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

NIH-NIAID-DAIDS-07-27
MANAGEMENT OF INFORMATION RESOURCES ON THERAPEUTIC AGENTS FOR HIV AND OPPORTUNISTIC INFECTIONS

OMB control number 0990-0115

1. **OFFEROR S 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 4, 2006	5. **Small Bus. Set-Aside:** [X]Yes [] No
September 25, 2006	**Time:** 3:00 p.m., EST	**8(a) Set-Aside:** [ ]Yes [X] No
		NAICS #: 518210
		(See Part IV, Section L.)

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

9. **Issued By:**	10. [X] **NIAID reserves the right to make awards without discussions.**	
Jill Johnson, Contracting Officer Office of Acquisitions, DEA NIAID, NIH, DHHS 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:** Up to 7 years beginning on or about August 20, 2007

13. **Primary Point of Contact:**	14. **Secondary Point of Contact:**	15. **Protest Officer:**
Name : Jill Johnson	**Name: Eileen Webster-Cissel**	Charles W. Grewe
Phone: 301-451-6396	**Phone:** 301-496-0349	Director, Office of Acquisitions
Fax: 301-402-0972	**Fax:** 301-402-0972	**Address (See block 9.)**
E-Mail: JMJohnson@niaid.nih.gov	**E-Mail:** Webstere@mail.nih.gov	

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**
Jill Johnson Office of Acquisitions, DEA NIAID, NIH, DHHS 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	Jill Johnson Office of Acquisitions, DEA NIAID, NIH, DHHS 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)

PART I - THE SCHEDULE

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

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

To provide the management of chemical and biological databases which serve as tools for the rational selection and discovery of potential therapies for AIDS and opportunistic infections (OIs). The Contractor shall update the databases with pertinent published literature and NIAID confidential data and information on the chemical, virological, immunological and microbiological aspects of therapeutic agents for HIV, OIs, and TB, and on microbicides.

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.

See Attachment for Advance Understandings which will be included in any resultant contract.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated September 25, 2006, attached hereto and made a part of this Solicitation (See Section J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

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

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

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

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of any resultant contract. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
National Institute of Allergy and Infectious Diseases
Office of Acquisition, DEA
6700B Rockledge Drive, Room 3214
Bethesda, Maryland 20892 - 7612

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

SECTION D - PACKAGING, MARKING AND SHIPPING

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

SECTION E - INSPECTION AND ACCEPTANCE

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

b. For the purpose of this SECTION, TBD is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at 6700B Rockledge Drive, Bethesda, MD 20817.

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

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

FAR Clause 52.246-8, Inspection of Research and Development - Cost-Reimbursement (May 2001).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

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

a. The items specified below as described in SECTION C, ARTICLE C.2. will be required to be delivered F.O.B. Destination as set forth in FAR Clause 52.247-35, F.o.b. Destination, Within Consignees Premises (April 1984), and in accordance with and by the date(s) specified in Section C, Article C.2. and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of the contract. (Please refer to Attachment 5, “Reporting Requirements and Deliverables” under this solicitation).

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

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

SECTION G - CONTRACT ADMINISTRATION DATA

Any contract awarded from this RFP will contain the following:

ARTICLE G.1. PROJECT OFFICER

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

[To be specified prior to award]

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical

evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

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

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL

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

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

NAME	TITLE
[To be specified prior to award]	

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

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

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

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

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

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

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

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

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

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

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

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

ARTICLE G.4. INDIRECT COST RATES

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

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

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

ARTICLE G.5. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

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

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

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

b. Electronic Access to Contractor Performance Evaluations

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

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

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

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 HHS Publication, entitled, **Contractor's Guide for Control of Government Property**, which can be found at:

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

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

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

ARTICLE H.2. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

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

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

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

[Applicable information to be included at award]

ARTICLE H.3. 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. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to the P.L.(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown or the applicable Executive Level for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as “indirect costs” or “facilities and administrative (F&A) costs”). Direct salary has the same meaning as the term “institutional base salary.” An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor. The per year salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

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

[Applicable information to be included at award]

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

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

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

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

ARTICLE H.5. INFORMATION SECURITY

The Statement of Work (SOW) requires the Contractor to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s); Pursuant to Federal and HHS Information Security Program Policies, the Contractor and any subcontractor performing under this contract shall comply with the following requirements:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); http://csrc.nist.gov/policies/FISMA-final.pdf

a. Information Type

Mission Based Information

b. Security Categories and Levels

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

c. Position Sensitivity Designations

(1) The following position sensitivity designations and associated clearance and investigation requirements apply under this contract.

