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

RFP-NIH-NIAID-DMID-06-09
Services for Pre-Clinical Development of Therapeutic Agents

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

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

3. **Issue Date:**	4. **Due Date:** **December 16, 2005** **Time:** **4:00 p.m. , EST**	5. **Small Bus. Set-Aside:** [ ]Yes [X] No **8(a) Set-Aside:** [ ]Yes [X] No **NAICS #:** 541710 (See Part IV, Section L.)
August 16, 2005		

6. **Just In Time:**	7. **Number of Awards:**	8. **Technical Proposal Page Limits:**
[X] No [ ] Yes (See Part IV, Section L.)	[X] Only 1 Award [ ] Multiple Awards	Number of Copies: See Part III, Section J (Packaging and Delivery of Proposal) Page Limitations: Technical Proposal - 150 pages total (excluding all addenda and attachments)

9. **Issued By:**	10. [X] **NIAID reserves the right to make awards without discussion.**	
Lawrence Butler, Contracting Officer Contract Management Program, DEA NIH, NIAID 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	11. **Options:** **[X] No** **[ ] Yes** (See Part IV, Section L.)	12. **Period of Performance:** 5 years beginning on or about September 15, 2006

13. **Primary Point of Contact:**	14. **Secondary Point of Contact:**	15. **Protest Officer:**
Name : Erin Goldstein **Phone:** 301-496-6423 **Fax:** 301-402-0972 **E-Mail:** EGoldstein@niaid.nih.gov	**Name :** Amy Siller **Phone:** 301-496-6424 **Fax:** 301-402-0972 **E-Mail:** EGoldstein@niaid.nih.gov	Charles W. Grewe Program Director, CMP Address (see Block 9.)

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

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

DELIVERY ADDRESS INFORMATION

18. **Hand Delivery or Overnight Service:**	19. **U.S. Postal Service or an Express Delivery Service**
Erin Goldstein Contract Management Program, DEA NIAID, NIH 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	**Erin Goldstein** 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 HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

Updated thru FAC 2001-27 (3/28/2005)

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

This effort is for the purpose of establishing a resource to facilitate preclinical development of therapeutic agents (drugs or biological products) including activities required for Investigational New Drug applications.

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.

In Addition the following clauses will be included in the contract:

1) **Data Rights**

Because the goal of this preclinical development contract is to promote the development of critical biological information and antimicrobial and anti-toxin therapeutic agents, it will be necessary to restrict certain rights of the Contractor and its subcontractors to enable the NIAID to attract Third Party Suppliers of proprietary compositions. It is anticipated that the great majority of materials that will be submitted for evaluation and further development will be proprietary in nature, and the NIAID's experience has demonstrated that third parties are reluctant to provide their proprietary materials or ideas without complete assurance that their intellectual property rights are protected. Therefore, the NIAID requires the Contractor and its subcontractors to agree to protect the proprietary materials, data and other information of these Third Party Suppliers.

Furthermore, the Government reserves the right to have complete access to the databases, provide access to third parties and to transfer all rights and custody to a successor contractor.

2. **CONFIDENTIALITY, PUBLICATIONS AND INVENTIONS**

Because the Contractor and its subcontractors will utilize and evaluate proprietary materials, data and other information provided to NIAID by Third Party Suppliers, it is essential to include provisions in the contract that will protect the intellectual property and other proprietary rights of those third parties. The Contractor and all subcontractors are required to maintain the confidentiality of proprietary data and other information provided to them during the performance of this contract. The Contractor and all subcontractors are required to abide by the terms of agreements between the Third Party Suppliers and the NIAID, which have been authorized by the Director of the NIAID Division of Microbiology and Infectious Diseases (DMID); copies of the agreements will be

provided to the Contractor prior to, or simultaneous with, the delivery of the proprietary materials, data and other information covered by those agreements. All data and other information provided by a Third Party Supplier or the Project Officer should be assumed to be confidential unless specifically identified as non-confidential in writing by the Project Officer. The Contractor and its subcontractors shall utilize all materials supplied under this contract solely for contract-related purposes and no unauthorized use or distribution of these materials is permitted.

No later than one month following award, the Contractor shall provide a plan describing the specific procedures it will employ to safeguard any proprietary data and other information obtained or generated under this contract, including the restricted-access files that are required. The Contractor shall require all subcontractors to employ these procedures.

Any proposed publication containing data or other information obtained or generated under this contract must be submitted to the Project Officer for review no less than 45 calendar days before submission for public presentation or publication. A “publication’ is defined as an issue of printed material offered for distribution or any written or oral communication or presentation of data or other information. Examples of publications are manuscripts, abstracts and presentation materials. Contract support shall be acknowledged in all such publications. The Project Officer will review all proposed publications within 30 calendar days of receipt of the proposed publication.

Should subject inventions arise under this contract and any subcontracts, they will be subject to federal laws and regulations governing federally-funded inventions. Any U.S. patent applications filed on these subject inventions and any resulting U.S. patents are required to include the following language: “This invention was made with government support under contract [TBD] awarded by the National Institute for Allergy and Infectious Diseases, NIH, HHS. The government has certain rights in the invention.”

3. **PLANNED DEVIATIONS TO REQUIRED GENERAL CONTRACT CLAUSES FAR 52.227-11 AND FAR 52.227-14**

The NIAID proposes to seek a deviation from FAR clause 52.227-11, Patent Rights-Retention by the Contractor (Short Form) (June 1989). Pursuant to a Determination of Exceptional Circumstances (DEC) as required by FAR 27.303, the NIAID proposes to modify this FAR clause to restrict the Contractor's rights to subject inventions arising under the contract. Subcontracts at all tiers awarded by the prime contractor would need to comply with the deviated Patent Rights FAR clause if a DEC is implemented. Specifically, the Contractor and its subcontractors at all tiers would be required to assign to the Government or, if deemed appropriate by the NIAID and subject to certain rights reserved by the Government in the fields of antimicrobial (anti-bacterials, anti-fungals, anti-parasitics and anti-virals) and anti-toxin therapeutics, to a Third Party Supplier or other collaborating party designated by the Government, the entire right, title, and interest throughout the world to each subject invention, except to the extent that rights are retained by the Contractor under the Greater Rights Determination provision of the clause. The NIAID recognizes that inventions in areas outside of the antimicrobial (anti-bacterials, anti-fungals, anti-parasitics and anti-virals) and anti-toxin therapeutics fields may be of significant benefit to U.S. public health objectives and therefore, the Contractor would be encouraged to request greater rights to identified inventions outside the fields of antimicrobial (anti-bacterials, anti-fungals, anti-parasitics and anti-virals) and anti-toxin therapeutics. Further, the NIAID/NIH would consider whether granting the requested rights would interfere with the rights of the Government or any Third Party Supplier or other collaborating party or might otherwise impede the ability of the Government or others to develop new candidates for antimicrobial (anti-bacterials, anti-fungals, anti-parasitics and anti-virals) and anti-toxin therapeutics as well as potential enabling technologies that may result from data ensuing from evaluations performed under the contract useful for antimicrobial (anti-bacterials, anti-fungals, anti-parasitics and anti-virals) and anti-toxin therapeutics discovery and development. The Contractor would also be encouraged to request greater rights for inventions that relate to technology outside the NIAID's program and for which the Contractor has negotiated with a Third Party Supplier for the disposition of patent rights concerning a subject invention related to the compound for a field of use outside of antimicrobial (anti-bacterials, anti-fungals, anti-parasitics and anti-virals) and anti-toxin therapeutics. Furthermore, the timing of data publication would need to be restricted to allow adequate time for patent applications to be filed on inventions arising from the proposed contract. The NIAID intends to accomplish this restriction by a deviation from FAR clause 52.227-14, Rights in Data-General (June 1987). Specifically, although the NIAID encourages the publication of articles on research results, this FAR clause would be narrowly modified to restrict the Contractor's right to use, release to others, reproduce, distribute, and publish data produced or used by the Contractor in the performance of this contract to allow adequate time for the filing of patent applications and to protect data that would be submitted as part of a regulatory filing. The NIAID would reserve the right to coordinate the timing of data publication so that appropriate domestic and international intellectual property applications may be filed as

appropriate. The deviated data rights FAR clause would apply to the Contractor and subcontractors at all tiers. Potential Offerors are afforded an opportunity herewith to comment on the proposed use of these deviations and to identify the impact these deviations may have on their conduct of the work should they be awarded a contract. Comments should be provided, in writing, to the Point of Contact for this RFP, whose name and other information appears at the bottom of the first page of this RFP. Comments should be provided within 30 calendar days of the issue date of this RFP. Thereafter, the NIAID will consider this input and determine whether alternative courses of action may be appropriate.

4. **Information Security**

The effort must be in compliance with applicable public laws, federal regulations, and Executive Orders (E.O.), including the Federal Information Security Management Act of 2002 (FISMA); the Office of Management and Budget (OMB) Circular A-130, Management of Federal Information Resources, dated November 28, 2000; and the Health Insurance Portability and Accountability Act of 1996 (HIPAA). To meet these requirements, HHS has instituted the HHS Information Security Program Policy and developed the accompanying HHS Information Security Program Handbook.

