as a separate excel file on the Business Proposal Compact Disks.	N/A

GOVERNMENT PROPERTY TO BE PROVIDED

Description of Equipment over $5,000	Quantity
Sybase Server & Space	1
Web Server	1
LAN Switch	1
Sybase Storage Space	33
NetApp Storage Space	600
Tape Back-up System Exp.	1
NT Servers	2
Freezer -80	5
Microfuge (refridgerated)	3
High Speed Centrifuge	1
Tetrad PTC 225	2
Scanner	2
Microarrayer	1
Gel Doc System	1
Spectrophotometer	1
ABI 480 PCR Machine	1
Biorad Gene Pulser	1
Realtime PCR Machine	1
Realtime PCR Florescence Det.	1
Pippetting Robot	1
IT Equipment – Sequence Data	1
IT Equipment – Gene Chip Analysis	1
Affymetrix Chip Reader	1
Sequencer	1
Freezer -80	1
Microfuge (refridgerated)	2
Tetrad PTC 225	1
Scanner	2
Microarrayer	1
ABI 480 PCR Machine	1
ABI Prism 3730 DNA Analyzer	1
Freezer -80	1
Scanner	2
Freezer –80	8
Desiccant Cabinet	1
Spectrophotometer	2
Single Thermocycler	2
Stacking Heat Sealer	1
Caliper ASM90SE	2
Liquid Handler	2
Protein Array Work Station	1
Robotic Replicator	1
Biomek FX w/ 8 span	2
Centrifuge w/ Rotor	3

Shaker rotary platforms w/ flask	5
Biomek FX 96	1
Lucidia Microarrayer	1
Protein Arrayer	1
Mass spec and HPLC system	1
Freezer -80	9
Lucidia Microarrayer	1
Mass spec and HPLC system	1
Affy Hybridization System	1
Affy Chip Reader	1
1100 Series Nanoflow LC System &	1
2100 Bioanalyzer with LabChip Kit	1
IPGphor II Electrophoresis Apparatus	1
Protean Plus Dodeca Cell Apparatus	1
HPLC Platform	1
Speedvac Concerntrator	1
Mass Spectrometry Mascot Software	1
Biophile Storage Units with Individual Retrieval System Conveyor	5
Retrieval System Conveyor	
CO2 Regulatory Backup Gas Delivery System	5
Individual Vial Handler (IVH)	1
-40C Freezer for IVH	1
Sybase Server & Space	1
Savant Model SPD2010 Integrated SpeedVac System	1
Savant DNA12-115 SpeedVac System	2
Toyo Living Super Dry 02 Series Desiccant Cabinet	1
Milli Q Water System with Pyrogen Filter	1
Genetix QFill2 Liquid Media Handling Unit	1
Eppendorf 5810R Centrifuge	3
Agilent Technologies 1100 Series Microflow LC System for MS	1
Velocity 11 PlateLoc	1
ATR Double Microtitration Orbital Shaking Incubator	1
Beckman Coulter Type 50.4 and 70.1 Ti rotor assemblies	2
Fisher Scientific MDL C025KC Refrigerated Shaker Incubator	1
Applied Biosystems (ABI) MALDI-TOFTOFF 4700 Proteomics Discovery System Refurbished	1
Tecan GENios Pro MultiDetection Microplate Reader with Fluorescence Polarization Option	1
Fluidics Station FS450 Module Upgrade	1
GCS3000 Microarray Scanner Upgrade	1
Autoloader Upgrade	1
	1

1100 Series Nanoflow LC System & 2100 Bioanalyzer with LabChip Kit	1
IPGphor II Electrophoresis Apparatus	1
Protean Plus Dodeca Cell Apparatus	1
HPLC Platform	1
Speedvac Concerntrator	1
Mass Spectrometry Mascot Software	1