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

[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).

(2) The Contractor shall submit a roster, by name, position and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. Any revisions to the roster as a result of staffing changes shall be submitted within 15 calendar days of the change. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for Contractor use at: http://ais.nci.nih.gov/forms/Suitability-roster.xls.

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

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

(3) Contractor/subcontractor employees shall comply with the HHS criteria for the assigned position sensitivity designations prior to performing any work under this contract. The following exceptions apply:

Levels 5 and 1: Contractor/subcontractor employees may begin work under the contract after he Contractor has submitted the name, position and responsibility of the employee to the Project Officer, as described in paragraph c. (2) above.

Level 6: In special circumstances the Project Officer may request a waiver of the pre-appointment investigation. If the waiver is granted, the Project Officer will provide written authorization for the Contractor/subcontractor employee to work under the contract.

d. Information Security Training

The Contractor shall ensure that each Contractor/subcontractor employee has completed the NIH Computer Security Awareness Training course at: (http://irtsectraining.nih.gov/) prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of this contract.

The Contractor shall maintain a listing by name and title of each Contractor/subcontractor employee working under this contract that has completed the NIH required training. Any additional security training completed by Contractor/subcontractor staff shall be included on this listing. The listing of completed training shall be included in the first technical progress report. (See Article C.2. Reporting Requirements.) Any revisions to this listing as a result of staffing changes shall be submitted with next required technical progress report.

e. Rules of Behavior

The Contractor/subcontractor employees shall comply with DHHS Information Security Program Policy Handbook, Appendix G at: http://intranet.hhs.gov/infosec/docs/policies_guides /ISPPH/PG_ISHbkv2_11_12_2004.pdf and the NIH Information Technology General Rules of Behavior at: http://irm.cit.nih.gov/security/nihitrob.html.

f. Personnel Security Responsibilities

The Contractor shall perform and document the actions identified in the "Employee Separation Checklist", attached and made a part of this contract, when a Contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request.

g. Commitment to Protect Non-Public Departmental Information Systems and Data

(1) Contractor Agreement

The Contractor and its subcontractors performing under this SOW shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

-18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
-18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
-Public Law 96-511 (Paperwork Reduction Act)

(2) Contractor-Employee Non-Disclosure Agreements

Each Contractor/subcontractor employee who may have access to non-public Department information under this contract shall complete the Commitment to Protect Non-Public Information - Contractor Agreement. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer prior to performing any work under the contract.

For additional Information and assistance for completion of this item, See Table 3, Federal Information Security Safeguard Requirements-Summary at: http://irm.cit.nih.gov/security /table3.htm.

h. NIST SP 800-26 Self-Assessment Questionnaire

The Contractor shall annually update and re-submit its Self-Assessment Questionnaire required by NIST Draft SP 800-26, Revision 1, Guide for Information Security Program Assessments and System Reporting Form (http://csrc.nist.gov/publications/drafts/Draft-sp800-26Rev1.pdf - See Appendix B for format).

Subcontracts: The Contractor's annual update to its Self-Assessment Questionnaire shall include similar information for any subcontractor that performs under the SOW to (1) develop a Federal information system(s) at the Contractor's/subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the Contractor's/subcontractor's facility.

The annual update shall be submitted to the Project Officer, with a copy to the Contracting Officer no later than 30 days after yearly anniversary date of contract award.

i. Information System Security Plan

The Contractor's draft ISSP submitted with its proposal shall be finalized in coordination with the Project Officer no later than 180 calendar days after contract award.

Following approval of its draft ISSP, the Contractor shall update and resubmit its ISSP to the Project Officer every three years or when a major modification has been made to its internal system. The Contractor shall use the current ISSP template in Appendix A of NIST SP 800-18, *Guide to Developing Security Plans for Federal Information Systems*. (http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf). The details contained in the Contractor's ISSP shall be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels of this Article.