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 16, 2005, attached hereto and made a part of this Solicitation (See Section J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

a. Technical Progress Reports

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

For proposal preparation purposes only, it is estimated that 3 copies of these reports will be required as follows:

(x) Quarterly
(x) Final - Upon final completion of the contract

Specifically, the Contractor shall submit to the NIAID Contracting Officer and to the NIAID Project Officer technical progress reports covering the work accomplished by the Contractor and subcontractors during each reporting period. These reports are subject to 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) **QUARTERLY TECHNICAL PROGRESS REPORTS** shall include the following specific information:

(a) A cover page that lists the contract number and title, the period of performance being reported, the Contractor's name and address, the author(s), telephone, fax, E-mail address, and the date of submission;

(b) SECTION I - An introduction covering the purpose and scope of the contract effort;

(c) SECTION II – PROGRESS;

SECTION II PART A: OVERALL PROGRESS–A description of overall progress;

SECTION II PART B: NON-PROJECT SPECIFIC PROGRESS – A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. development of a process soliciting, evaluating, and managing subcontracts); and

SECTION II PART C: PROJECT-SPECIFIC PROGRESS - For each project, a completed table as provided below, identifying the project deliverables, the date the deliverable is due, and percent completion of the deliverable. In addition, text, graphs, tables, photographs etc., shall be provided for each deliverable and milestone to detail, document, and summarize the results of work done during the period covered for each project. These reports shall be in sufficient detail to explain comprehensively the results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from

analysis and scientific evaluation of data accumulated to date under the project. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project. Also to be included in the report is a summary of work proposed for the next reporting period. Specific requirements are set forth in the Statement of Work. A Quarterly Report will not be required for the period when the Final Report is due. Preprints and reprints of papers and abstracts shall be submitted with the Quarterly Report.

PROJECT [Insert Project Number]

Status of Project-specific Deliverables			
Item	Deliverable	Date Due (MM/DD/YYYY)	Progress (% completion)
1.			
2.			
3.			
4.			

(2) **FINAL PROJECT REPORTS** - A Final Project Report shall be provided within 30 days of project completion and final data analysis, unless a longer time period is agreed to before the start of the study. Final Project Reports shall include the protocol, a detailed description of materials and methods, raw data when specified by the NIAID Project Officer, results, data analysis and conclusions, and when applicable and specified by the NIAID Project Officer, in a form for submission to the FDA in support of an IND, NDA or BLA.

(3) **FINAL REPORT** shall include the following specific information:

(a) A cover page that lists the contract number and title, the period of performance being reported, the Contractor's name and address, the author(s), telephone, fax, E-mail address, and the date of submission;

(b) SECTION I – An introduction covering the purpose and scope of the contract effort. In addition, the Contractor shall submit a "Summary of Salient Results", not to exceed 200 words, detailing the important results achieved during the performance of the contract;

(c) SECTION II – An executive summary, to include fulfillment of preclinical development goals and of the specific aims set forth in the contract;

(d) SECTION III – A summary of each project and non-project activity performed under the contract; to include a description of the project and salient conclusions. Preprints and reprints not submitted previously shall be submitted

(e) For proposal preparation purposes only, it is estimated that 3 copies of these reports will be required within 30 days of final study analysis or conclusion of experiment.

b. Other Reports and Deliverables

(1) Databases and relevant source codes, electronic records and data contained within the databases. The Government reserves the right to have complete access to the databases, provide access to third parties, and to transfer all rights and custody to a successor contractor.

(2) All physical materials produced under the contract, including but not limited to reagents, and test products, including test products remaining from studies.

(3) Project Plans, Contract Transition Plan, Assay Development Reports, Process Development Reports, Validation Protocols, Validation Reports, testing protocols, Technology Transfer Reports, interim and final GLP and cGMP audit reports, SOPs, regulatory documentation required by the FDA, presentations made at bi-annual meetings, Confidentiality Plans, Confidentiality Agreements, Literature Review and Compound Recommendation Reports, Preclinical Development Plan Reports, Preclinical Development Evaluation Reports and all other reports and documentation produced by the Contractor or subcontractor in the performance of contract activities and projects.

(4) System Security Plan (SSP)
The Contractor shall submit a draft System Security Plan (SSP) for the effort 60 days following award. The Contractor shall use the NIH Application/System Security Plan Template to develop the SSP. Following review by the Contracting Officer and the NIAID technology staff, the Contractor shall submit a revised SSP incorporating any requested modifications within 30 days of the review.

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

(5) Contract Transition Plan
(6) The Contractor shall submit a Contract Transition Plan three (3) months prior to the completion date of the contract. The Contract Transition Plan shall include a timeline and address: transportation of all deliverables listed under the Reporting Requirements and Deliverables section of the contract; relocation/disposition of animals and frozen specimens, equipment, unused materials and supplies; inventory status of materials within repository of specimens, animal profiles, manuals and directories developed by the Contractor; subcontracts; all government property, and contract-developed data base programs, entries, and files necessary for an orderly transition of this work to a new contractor or to the Government.

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, (To be specified before award) is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at 6610 Rockledge Drive, Bethesda, MD. .

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]:

b. Technical Report Distribution

Copies of the technical reports shall be submitted as follows:

Type of report	No. Copies	Addressee	Due Dates
Quarterly Reports	2 (1 paper and 1 electronic)	Project Officer DMID/NIAID/NIH 6610 Rockledge Dr., MSC 6605, Room 5117 Bethesda, MD 20892-6605	Specific dates will be listed in the contract document
Quarterly Reports	1 paper	Contracting Officer CMB/NIAID/NIH 6700-B Rockledge Dr, MSC 7612, Room 2230 Bethesda, MD 20892-7612	Same as above
Final Project Reports	3 (2 paper and 1 electronic)	Project Officer (same address as above)	Within 30 days of final study analysis or conclusion of experiment
Final Project Reports	1 paper	Contracting Officer (same address as above)	Within 30 days of final study analysis or conclusion of experiment
Final Report	2 (1 paper and 1 electronic	Project Officer; (same address as above)	30 days before completion of contract
Final Report	1 paper	Contracting Officer (same address as above)	30 days before completion of contract
Draft System Security Plan	1 electronic	Contracting Officer (same address as above)	Within 60 days of contract award.
Final System Security Plan	1 electronic 1 paper	Contracting Officer	Within 30 days of review by

			CO and NIAID technology staff
Other deliverables	TBD	Contracting Officer (same address as above) Project Officer; (same address as above)	As required by Contracting or Project Officer

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

Pursuant to the Key Personnel clause incorporated in this contract, the following individual(s) is/are considered to be essential to the work being performed hereunder:

NAME		TITLE
	[To be specified prior to award]]	

Note: Invoicing clauses will depend on type of awardee

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST

a. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts NIH(RC)-1 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.

(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. HHSN261200411000C.)

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:

Contract Management Program
DEA, NIAID, NIH, DHHS
6700B Rockledge Drive, Room 3115, MSC 7612
Bethesda, MD 20892-7612

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

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. HHSN261200411000C.)

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:

Contract Management Program
DEA, NIAID, NIH, DHHS

6700B Rockledge Drive, Room 3115, MSC 7612
Bethesda, MD 20892-7612

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

ARTICLE G.3. LETTER OF CREDIT PAYMENT INFORMATION

a. Advance payments will be provided under Letter of Credit Number _____ in accordance with Alternate V, Advance Payments Without Special Bank Account, of FAR Clause 52.232-12, Advance Payments. This clause is provided in full text in Article I.4. of this contract.

The contractor shall withdraw funds pursuant to Department of Treasury Circular 1075 (31 CFR Part 205, http://www.access.gpo.gov/nara/cfr/waisidx_00/31cfr205_00.html).

(1) Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-1, are attached and made a part of this contract for the submission of completion and/or final invoices. The invoice instructions and the following directions for the submission of invoices/financing requests must be followed to meet the requirements of a "proper" invoice, pursuant to FAR 32.9. The completion and/or final invoice shall be submitted as follows:

An original and two copies to the following office:

Contract Management Program
DEA, NIAID, NIH, DHHS
6700B Rockledge Drive, Room 3115, MSC 7612
Bethesda, MD 20892-7612

(2) Inquiries regarding payments should be directed to the following office administering advance payments:
Division of Payment Management
11400 Rockville Pike
Rockwall Building #1, Suite 700
Rockville, MD 20852
(http://www.dpm.psc.gov/ under Contacts)

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 ARTICLE H. . of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with P.L. [cite the applicable Public Law Number for the applicable Fiscal Year as stated in ARTICLE H. .] and ARTICLE H. . of the above referenced contract."

ARTICLE G.4. CONTRACT FINANCIAL REPORT

a. Financial reports on the attached Form NIH 2706, Financial Report of Individual Project/Contract, shall be submitted by the Contractor in accordance with the Instructions for Completing Form NIH 2706, which accompany the form, in an original and two copies, not later than the 30th working day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are listed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. Unless otherwise stated in that part of the Instructions for Completing Form NIH 2706, entitled "**PREPARATION INSTRUCTIONS**," all columns A through J, shall be completed for each report submitted.

c. The first financial report shall cover the period consisting of the (FIRST FULL CALENDAR MONTH/FIRST FULL THREE CALENDAR MONTHS) following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a (monthly/quarterly) basis.

d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

e. The following is a listing of expenditure categories to be reported:

Expenditure Category A	**Percentage of Effort/Hours**
(1) Direct Labor	
(a) Principal Investigator	
(b) Co-Principal Investigator	
(c) Key Personnel	
(i)	
(ii)	
(iii)	
(2) Other Professional Personnel	
(3) Personnel - Other	
(4)Fringe Benefits	
(5)Accountable Personal Property	
(6)Materials/Supplies	
(7)Patient Care Costs	
(8)Travel	
(9)Consultant Costs	
(10)Premium Pay	
(11)Computer Costs	
(12)Subcontract Costs	
(13)Other Direct Costs	
(14)Indirect Costs	
(15)G&A Expense	
(16)Total Cost	
(17)Fee	
(18)Total Cost Plus Fixed Fee	

f. The Government may unilaterally revise the NIH 2706 to reflect the allotment of additional funds.