Subcontracts: The Contractor shall include similar information for any subcontractor performing under the SOW with the Contractor whenever the submission of an ISSP is required.

ARTICLE H.6. ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS

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

ARTICLE H.7. PUBLICATION AND PUBLICITY

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

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

ARTICLE H.8. PRESS RELEASES

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

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

[Applicable information to be included at award]

ARTICLE H.9. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

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

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

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

a. Sharing of Model Organisms for Biomedical Research

The plan for sharing model organisms submitted by the Contractor is acceptable/The Contractor's data sharing plan, dated__TBD_____, is hereby incorporated by reference. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

ARTICLE H.12. SHARING RESEARCH DATA

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

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge,

products, and procedures to improve human health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

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

ARTICLE H.13. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

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

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

ARTICLE H.14. 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.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

TBD

(End of Clause)

3. Commercial Supply Products Warranty

YEAR 2000 WARRANTY--COMMERCIAL SUPPLY ITEMS

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

YEAR 2000 COMPLIANT ITEMS

TBD

(End of Clause)

ARTICLE H.16. CONFIDENTIALITY OF INFORMATION

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

All information provided by the Provider or Project Officer shall be assumed to be confidential unless specifically identified as non-confidential in writing by the Project Officer. All materials supplied to the Contractor and all test results similarly are to be considered confidential.

ARTICLE H.17. 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.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

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

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

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

		Pricing Data - Modifications
52.216-7	Dec 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	May 2004	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Jul 2005	Small Business Subcontracting Plan (Over $500,000, $1,000,000 for Construction)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000, $1,000,000 for Construction)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor
52.222-21	Feb 1999	Prohibition of Segregated Facilities
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-50	Apr 2006	Combating Trafficking in Persons
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Aug 2003	Toxic Chemical Release Reporting (Over $100,000)
52.225-1	Jun 2003	Buy American Act - Supplies
52.225-13	Feb 2006	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data - General
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims

52.232-25	Oct 2003	Prompt Payment, Alternate I (Feb 2002)
52.232-33	Oct 2003	Payment by Electronic Funds Transfer--Central Contractor Registration
52.233-1	Jul 2002	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate I (January 2006)
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.244-6	Feb 2006	Subcontracts for Commercial Items
52.245-5	May 2004	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract)
52.245-9	Aug 2005	Use and Charges
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

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

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

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

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

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

FAR Clauses **52.215-15, Pension Adjustments and Asset Reversions** (October 2004); **52.215-18, Reversion or Adjustment of Plans for Post Retirement Benefits (PRB) Other Than Pensions** (July 2005); and, **52.215-19, Notification of Ownership Changes** (October 1997), are deleted in their entirety.

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

FAR Clauses **52.219-9, Small Business Subcontracting Plan** (July 2005), and **52.219-16, Liquidated Damages--Subcontracting Plan** (January 1999) are deleted in their entirety.

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

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

(1) FAR Clause 52.204-9, Personal Identity Verification of Contractor Personnel

(2) FAR Clause 52.215-17, Waiver of Facilities Capital Cost of Money (October 1997)

(3) FAR Clause 52.219-6, Notice of Total Small Business Set-Aside (June 2003)

(4) FAR Clause 52.219-14, Limitations on Subcontracting (December 1996)

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

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

Additional purposes for which the limited rights data may be used are: None

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

Additions to, or limitations on, the restricted rights set forth in the Restricted Rights Notice of subparagraph (g)(3) of the clause are expressly stated as follows: None

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

Specific data items that are not subject to paragraph (j) include: None

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

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

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

(11) FAR Clause 52.237-3, Continuity of Services (January 1991)

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

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

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

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

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

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

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

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

This contract incorporates the following clauses in full text.