ARTICLE G.5. 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

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

ARTICLE G.6. 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.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluations will be prepared annually to coincide with the 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

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

ARTICLE H.2. ARTICLE H.4. 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.3. 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.4. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at:
http://grants1.nih.gov/grants/olaw/references/phspol.htm

ARTICLE H.5. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

(1) The Small Business Subcontracting Plan, dated TBD is attached hereto and made a part of this contract.

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

b. Subcontracting Reports

(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:

Contract Management Program
DEA, NIAID, NIH, DHHS
6700B Rockledge Drive, Room 3115, 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.6. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to the P.L.(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown or the applicable Executive Level for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as “indirect costs” or “facilities and administrative (F&A) costs”). Direct salary has the same meaning as the term “institutional base salary.” An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an

individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The per year salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

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

[Applicable information to be included at award]

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

* For the period 10/1/04 - 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.7. INFORMATION TECHNOLOGY SYSTEMS SECURITY SPECIFICATIONS

The contractor agrees to comply with the Information Technology (IT) systems security and/or privacy specifications set forth herein; the Computer Security Act of 1987; Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems," and the DHHS Automated Information Systems Security Program (AISSP) Handbook, which may be found at the following websites:

Computer Security Act of 1987: http://csrc.ncsl.nist.gov/secplcy/csa_87.txt
OMB A-130, Appendix III: http://csrc.ncsl.nist.gov/secplcy/a130app3.txt

http://intranet.hhs.gov/infosec/docs/policies_guides/ISPPH/PG_ISPolicyv2_12_15_2004.doc

The contractor further agrees to include this provision in any subcontract awarded pursuant to this prime contract. Failure to comply with these requirements shall constitute cause for termination.

ARTICLE H.8 . ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS

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

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

ARTICLE H.9 . 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.10 . ACCESS TO NATIONAL INSTITUTES OF HEALTH (NIH) ELECTRONIC MAIL

All Contractor staff that have access to and use of NIH electronic mail (e-mail) must identify themselves as contractors on all outgoing e-mail messages, including those that are sent in reply or are forwarded to another user. To best comply with this requirement, the contractor staff shall set up an e-mail signature ("AutoSignature") or an electronic business card ("V-card") on each contractor employee's computer system and/or Personal Digital Assistant (PDA) that will automatically display "Contractor" in the signature area of all e-mails sent.

ARTICLE H.11 . CONFIDENTIALITY OF INFORMATION

The following information is covered by HHSAR 352.224-70, Confidentiality of Information (MARCH 2005):
1) Proprietary data provided to Contractor during performance of contract. See Article B.4.

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 eHtips@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. YEAR 2000 COMPLIANCE

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

1. Service Involving the Use of Information Technology

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

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

(End of Clause)

2. Noncommercial Supply Items Warranty

YEAR 2000 WARRANTY--NONCOMMERCIAL SUPPLY ITEMS

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

YEAR 2000 COMPLIANT ITEMS

(End of Clause)

3. Commercial Supply Products Warranty

YEAR 2000 WARRANTY--COMMERCIAL SUPPLY ITEMS

The contractor warrants that each hardware, software and firmware product delivered under this contract

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

YEAR 2000 COMPLIANT ITEMS

(End of Clause)

ARTICLE H.16. 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.17 . LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES

a. Pursuant to Public Laws(s) cited in paragraph b., above, contract funds shall not be used to support activities that promote the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act (21 U.S.C. 812). This limitation shall not apply when the contractor makes known to the contracting officer that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

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

[Applicable information to be included at award]

ARTICLE H.18 . 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.19 . 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.20 . HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

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

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

ARTICLE H.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.

ARTICLE H.22 . 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:

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 **52.223-12, Refrigeration Equipment and Air Conditioners** (May 1995).

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

(5) 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 **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).

(4) HHSAR Clause **352.270-9, Care of Live Vertebrate Animals** (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:

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

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

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

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

Notice to Employees:

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

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

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

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

1-866-316-6572 (TTY)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS:

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal	http://www.niaid.nih.gov/contract/eproposal.htm
Attachment 2:	Proposal Intent Response Sheet **SUBMIT ON OR BEFORE: 11/16/05**	http://www.niaid.nih.gov/contract/forms/form1.pdf
Attachment 3:	Statement of Work	See Attachment Section at the end of this RFP
Attachment 4:	Information Technology Systems Security - Prospective Offeror Non-Disclosure Agreement	http://rcb.cancer.gov/rcb-internet/forms/IT-security-nondisclosure.pdf
Attachment 5:	Appendix A Additional Technical Proposal Instructions	See Attachment Section at the end of this RFP
Attachment 6:	Appendix B Business Proposal Instructions (Uniform Assumptions)	See Attachment Section at the end of this RFP

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

Attachment No.	Title	Location
Attachment 7:	Technical Proposal Cover Sheet	http://www.niaid.nih.gov/contract/forms.htm
Attachment 8:	Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Attachment 9:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Attachment 10:	Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
Attachment 11:	Project Objectives, NIH 1688-1	http://www.niaid.nih.gov/contract/forms/form1688.pdf

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

Attachment No.	Title	Location
Attachment 12:	Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms/NIH-2043.pdf
Attachment 13:	Small Business Subcontracting Plan	http://rcb.cancer.gov/rcb-internet/forms/sb-subplan-nci.pdf
Attachment 14:	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 15:	Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Attachment 16:	Certificate of Current Cost or Pricing Data	http://rcb.cancer.gov/rcb-internet/forms/cert-current-cost.pdf

Attachment 17:	Wage Rate Determination: Washington D.C.: Baltimore:	 http://rcb.cancer.gov/rcb-internet/forms/WR-DC-5-27-2004(94-2103).pdf http://rcb.cancer.gov/rcb-internet/forms/WR-Balt-5-27-2004(94-2247).pdf
Attachment 18:	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. Note: not all Attachments may apply.)

Attachment No.	Title	Location
Attachment 19:	Invoice/Financing Request Instructions--Cost-Reimbursement, NIH(RC)-1	http://rcb.cancer.gov/rcb-internet/forms/rc1.pdf
Attachment 20:	Invoice Instructions for NIH Fixed-Price Contracts, NIH(RC)-2	http://rcb.cancer.gov/rcb-internet/forms/rc2.pdf
Attachment 21:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 22:	Financial Report of Individual Project/Contract, NIH 2706	http://rcb.cancer.gov/rcb-internet/forms/rc2.pdf
Attachment 23:	Instructions for Completing Form NIH 2706	http://rcb.cancer.gov/rcb-internet/forms/rc2.pdf
Attachment 24:	Safety and Health, HHSAR Clause 352.223-70	http://www.niaid.nih.gov/contract/forms/form10.pdf
Attachment 25:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/form10.pdf
Attachment 26:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf
Attachment 27:	Commitment To Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Attachment 28:	Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Attachment 29:	Employee Separation Checklist	http://ais.nci.nih.gov/forms/Suitability-roster.xls

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.

(1) 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.

(2) *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.
- (i) (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.

(3) 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.

(4) 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.

(5) 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.

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

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

(3) 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.

(4) 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.

(5) 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.

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

(7) 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.

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

(9) 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.

(10) 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.

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(s) will be made on/about .

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

d. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 26,880 labor hours. 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:

Contracting Officer
Clinical Research Contracts Branch
National Institute for Allergy and Infectious Diseases
Room 3115
6700B Rockledge Drive 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.

(2) **Authorized Official and Submission of Proposal**

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

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

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

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See 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.

(5) **Alternate Proposals**

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

(6) **Evaluation of Proposals**

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

(7) **Potential Award Without Discussions**

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

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

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

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

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

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

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

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

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

Decisions about the applicability and implementation of the Privacy Rule reside with the contractor and his/her institution. The OCR Web site (http://www.hhs.gov/ocr/) provides information of the Privacy Rule, including a complete Regulation Text and a set of decision tools on “Am I a covered entity?” Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements and contracts can be found at:

http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

(10) **Care of Live Vertebrate Animals**

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

Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (Revised 1986, Reprinted 2000)

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER, OLAW. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at http://www.grants.nih.gov/grants/olaw/olaw.htm.

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

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

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

- The Animal Welfare Assurance number.
- The date last certified by OLAW. (i.e. assurance letter from OLAW)
- Evidence of recent AAALAC Accreditation.

(11) **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/FinalRule-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.

(12) **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

[If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award.

Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. Coordinating Center proposals should describe methods to coordinate the dissemination planning and implementation. The Coordinating Center must include a budget and justification for any additional costs of this collaborative effort.]

(13) **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.

(14) **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.

(15) **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, Attachment to this RFP is an example of such a plan.

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

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

c) The offeror understands that:

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

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

performance of the contract.

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

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

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

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

d) Each plan must contain the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

___% for Small Business; ___% for Small Disadvantaged Business; ___% for Women-Owned Small Business; ___% for HUBZone Small Business; and ___% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

(16) **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.

(17) **Extent of Small Disadvantaged Business Participation**

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

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

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) code, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). TheNAICS codes can be found at:
http://www.sba.gov/size

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

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

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Subsector(s). The applicable authorized NAICS Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must

provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE		
Targets for SDB Participation - NAICS Subsector 223		
	SDB Percentage of Total Contract Value	**SDB Dollars**
Total Contract Value- $1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by 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.

(18) **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.*

(19) **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.

(20) **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.

- **Past Performance Information**

a) Offerors shall submit the following information as part of their [business/technical] proposal.

A list of the last five contracts completed during the past three years and the last contracts 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 $500,000 or more over the total period of the effort. .

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) **Electronic and Information Technology Accessibility**

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

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

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

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

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

(22) **Prohibition on Contractor Involvement with Terrorist Activities**

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

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

(1) Technical Discussions

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

a) Project Objectives, NIH-1688-1

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

- For an **Institution of Higher Education:** The form MUST be completed in its entirety.
- For **OTHER** than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank.

The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled, **"INSTRUCTIONS:"**

b) Statement of Work

(1) Objectives

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

(2) Approach

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

(3) Methods

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

(4) Schedule

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

c) **Personnel**

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

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

(1) Principal Investigator/Project Director

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

(2) Other Investigators

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

(3) Additional Personnel

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

-The specific items or expertise they will provide.

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

-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) Resumes

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

(2) **Technical Evaluation**

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

(3) **Additional Technical Proposal Information**

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

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

(4) **Other Considerations**

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

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

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

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

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

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

(5) **Information Technology Systems Security**

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

The Statement of Work (SOW) requires the successful offeror to develop or access Federal automated information systems. Pursuant to the DHHS Information Security Program Policy (http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc), the following requirements apply:

(1) Information Type

[ ] Administrative, Management and Support Information:

[x] Mission Based Information:

(2) Security Categories and Levels

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

(3) Position Sensitivity Designations

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

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

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

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

Upon award, the contractor will be required to submit a roster of all IT staff working under the contract. The Government will determine the appropriate level of suitability investigation required for each staff member.

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

(4) Systems Security Plan

The offeror's proposal must:

(1) Include a plan commensurate with the size and complexity of the requirements of the Statement of Work. The minimum areas to be addressed include, but are not limited to administrative, technical, and physical security as follows:

(i) Security Awareness Training
(ii) Logical Access Control
-Network (ex: firewall)
-System (ex: network OS, tcp wrappers, SSH)
-Application (ex: S-LDAP, SSL)
-Remote Access (ex: VPN)
-Monitoring and support (ex: IDS, pager, NOC)
(iii) Protection against data loss
-OS security (ex: patch management, configuration)
-Application security (ex: patch management)
-Database security
-Back-up and recovery
-Fault tolerance, high availability
(iv) Malicious Code Protection (ex: Antivirus, filtering of e-mail attachments, etc)
(v) Physical Security
-Access control (ex: locks, guards)
-Power conditioning and/or UPS
-Air conditioning
-Fire protection

Include an acknowledgment of its understanding of the security requirements.
Provide similar information for any proposed subcontractor developing or accessing an AIS.

The resultant contract will require completion of the SSP no later than 90 days after contract award.

(e) Information Systems Security Training

DHHS policy requires contractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each contractor employee has completed the NIH Computer Security Awareness Training course(http://irtsectraining.nih.gov/) prior to performing any contract work. The successful offeror shall maintain a listing of all individuals who have completed this training and shall submit this listing to the Project Officer.

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

(f) Prospective Offeror Non-Disclosure Agreement

The Government has determined that prospective offerors will require access to Federal information described below in order to prepare an offer.

Any individual having access to this information must possess a valid and current suitability determination at the following level:

[ ] Level 6: Public Trust - High Risk
[x] Level 5: Public Trust - Moderate Risk

To be considered for access to Federal information, a prospective offeror must:

(1) Submit a written request to the Contracting Officer identified in the solicitation;
(2) Complete and submit the "Prospective Offeror Non-Disclosure Agreement" provided as an attachment in Section J of this solicitation; and
(3) Receive written approval from the Contracting Officer.

Prospective offerors are required to process their requests for access, receive Government approval, and then access the Federal information within the period of time provided in the solicitation for the preparation of offers.

Nothing in this provision shall be construed, in any manner, by a prospective offeror as an extension to the stated date, time, and location in the solicitation for the submission of offers.

(g) References

(1) DHHS Information Security Program Policy: http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc
(2) DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf
(3) NIH Systems Security Plan Template: http://irm.cit.nih.gov/security/secplantemp.doc
(4) NIH Systems Security Plan Outline: http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc
(5) NIH Computer Security Awareness Training Course: http://irtsectraining.nih.gov/
(6) NIST Special Publication 800-16, Information Technology Security Training Requirements: http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf
Appendix A-D:
http://csrc.nist.gov/publications/nistpubs/800-16/AppendixA-D.pdf
(7) NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems: http://csrc.nist.gov/publications/nistpubs/index.html
(8) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I: http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V1-final.pdf
(9) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume II: Hyperlink is same as above

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) Cost and Pricing Data

1. General Instructions

A. You must provide the following information 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 of contract administration office (if available);
(5) Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
(6) Proposed cost; profit or fee; and total;
(7) Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
(8) Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
(9) The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
(10) Date of submission; and
(11) Name, title and signature of authorized representative.

B. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future

additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

C. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including--

(1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
(2) The nature and amount of any contingencies included in the proposed price.

D. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.

F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.

G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

2. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

A. **Materials and services**. Provide a consolidated priced 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.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A(2) of this table. These requirements also apply to all subcontractors if required to

submit cost or pricing data.

(1) *Adequate Price Competition*. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).

(2) *All Other*. Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

B. **Direct Labor**. Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.

C. **Indirect Costs**. Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

D. **Other Costs**. List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

E. **Royalties**. If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

(1) Name and address of licensor.
(2) Date of license agreement.
(3) Patent numbers.
(4) Patent application serial numbers, or other basis on which the royalty is payable.
(5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
(6) Percentage or dollar rate of royalty per unit.
(7) Unit price of contract item.
(8) Number of units.
(9) Total dollar amount of royalties.
(10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).

F. **Facilities Capital Cost of Money**. When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

3. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (Section J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

4. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

5. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

[NOTE: Data substantiating the costs or prices proposed (i.e. payroll documentation, vendor quotes, invoice price, etc.) shall not be submitted with the initial proposal. This information will be requested from the offeror during the negotiation process. The initial proposal need only

indicate from what source the proposed costs and prices are substantiated.]

(3) **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.

(4) **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.

(5) **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

(6) **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.

(7) **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.

(8) **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.

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(s) to that Offeror whose proposal provides the best overall value to the Government.

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

MANDATORY QUALIFICATION CRITERIA

The mandatory qualification criterion establishes conditions that must be met **at the time of receipt of the Original Proposal submission** by the NIAID Contracting Officer in order for your proposal to be considered any further for award.

Listed below are the mandatory qualification criteria. **The Offeror should include all information that documents and/or supports the Qualification Criteria in one clearly marked section of its proposal.**

Mandatory Criterion #1: The Offeror must document access to BSL2 and 3 facilities as required to fulfill part 1.c. of the Statement of Work: *In Vitro* Microbiological Services;

Mandatory Criterion #2: The Offeror must document access to an AAALAC-accredited (or equivalent) animal facility and the capacity (appropriate cage space, etc.) as required to fulfill part 1.d. of the Statement of Work: *In Vitro* and *In Vivo* Preclinical Safety, Toxicology, and Biokinetics Services. To assess capacity, assume the following studies involving animals will be done each year:

(a) toxicology and pharmacokinetic studies for one compound per year under GLP: acute and oral intravenous (iv) toxicity and pharmacokinetics (PK) studies in rats; acute oral toxicity and PK studies in dogs; 14 day oral toxicity study in rats with toxicokinetics; 14 day oral toxicity study in dogs with toxicokinetics; and
(b) reproductive toxicity testing of two compounds per year.

Mandatory Criterion # 3: The Offeror must document prior successful completion and submission to the FDA of preclinical studies performed under GLP by the Offeror or proposed subcontractors as required to fulfill the services included in the Statement of Work that require studies/assays to be performed according to GLP guidelines. Include an indication of FDA acceptance of studies.

2. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing technical proposals. 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 EVALUATION OF PROPOSALS.

CRITERIA WEIGHT

A. TECHNICAL APPROACH/METHODOLOGY: Preclinical Development Services; Storage and Shipping; Technology Transfer 40 points

(1) Preclinical Therapeutic Development Services: Experience, adequacy, thoroughness, soundness and feasibility of the proposed technical approach to providing preclinical development services and resources for therapeutic agents in the following five (5) categories: (a) lead identification and development services; (b) chemistry and manufacturing services; (c) *in vitro* microbiological services; (d) *in vitro* and *in vivo* preclinical safety, toxicology, and biokinetics services; and (e) preclinical development planning and evaluation services.
(20 points)

(2) Soundness of technical approach for the two project proposals requested (See Appendix A: Additional Technical Proposal Instructions). This includes an evaluation of the demonstrated understanding of and technical approach for: the services and resources required for the projects; regulatory requirements for preclinical activities leading to submission of INDs; appropriate quality assurance/quality control methods; defining milestones and approaches to tracking progress toward milestone achievement; and problems/obstacles likely to occur at various stages of preclinical therapeutic development and proposed approaches for addressing such problems/obstacles.
(10 points)

(3) Adequacy of the documented experience with, and appropriateness of plans for:
- **a.** receiving, formatting, storing and shipping compounds and biological agents:
- **b.** technology transfer processes:
- **c.** shipping, handling and storing pathogens or toxins that require select agent registration; and
- **d.** providing and evaluating preclinical product development plans for therapeutic agents for which the Animal Efficacy Rule (21CFR Parts 314 and 601) may impact the licensure path.

(10 points)

B. QUALIFICATIONS OF PERSONNEL AND SAFETY 30 points

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

(1) Qualifications of the proposed Principal Investigator to lead and direct the activities to be carried out under this contract either directly or indirectly through subcontracts. This includes: scientific and technical expertise for preclinical therapeutic development projects to be undertaken in-house by the Contractor; appropriate knowledge and expertise to solicit for and evaluate the technical merit of subcontract proposals; and the capacity to monitor progress, assess performance, identify performance problems and implement corrective actions;

(2) Qualifications of the proposed Project Managers to oversee, coordinate, integrate and manage the work performed, including activities carried out under subcontract;

(3) Qualifications of all other scientific and technical staff, including subcontractors, with respect to conducting the range of preclinical therapeutic development services required, including a proven track record in therapeutic and related product development services and applicable regulatory requirements;

(4) Qualifications and experience of contract management staff in the acquisition, award and monitoring of subcontracts, including financial monitoring and reporting and adherence to subcontract terms and conditions;

(5) Appropriateness of the proposed mix and balance of key personnel in relation to their specific responsibilities and time commitments; and

(6) Experience working with potential biohazards, toxic chemicals, and radioisotopes; and adequacy of the plan for training, implementation, and monitoring of safety procedures.

C. PROJECT MANAGEMENT and OPERATIONS: Project Management; Subcontracting Acquisition and Management; Databases, Data, Document, Product, Specimen and Reagent Management; Plan for Safeguarding Confidentiality and Intellectual Property; Contract Transition 15 points

Adequacy, thoroughness and feasibility of the plans and procedures for providing, overseeing and managing support services for preclinical therapeutic development.

(1) Proposed organizational management structure for the direction and oversight of all contract activities, with clear lines of responsibility and accountability for the five categories of preclinical therapeutic development services.

(2) Procedures for closely monitoring, coordinating and managing all contract activities, and for interacting with the NIAID Project Officer and NIAID Contracting Officer:
   (a) Plans for establishment of standardized policies and procedures governing Contractor operations and working relationships with other participating organizations;
   (b) Project Management controls to keep multiple project tasks on time and on budget;
   (c) Maintenance and implementation of data management systems to support contract activities;
   (d) Plans to develop, implement, and maintain a “secure-in-house” database that will contain confidential information;
   (e) Plans to mine publicly available data/information and produce Literature Review and Compound Recommendation Reports that can be used to identify and support selection and prioritization of compounds for further evaluation; and
   (f) Plans for safeguarding confidentiality and intellectual property and security systems for safeguarding proprietary information.

(3) Adequacy, thoroughness and feasibility of the detailed technical approaches and plans proposed for soliciting, evaluating, executing and post-award administration of subcontracts. This includes:

   (a) Experience using contracting procedures and requirements as set forth in the Federal Acquisition Regulations, Clause 52.244-2, “Subcontracts.”;
   (b) Plans and procedures for developing solicitations, performing qualified, non-conflicted peer reviews of proposals received, performing cost analyses, and

negotiating and awarding subcontracts in an objective and efficient manner, with adequate interactions with the NIAID Project Officer; and

(c) Plans for closely monitoring and assessing technical, administrative and operational aspects of all subcontractor performance and for taking remedial actions, including termination and replacement, as necessary to ensure successful completion of requirements.

(4) Plans for an orderly transition to another contractor or to the Government upon completion of the contract.

D. FACILITIES AND RESOURCES 15 points

(1) Availability of adequate facilities, equipment, and resources necessary to safely and efficiently accomplish the work described in the Statement of Work either directly or indirectly through subcontracts.

(2) Capacity to perform required testing in a timely and efficient manner (resources dedicated to this project).

(3) Appropriateness and completeness of the animal care and use facilities and procedures.

TOTAL POSSIBLE POINTS: 100

The following information will be evaluated only for those Offerors found to be in the competitive range.

3. PRE-AWARD SITE VISIT

Offerors determined to be in the competitive range shall undergo a pre-award site visit with an emphasis on assessing their GMP, GLP, and QC/QA capabilities. The results of this pre-award site visit shall be a factor in final Source Selection for award of Contract. Offerors will be requested to make all records, including previous regulatory inspection reports, and staff available in response to a pre-award site visit or audit by NIAID or its designee.

4. PAST PERFORMANCE FACTOR

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

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

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

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an Offeror's performance on a list of contracts but rather the product of

subjective judgment by the Government after it considers relevant information.

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

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

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

5. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

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

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

Offers will be evaluated on the following sub-factors:
(a) extent of commitment to use SDB concerns
(b) realism of the proposal, and
(c) extent of participation of SDB concerns in terms of the value of the total acquisition.

SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP

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

STATEMENT OF WORK

INTRODUCTION/BACKGROUND
Services for the Pre-Clinical Development of Therapeutic Agents
DMID-06-09

Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), strives to understand, treat and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports extramural research to control and prevent diseases caused by virtually all infectious agents. This includes basic and applied research to develop and evaluate therapeutics, vaccines, and diagnostics, which are funded through a variety of research grants and contracts.

The development and introduction of new therapeutics against potential agents of bioterrorism, drug resistant pathogens, emerging and re-emerging infectious diseases, as well as infectious diseases prevalent in resource-limited countries remains a high public health priority. The commercial development of new therapeutics is limited, at least in part, because commercial returns on equity are perceived to be insufficient to generate adequate private investments. Increased support for the preclinical development of therapeutics was a major recommendation of the NIAID 2004 Summit on the State of Anti-Infective Development (http://www.niaid.nih.gov/dmid/meetings/anti_infective_mtg_2004.pdf).

To assist in filling these public health gaps, the NIAID requires a nontraditional, proactive, and product development oriented program to provide preclinical development support for promising therapeutic candidates. This initiative is intended to rapidly and efficiently close gaps in the preclinical development of promising, new therapeutic agents that emerge from academia, the private sector, or other sources.

The purpose of this new solicitation is to establish an NIAID resource to provide a suite of services for activities commonly associated with preclinical development of therapeutic agents, including those activities required for the submission of Investigational New Drug (IND) applications. While the overall suite of services is comprehensive, the intent is to provide individual services on a case-by-case basis for a diverse collection of product candidates, rather than carry a single product candidate through an entire preclinical development pathway.

One award is expected to be made in response to this solicitation. NIAID recognizes that no single organization or institution may have the expertise and facilities required to perform all of the preclinical development services set forth in the Statement of Work and, consequently, that the Contractor may need to utilize the expertise and resources of subcontractors to perform the tasks required. Therefore, the services to be provided under the contract shall be performed either directly by the Contractor or indirectly through subcontractors. The Contractor shall be responsible for ALL work performed under this contract including that performed by any subcontractor(s).

STATEMENT OF WORK

Services for the Preclinical Development of Therapeutic Agents
DMID– 06-09

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

For the purposes of this solicitation a therapeutic agent is defined as a drug (synthetic or natural product) or a biological product (i.e., monoclonal antibody or a derivative of a monoclonal) intended for use in cure, mitigation or treatment of disease and is currently regulated by the Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA).

Preclinical development services for therapeutics shall be directed at the following:

- diseases caused by NIAID Category A, B, and C priority pathogens and toxins (http://www2.niaid.nih.gov/Biodefense/bandc_priority.htm);
- emerging and re-emerging infectious diseases (e.g., tuberculosis, syphilis);
- antimicrobial resistant and multi-drug resistant infections (e.g., sepsis, Staphylococcus);
- other bacterial infections;
- fungal infections (e.g., coccidioidomycosis, aspergillosis);
- viral infections (e.g., influenza, hepatitis, polio, opportunistic cytomegalovirus, human papillomavirus); and
- parasitic diseases (e.g., malaria, human African trypanosomiasis, Chagas disease, leishmaniasis, filariasis and schistosomiasis).

Note: This contract shall not include services directed toward any vaccines or devices, or animal infection or intoxication models.

The major functions to be carried out by this contract are:

1) Preclinical Development Services:
   (a) Lead Identification and Development Services
   (b) Chemistry and Manufacturing Services
   (c) *In Vitro* Microbiological Services
   (d) *In Vitro* and *In Vivo* Preclinical Safety, Toxicology, and Biokinetics Services
   (e) Preclinical Development Planning and Evaluation Services
2) Technology Transfer
3) Receive, Format, Store, Ship and Record Compounds/Products and Biological Agents
4) Biocontainment, Safety Procedures and Training
5) Project Planning, Initiation, Implementation, and Management
6) Databases, Data, Document, Product and Specimen/Reagent Management and Inventory
7) Bi-Annual Meetings
8) Contract Transition

The Contractor shall provide services for preclinical development of therapeutic agents identified through NIAID-funded grants and contracts, the private sector, or other sources selected by the NIAID Project Officer. The specific services required will depend on the status of the individual candidate(s) as part of an overall product development plan and/or regulatory submission plan to the FDA. The Contractor shall carry out activities only as requested and directed by the NIAID Project Officer and may not conduct work on the contract without pre-approval by NIAID. The Contractor shall be

responsible for project planning, initiation, implementation, management and communication, including evaluation, selection, and management of subcontractors, as well as for all deliverables specified in this solicitation. The Contractor/subcontractors will use state-of-the-art techniques and technologies in evaluating promising therapeutics and will incorporate new and improved techniques and technologies into the contract activities.

The services to be provided under the contract shall be performed either directly by the Contractor or indirectly through subcontractors. At a minimum, the Contractor shall:

(1) Provide an infrastructure for the overall technical and administrative management of the projects;
(2) Provide the personnel, equipment, technical expertise, and infrastructure either at their own facilities or identify qualified subcontractors to complete all parts of the Statement of Work and to provide deliverables of a predetermined quality and according to agreed schedules;
(3) Develop Project Plans, including a description of the developmental approach, key objectives, project milestones, timelines for the completion of milestones and deliverables, and a detailed budget for each activity;
(4) Solicit for and evaluate the technical merit and proposed costs of subcontracts, and execute, manage and assess subcontractor performance;
(5) Retain all records, samples, histopathological slides, etc., and make them available as directed by the NIAID Project Officer and as indicated by GLP and cGMP guidelines;
(6) Maintain awareness of evolving regulatory requirements for preclinical evaluations of therapeutic agents;
(7) Arrange for site visits and independent audits, as needed or as requested by the NIAID Project Officer. Audits may be requested to assure Contractor and subcontractor facilities and all planned procedures meet the FDA-required GLP and GMP standards. The Contractor shall ensure that all Contractor or subcontractor records and staff are available in response to site visits or study-specific audits by NIAID or its designee and provide interim and final audit reports to the NIAID Project Officer;
(8) Develop and/or submit to NIAID, Standard Operating Procedures (SOPs) for any of the assays, processes, procedures, etc. performed by the Contractor or a subcontractor in the execution of this contract;
(9) Participate as necessary in discussion with the FDA during pre-IND, IND, pre-new drug application (NDA), and pre-biologic license application (BLA) meetings; and
(10) Provide an orderly transition to a successor contractor or to the United States Government at the end of the contract.

Specifically, the Contractor and/or subcontractor shall perform the following:

1. PRECLINICAL DEVELOPMENT SERVICES

Provide preclinical development services in the five (5) categories listed below. As directed by the NIAID Project Officer, the Contractor shall validate assays and processes, conduct work under GLP or cGMP in accordance with FDA requirements, regulations and standards in effect during the course of the project period, and provide predetermined complete Quality Assurance (QA) and Quality Control (QC) information for all services provided. In addition, the Contractor shall evaluate the data resulting from the preclinical services and draw relevant conclusions specific to the objective of the service.

(a) Lead Identification and Development Services

(1) Perform chemical screens using assays developed by the Contractor or transferred to the Contractor from a third party specified by the NIAID Project Officer.

(2) Design a lead optimization scheme (LOS) for generating at least 50 – 500 chemical analogues based on a specific structural lead series with input from biological and biochemical data supplied by a third party specified by the NIAID Project Officer.
(3) Synthesize or resynthesize 50 - 500 chemical analogues in quantities sufficient for subsequent biological and biochemical analyses.
(4) Analyze structure activity data, as supplied by the NIAID Project Officer, for potential lead series as input for subsequent lead optimization activities.
(5) Custom synthesize specific radiolabeled compounds in quantities sufficient for subsequent *in vitro* and *in vivo* studies.
(6) Perform limited optimization of chemical lead series to improve a specific physiochemical or pharmacological property, such as solubility, bioavailability or metabolism.
(7) Synthesize prodrug derivative(s) of a selected lead compound to improve pharmacological properties.
(8) Utilize established *in silico* systems to predict absorption, distribution, metabolism, and excretion (ADME), as well as toxic properties of candidate therapeutic agents. It is anticipated that the majority of information for these predictions shall be identified and obtained by the Contractor from publicly available databases and publications.

(b) Chemistry and Manufacturing Services

(1) Develop and perform analytical methods to characterize therapeutic agents in various carriers in support of: product characterization, product release, in vivo safety, pharmacokinetic studies, and other preclinical evaluations as required.
(2) Perform cGMP compliant stability studies to support regulatory submission.
(3) Synthesize, resynthesize, purchase, or acquire reagent grade or clinical grade compounds/therapeutic agents.
(4) Develop cGMP compliant manufacturing processes and procedures.
(5) Manufacture pharmaceutical materials in compliance with cGMP regulations in amounts sufficient for preclinical evaluation and Phase I/II clinical trials.
(6) Conduct formulation studies appropriate for in vivo studies.
(7) Vial, package, label, store and ship reagent grade and GMP product.

(c) *In Vitro* Microbiological Services

(1) Develop and perform minimal inhibitory concentration (MIC) and minimal bactericidal concentration (MBC) assays, as well as kill curve kinetics with therapeutic candidates against a panel of microorganisms approved by the NIAID Project Officer. Perform assays according to the Clinical Laboratory Standard Institute (CLSI, http://www.clsi.org) guidelines where appropriate.
(2) Develop and perform *in vitro* antiviral, antibacterial, antifungal, antitoxin or anti-parasitic activity studies to determine the dose response of inhibitory activity as appropriate for the biological system.
(3) Conduct mechanism of action studies of therapeutic candidates against defined molecular targets to characterize enzyme inhibition kinetics and other relevant enzymological parameters.
(4) Perform drug resistance analysis involving microorganisms.

(d) *In Vitro* and *In Vivo* Preclinical Safety, Toxicology, and Biokinetics Services

Perform preclinical safety, toxicity and biokinetic pharmacology of therapeutic candidates *in vitro* or in relevant animal models (e.g., rodents and non-rodents, such as dogs and non-human primates). This activity includes all such tests that are required to support clinical use in humans; testing must be sufficient to meet requirements for IND/NDA/BLA filing and must be performed under GLP requirements (21 CFR 58), unless otherwise specified

by the NIAID Project Officer. The Contractor or its subcontractor is responsible for acquisition, housing, and care of animals. All animal work must be conducted in accordance with the Animal Welfare Act and Public Health Service Policy on Humane Care and Use of Laboratory Animals (http://grants.nih.gov/grants/olaw/references/phspol.htm), including the implementation of an animal care and use program, and animal use protocol approval process. *In Vitro* and *In Vivo* preclinical services to be provided include:

(1) Determination of maximum tolerated dose and no observed effect levels (NOEL);
(2) Determination of acute and subchronic toxicity;
(3) Single and repeated dose toxicity studies;
(4) Determination of relevant pharmacokinetic/toxicokinetic parameters;
(5) Bioavailability studies;
(6) Absorption, distribution, metabolism, and excretion studies;
(7) Genotoxicity testing;
(8) Carcinogenicity testing if relevant for therapeutic candidate;
(9) Reproductive toxicity studies;
(10) Biotransformation assays conducted *in vitro*;
(11) Cytotoxicity of compounds for actively dividing mammalian cells (e.g., IC_{50});
(12) Immunotoxicity studies to determine the toxicity of candidate compounds to the immune system, or other specialized target organ systems;
(13) Behavioral pharmacology (e.g., functional observational battery, locomotor activity, convulsant activity, gastrointestinal motility, sleep-time potentiation, etc.);
(14) Cell permeability; and
(15) All other safety and pharmacology assays and studies that may be required for a particular therapeutic candidate.

(e) Preclinical Development Planning and Evaluation Services

(1) Develop an overall preclinical development plan for specified therapeutic candidates and produce a Preclinical Development Plan Report.
(2) Review and evaluate preclinical therapeutic development activities/plans in terms of adequacy of potential regulatory submission within the context of an overall product development plan and produce a Preclinical Development Evaluation Report.

2. TECHNOLOGY TRANSFER

The Contractor shall transfer assays, processes, methods, SOPs, reagents, products or other materials, data and documentation developed under the contract to a third party designated by the NIAID Project Officer or directly to the NIAID Project Officer. The Technical Transfer packages shall include information (Technology Transfer Report), material reagents, and in place training of others at the Contractor's or subcontractor's site or the site of a third party sufficient to completely and effectively transfer the technology.

3. RECEIVE, FORMAT, STORE, SHIP and RECORD COMPOUNDS/PRODUCTS and BIOLOGICAL AGENTS

Develop and maintain efficient and effective procedures sufficient to support contract activities for receiving, storing, shipping and recording compounds/products and biological agents, including the following:

(a) Obtain the appropriate licenses and permits required by International, Federal, State, and local authorities for the safe transport, storage, and distribution of compounds/products and biological agents;
(b) Maintain stability of all shipments received by providing the appropriate temperature control in transit from the airport or other site to the Contractor/subcontractor facility;
(c) Pay costs for shipping from suppliers to the contract/subcontract site or to third parties, and from third parties to contract/subcontract site;
(d) Provide for safe packing, labeling, and shipping of compounds/products and biological agents to sites designated by the NIAID Project Officer so that shipments are coordinated for timely receipt;
(e) Provide shipping containers for compounds/products and biological agents that comply with domestic and international postal regulations and pertinent International Air Transport Association (www.iata.org) and the International Civil Aviation Organization (www.icao.int) regulations. The shipping containers shall provide a sufficient margin of safety for maintaining appropriate environmental safeguards and desired refrigeration levels for specific products in transit, depending on the mode of transportation employed;
(f) Provide secure, safe and stable storage of reagents, products and biological agents under the required conditions (e.g., Biosafety Level, cGMP, aseptic);
(g) Aliquot chemical compounds into microtiter plates or vials suitable for storage and distribution and compatible with automated transfer into 96 and 384 well plates for use in biochemical or cell-based screens. Distribute the formatted library to a third party(s) as specified by the NIAID Project Officer; and
(h) Maintain a secure electronic record of all therapeutic and biological agents received, such as in an Excel spreadsheet or database, compatible with Microsoft Office XP or software currently used and approved by NIAID, that includes searchable information such as compound identifiers, amounts available, storage locations, shipping data and other biological and chemical characteristics of the compound.

4. BIOCONTAINMENT, SAFETY, AND TRAINING

(a) Provide safe facilities and resources and conduct work in accordance with the Biosafety in Microbiological and Biomedical Laboratories guidelines, Centers for Disease Control and Prevention and the National Institutes of Health, third edition, HHS Pub. No. (CDC) 93-8395 published by the U.S. Government Printing Office, May 1993, stock number 17-0400-00523-7;
(b) Provide adequate biocontainment facilities and staff with the required training, experience and expertise to operate the facilities and conduct the services, when appropriate, in accordance with Biosafety Level (BSL) 2 and 3 guidelines (http://bmbl.od.nih.gov/index.htm);
(c) Conduct work in accordance with Recommendations for the Safe Handling of Cytotoxic Drugs, NIH Publication No. 92-2621 (http://www.nih.gov/od/ors/ds/pubs/cyto/) and the NIH Guidelines for the Laboratory Use of Chemical Carcinogens, NIH Publication No. 81-2385 (http://grants2.nih.gov/grants/guide/notice-files/not92-070.html);
(d) Provide training, protective garments, equipment, and monitoring to assure safe handling of potentially hazardous microorganisms and materials for all personnel involved in any activities provided under the contract. Safety and Health HHSAR 352.223-70 clauses shall apply;
(e) When appropriate, conduct work in accordance with the DHHS regulations regarding the transfer of select agents (42 CFR Part 72) (http://www.cdc.gov/ncidod/srp/specimens/shipping-packing.html); and
(f) When appropriate, follow the Federal Guidelines for Research involving Recombinant DNA molecules at http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html .

5. PROJECT PLANNING, INITIATION, IMPLEMENTATION, AND MANAGEMENT

(a) Overall Project Management

Provide a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation

and management of all projects carried out under this contract and effective communications with the NIAID Project Officer and the NIAID Contracting Officer. This infrastructure shall include a Principal Investigator with responsibility for overall project management and communications, tracking, monitoring and reporting on project status and progress, and recommending modifications to project requirements and timelines, including projects undertaken by subcontractors. This infrastructure shall also include Project Managers to coordinate and integrate all preclinical therapeutic development activities conducted under this contract and administrative staff with responsibility for financial management and financial reporting on all activities conducted by the Contractor and subcontractors.

(b) Plan for Project Initiation

Upon notification by the NIAID Project Officer of services to be provided, determine whether the work can be performed in-house by the Contractor, or whether subcontracting is required.

For services to be provided **by the Contractor**, develop a Project Plan to carry out the project. The Project Plan shall include: (i) specification of the resources and services to be provided; (ii) a description of the key development objectives; (iii) delineation of project milestones and timelines for the accomplishment of milestones; (iv) a description of the technical approach to carrying out the project and the physical facilities and other necessary resources to be made available; v) a description of the project deliverables and a timeline for their completion; (vi) a list of proposed scientific and technical personnel and a description of their qualifications and relevant experience; (vii) a plan for QA and QC of the project; and (viii) a proposed budget. The Project Plan should be submitted for review to the NIAID Project Officer within 30 days of notification for services. Project initiation shall proceed only upon written approval of the Project Plan from the NIAID Contracting Officer with the advice of the NIAID Project Officer.

For services to be carried out **by a subcontractor**, develop solicitations for the work specified within 14 calendar days of notification for services. The solicitation package shall be provided to the NIAID Project Officer for review prior to issuance.

Time frames, including milestones and deliverables, for projects carried out by both the Contractor and by subcontractors will be commensurate with the complexity of the requirement and discussed and agreed upon by the NIAID Project Officer and the NIAID Contracting Officer.

Provide all of the information to support the selection for subcontract award to the NIAID Contracting Officer and the NIAID Project Officer within two (2) weeks of receipt of proposals for review, except when the budget is expected to exceed $500,000 and then the timeline will be discussed and agreed upon by the Principal Investigator, NIAID Project Officer and NIAID Contracting Officer. Supporting documentation shall include a Project Plan (as outlined above) and a review of the strengths and weaknesses of the technical and cost proposals from potential subcontractors.

(c) Subcontract Execution, Management and Reporting

The Contractor shall manage the subcontracting activity and shall ensure that the award and management of subcontracts is in accordance with FAR Clause 52.244-2. Specifically, the Contractor shall carry out the following for each project to be initiated under a subcontract:

(1) Execute and manage subcontracts, oversee the technical, administrative and operational activities of subcontractors on a daily basis, including auditing subcontractor facilities, monitoring services and financial expenditures, and tracking deliverables and reporting requirements;

(2) Include in the quarterly technical reports, an assessment of subcontractor performance and progress toward achievement of defined milestones; and identify and resolve problems with subcontractor performance;
(3) Ensure that subcontractor personnel, equipment and facilities are compliant with regulatory requirements in effect throughout the contract period;
(4) Ensure the complete and effective transfer of technology by the subcontractors to the Contractor, the United States Government, or a third party as designated by the NIAID Project Officer; and
(5) Perform all necessary transition and closeout functions on each subcontract.

6. DATABASES, DATA, DOCUMENT, PRODUCT AND SPECIMEN/REAGENT MANAGEMENT AND INVENTORY

(a) Develop, implement, and maintain data management systems to support all contract activities described in the Statement of Work.
(b) Develop, implement and maintain secure in-house data management capabilities and equipment to submit, compile, store, collate, analyze, track and retrieve data, structures, results, specimens, reagents, biological agents, product produced and released, documents generated in product development, and data received from other compound screening activities performed by third parties. This database will contain confidential proprietary information that cannot be used for data-mining purposes by the Contractor or subcontractors.
(c) Conduct market surveys or review scientific and industry publications on new or related therapeutic agents, create and utilize databases from public information (separate and distinct from the secure-in-house database described above) identifying and comparing potential products, and prepare reports of product characteristics that can be used to identify and support selection and prioritization of candidates for further development, hereafter referred to as "Literature Review and Compound Recommendation Reports".
(d) Ensure secure electronic communications, including email, word processing and transmission of data files, between the Contractor, NIAID staff, subcontractors and consultants. Organize, maintain, and transfer information on protocols and test results and provide electronic copies of all reports to the NIAID Project Officer.
(e) Provide all data, information, and records required for the writing and submission of the Masterfile, Investigator's Brochure, and all other documents related to IND/NDA/BLA submission and maintenance to the NIAID Project Officer or to a designated third party.
(f) Provide all equipment and operational systems to maintain the confidentiality of data received from the NIAID or third parties and data generated within the scope of the contract.
(g) The Government reserves the right to have complete access to the databases, provide access to third parties, and to transfer all rights and custody to a successor contractor.

7. System Security Plan (SSP)
(a) The Contractor will develop a System Security Plan for the effort following award. The contract shall use the NIH Application/System Security Plan Template to develop the SSP (link provided below) and propose levels of sensitivity and criticality. This SSP will be reviewed by the Contracting Officer and NIAID technology staff. Upon completion of review, the contractor shall make any requested modifications and contractor management shall provide a revised plan via formal, secure transmittal to the Contracting Officer.
(b) The Template is available at: http://irm.cit.nih.gov/security/secplantemp.doc
(c) Additional information is available at: http://www.cit.nih.gov/security-planning.asp

8. BI-ANNUAL MEETINGS

Participate in two (2) meetings per year. Meetings will be held in a location and on a date designated by the NIAID Project Officer in consultation with the Principal Investigator. The Principal Investigator shall be responsible for

meeting arrangements/logistics. The Principal Investigator, Project Managers, Project Leaders, key subcontractor personnel and NIAID staff will attend these meetings. The agenda will be prepared by the NIAID Project Officer and NIAID Contracting Officer in consultation with the Principal Investigator. Meetings shall be closed to the public and shall involve oral and electronic presentations including: (1) updates to include results of studies completed since the prior meeting; (2) interim reports on active protocols; (3) a description of any problem that may have arisen; and (4) a discussion of potential future protocols influenced by evolving regulatory environment or other action items. Subcontractors may not be allowed to attend portions of the meeting in which potentially proprietary/confidential information will be presented/discussed.

9. CONTRACT TRANSITION

Provide an orderly transition to a successor contractor or to the Government at the end of the contract.

(a) Submit a Contract Transition Plan for review and approval to the NIAID Project Officer three (3) months prior to the completion date of the contract. The Contract Transition Plan shall address: transportation of all deliverables listed under the Reporting Requirements and Deliverables section of the contract; relocation/disposition of animals and frozen specimens, equipment, unused materials and supplies; inventory status of materials within repository of specimens, animal profiles, manuals and directories developed by the Contractor; all government property, and contract-developed data base programs, entries, and files necessary for an orderly transition of this work to a new contractor or to the Government. The Contract Transition Plan shall also include a time line of proposed activities and completion of the transition. Similarly, the Contractor is responsible for ensuring transition of all activities performed under subcontracts.

(b) Implement the approved Contract Transition Plan to achieve a complete, timely, and orderly transition of contract activities and resources.

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.

YOU ARE REMINDED THAT THE TOTAL PAGE LIMIT FOR THE TECHNICAL PROPOSAL PACKAGE IS 150 PAGES, EXCLUDING APPENDICES PROVIDING STANDARD OPERATING PROCEDURES. 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: TECHNICAL APPROACH AND METHODOLOGY: Preclinical Development Services; Storage and Shipping of Reagents/Products; Technology Transfer

(1) Provide a table that for each type of preclinical service described in the Statement of Work under each of the five main categories, includes: a) information on past experience of the Offeror and/or the proposed subcontractor for each service; b) the pathogen and/or toxin that each activity was focused on; c) a brief description of the technical approach; d) whether the particular service has been qualified, validated, performed under GLP, or where applicable cGMP; e) the level of biocontainment required for the activity.

(2) Describe experience with select agents and how the expected licensure path involved the Animal Efficacy Rule (21 CFR Parts 314 and 601), and any subsequent or expected effect on preclinical development.

(3) Describe experience with and a plan for receiving, formatting, storing, and shipping compounds and biological agents and the management of associated records and documents.

(4) Describe experience with and a strategy for how technical transfers will be performed both into and out of the Contractor's or subcontractor's facility.

(5) Prepare a Project Plan as described in the Statement of Work (Project Planning, Initiation, Implementation, and Management) in response to the following two requests. Each Project Plan should not exceed 20 pages. Do not include SOPs.

(a) Propose a plan to manufacture 10 g of GMP bulk drug product (BDP) of a monoclonal antibody that has demonstrated in vitro and in vivo activity against ricin for use in preclinical studies and a Phase I clinical trial. Assume that you receive a GMP master cell bank; that qualified analytical assays and the manufacturing process were developed by another party that will transfer the cell bank, assays, and manufacturing process to your facility. Include the steps to obtain and transfer the master cell bank and the technology to your facility; manufacture, and characterize the BDP.

(b) Propose a project consisting of all relevant preclinical studies that would be required to support regulatory approval for clinical testing of an existing candidate two drug combination currently in Phase II clinical trials for a potential indication during pregnancy. Assume that one of the drug candidates has not undergone

reproductive toxicity assessment. Include a listing of SOPs for proposed tests that would be conducted in order to comprehensively evaluate the drug combination.

SECTION 2: PERSONNEL AND SAFETY

(1) Document the qualifications, knowledge, experience, education, competence (as they relate to the Statement of Work), and availability of key personnel of the Contractor and of all proposed subcontractors, including recent experience with similar efforts. Limit CVs to 2-3 pages for key personnel. Qualifications and experience are supported by academic degree(s) and expertise, specialized training, and relevant work involving preclinical therapeutic development projects and services.

(2) Describe a plan for training, implementation, and monitoring of safety procedures related to protection of personnel and the environment from chemical and biological hazards.

(3) Describe expertise in the use of a broad range of analytical equipment that would be needed to carry out the Statement of Work.

(4) Describe experience and standard operations in working with potential biohazards, toxic chemicals, and radioisotopes.

SECTION 3: PROJECT MANAGEMENT AND OPERATIONS, **Project Management; Subcontracting Acquisition and Management; Plan for Safeguarding Confidentiality and Intellectual Property; Databases, Data, Document, Product, Specimen and Reagent Management; Contract Transition**

Project Management Plan

(a) Describe how the project will be staffed, organized and managed. Describe in detail the responsibilities and level of effort for all proposed personnel who will be assigned to the contract, and an administrative framework indicating clear lines of authority and responsibility for the personnel.
(b) Provide a description of proposed project management controls to keep multiple tasks on time and on budget.
(c) Outline how the Principal Investigator will communicate and interact with the NIAID Contracting Officer and NIAID Project Officer and how the Principal Investigator will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).

Subcontract Acquisition and Management

(a) Provide experience and a plan for soliciting, evaluating, negotiating, awarding, and managing subcontracts using a broad range of contract vehicles and mechanisms, in accordance with the requirements established by Federal contracting regulations, utilizing the process identified in the Statement of Work.
(b) Describe experience and education of contract management staff in the acquisition and management of subcontracts under a Federal contract.
(c) Provide experience with identification and remediation of subcontractor performance or noncompliance with subcontract terms and conditions.

Confidentiality and Intellectual Property

(a) Provide a plan for how the Contractor will safeguard confidentiality and intellectual property of data and materials provided to them by third parties or the United States Government, as well as data generated, during the contract.

Information Systems for Data, Document, Product, Specimen and Reagent Management

(a) Describe the data management system that will be used for all studies and include a description of the data entry and validation, documentation of data corrections, routine maintenance and backup, data reporting and exporting system, access control, and disaster recover. Include information on data management for GLP and cGMP activities. Include a description of the specific database being proposed and its management in response to part 6.a. of the Statement of Work.
(b) Provide a plan to mine publicly available data/information and produce reports that can be used to identify and support selection and prioritization of compounds for further evaluation.
(c) The NIAID is connected to the INTERNET and uses IBM-compatible computers that currently run on the Microsoft XP operating system and Microsoft Office 2000 software. MAC users must guarantee that data can be transferred to the NIAID Project Officer without corruption of data or figures.

Contract Transition

Propose a Contract Transition Plan as follows:

(a) In the event that this Contract is re-competed, and an organization other than the incumbent Contractor is selected, the incumbent Contractor shall move all Government property, including that held at subcontractor sites, to the new site by the completion date of the Contract. It is estimated that this shall take no longer than 45 calendar days; and
(b) The Contract Transition Plan shall include: relocation/disposition of animals and frozen specimens, equipment, unused materials and supplies; inventory status of materials within repository of specimens, animal profiles, manuals and directories developed by the Contractor; all government property, and contract-developed data base programs, entries, and files necessary for an orderly transition of this work to a new contractor or to the Government. The Contract Transition Plan shall also include a time line of proposed activities and completion of the transition.

SECTION 4: RESEARCH FACILITIES AND RESOURCES

Describe the following:

(1) Availability of adequate facilities, equipment, and resources necessary to safely and efficiently accomplish the work described in the Statement of Work either directly or indirectly through subcontracts.

(2) Capacity to perform required testing in a timely and efficient manner (resources dedicated to this project).

(3) Procedures for the care and housing of breeding and experimental animals, the extent of appropriate veterinary coverage, a description of the physical plant housing all animals and laboratories, and the expertise and training of the technical staff employed.

(4) Include a letter signed by the appropriate authority allowing for pre-award site visits to the Contractor's facility and proposed subcontractor's facilities. Site visits may include GLP and cGMP audits performed by professional auditors contracted by NIAID. Include an audit history of the facilities proposed for GLP and cGMP work.

APPENDIX B – BUSINESS PROPOSAL INSTRUCTIONS
[UNIFORM ASSUMPTIONS]

INCLUDE THE FOLLOWING IN THE BUDGET PROPOSAL– ASSUME THE SAME ACTIVITIES FOR EACH YEAR: (Except the final year should budget $100,000 for Contract Transition)

(1) Estimated Level of Effort - Fourteen, 14 Full Time Equivalents (FTE's) per year

(2) Project Planning, Initiation, Implementation, and Management
Resources to support project planning, initiation, implementation and management to include overall contract/project management and solicitation, selection, and management of subcontracts. Budget should be based on managing 10 - 15 projects per year.

(3) Travel
(a) Resources to support planning and provide logistics (e.g. travel, per diem, conference room, audio-visual) for bi-annual meetings. Resources for travel and per diem of six (6) individuals to the bi-annual meetings including the Principal Investigator, Project Manager, Co-Investigators, and selected subcontractors. For cost estimating purposes, assume that each meeting will last two full days and will alternate between the Contractor's site and Bethesda, MD.
(b) Resources to support travel required for oversight of subcontracts.

(4) Databases, Data, Document, Product and Specimen/Reagent Management and Inventory
(a) Resources to support data management for all activities described in the Statement of Work. Assume 10-15 projects per year. Base budget on projects described below under "7. Preclinical Development".
(b) Resources to develop, implement, and maintain a secure in-house data management and handling system for confidential data received from third parties, as well as confidential data generated under the contract, as described in the Statement of Work for each year of the contract. Assume that all projects involve confidential data received and confidential data generated.
(c) Resources to support production of Literature Review and Compound Recommendation Reports that can be used to identify and support selection and prioritization of compounds for further evaluation based on publicly available data/information. For budget purposes assume four reports per year for four different target pathogens and/or toxins.

(5) Store, Receive, Ship and Record Compounds/Products and Biological Agents
Resources to support storage, receipt, records and shipping of compounds/product based on the following anticipated work load – storage of 25,000 compounds, receipt of 5,000 new compounds per year, and shipping of 5,000 compounds per year. In addition, include resources for shipping, handling, and storing select agents that require BSL 2 (3 agents) and BSL 3 (2 agents) procedures and facilities per year.

(6) Confidentiality and Intellectual Property Safeguards
Resources to support the maintenance of the confidentiality of proprietary data and materials provided to the Contractor and generated under the contract. Assume that 10-15 projects will be performed per year and that each project involves confidential data and materials.

(7) Funds to maintain safety and training of staff
Resources to maintain safety and training of staff required to perform Preclinical Development Services described below for each year of the contract. Include resources required to maintain safety and training of staff to work with select agents in BSL2 and BSL3 facilities.

(8) Preclinical Development Services

Offerors shall include a budget for the following preclinical development services:

(a) Twice per year, design a lead optimization scheme for generating 200 potential chemical analogues based on a specific lead series structural class and produce the chemical analogues in a quantity sufficient for in vitro studies. Assume that a small molecular weight compound has been identified by an in vitro cell-free screen and also found to have activity in a cell-based screen.

(b) Twice per year, manufacture 10 g of GMP bulk drug product (BDP) of a monoclonal antibody for use in preclinical studies and a Phase 1 clinical trial. Assume that you receive a GMP master cell bank; that qualified analytical assays and the manufacturing process were developed by another party that will transfer the cell bank, assays, and manufacturing process to your facility. Include the steps to obtain and transfer the master cell bank and the technology to your facility; manufacture, and characterize the BDP.

(c) Twice per year, develop a manufacturing process for a 4-6 step synthesis, produce 1 kg non GMP material, and 200 g GMP drug substance, and perform stability studies.

(d) Custom synthesize one radiolabeled compound per year.

(e) Determine and characterize the antiviral activity of an agent against five isolates of influenza virus per year.

(f) Determine and characterize the antimicrobial activity of an agent against anthrax per year.

(g) Determine and characterize the activity of an agent against *Trypanosoma brucei rhodesiense* once per year.

(h) Perform the following toxicology and pharmacokinetic studies under GLP for one compound each year:
- (i) Acute oral and IV toxicity and PK studies in rats
- (ii) Acute oral toxicity and PK studies in dogs
- (iii) 14 day oral toxicity study in rats with toxicokinetics
- (iv) 14 day oral toxicity study in dogs with toxicokinetics

(i) Genotoxicity testing of one compound per year; include Ames mutagenicity, chromosomal aberration, and mouse micronucleus studies.

(j) Reproductive toxicity testing of two compounds per year.

(k) Develop three Preclinical Development Plan Reports and one Preclinical Development Plan Evaluation Report per year.