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

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

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

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

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

Notice to Employees

Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However,

employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

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

SOLICITATION ATTACHMENTS:

Attachment No.	Title	Location
Attachment 1	Packaging and Delivery of Proposal	See Attachment Section at the end of this RFP
Attachment 2	Proposal Intent Response Sheet	See Attachment Section at the end of this RFP
Attachment 3	Background	See Attachment Section at the end of this RFP
Attachment 4	Statement of Work	See Attachment Section at the end of this RFP
Attachment 5	Reporting Requirements and Deliverables	See Attachment Section at the end of this RFP
Attachment 6	Appendix A - Additional Technical Proposal Instructions and Format for Technical Proposal Table of Contents	See Attachment Section at the end of this RFP
Attachment 7	Appendix B - Additional Business Proposal Instructions and Uniform Cost Assumptions	See Attachment Section at the end of this RFP
Attachment 8	Appendix C - Advance Understandings	See Attachment Section at the end of this RFP
Attachment 9	Appendix D – Master Database	See Attachment Section at the end of this RFP

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

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

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

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

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

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

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

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

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

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

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

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

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

(1) 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.

(2) 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).

(3) Submission, modification, revision, and withdrawal of proposals. (a) 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.

(b) 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.

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

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be

considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

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

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

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

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

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

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

(e) 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.

(f) 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.

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

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

(4) 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).

(5) Restriction on disclosure and use of data. (a) 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).

(b) 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.

(d) 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.

(6) Contract award. (a) 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 sub factors in the solicitation.

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

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

(d) 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.

(e) 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.

(f) 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.

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

(h) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or sub line 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.

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

(j) 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.

(k) 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. NOTICE OF SMALL BUSINESS SET-ASIDE

(1) General. Bids or proposals under this procurement are solicited only from small business concerns. The procurement is to be awarded only to one or more such concerns, organizations, or individuals. This action is based on a determination by the Contracting Officer, alone or in conjunction with a representative of the Small Business Administration, that it is in the interest of maintaining or mobilizing the Nation's full productive capacity, or in the interest of war or national defense programs, or in the interest of assuring that a fair proportion of Government procurement is placed with small business concerns. Bids or proposals received from others will be considered non-responsive.

(2) Definitions. The term "small business concern" means a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts, and can further qualify under the criteria set forth in the regulations of the Small Business Administration (13 CFR 121.3-8). In addition to meeting these criteria, a manufacturer or a regular dealer submitting bids or proposals in his own name must agree to furnish in the performance of the contract end items manufactured or produced in the United States, its territories and possessions, Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia, by small business concerns. Provided, that this additional requirement does not apply in connection with construction or service contracts.

c. 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 518210.

(2) The small business size standard is $23 million.

d. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that one (1) award will be made from this solicitation and that the award will be made on/about August 20, 2007.

It is anticipated that the award from this solicitation will be a cost-reimbursement, completion type contract with a period of performance of seven (7) years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. 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 six (6) Full-Time Equivalents (FTEs) per year for the entire seven (7) years. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

f. 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.

g. 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.

h. 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.

i. 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.

j. PREPARATION COSTS

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

k. SERVICE OF PROTEST (AUGUST 1996) - FAR 52.233-2

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

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

(2) 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)

l. LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70

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

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

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

(1) Contract Type and General Clauses

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

(2) Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addresses, and marked as indicated in the Attachment entitled, PACKAGING

AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments. (See Attachment 6, Appendix A - Additional Technical Proposal Instructions and Format for Technical Proposal Table of Contents.)

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments. (See Attachment 7, Appendix B - Additional Business Proposal Instructions and Uniform Cost Assumptions.)

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

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

(4) Separation of Technical and Business Proposals

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

(5) Alternate Proposals

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

(6) Evaluation of Proposals

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

(7) Use of the Metric System of Measurement

It is the policy of the Department of Health and Human Services to support the Federal transition to the

metric system and to use the metric system of measurement in all procurement, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

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

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

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

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

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

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

(9) 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.

(10) 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.

(11) 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 sub grantees, 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.

(12) Institutional Management of Conflicting Interests

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

significantly affect the design, conduct, or reporting of the NIH-funded research.

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

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

(b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(13) Past Performance Information

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

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

Include the following information for each contract or subcontract:

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

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

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

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

(14) Electronic and Information Technology Accessibility

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

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

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

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

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

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

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

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

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

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.

(12) Technical Discussions

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

a) Project Objectives, NIH-1688-1

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

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

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

b) Statement of Work

(1) Objectives

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

(2) Approach

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

(3) Methods

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

(4) Schedule

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

c) Personnel

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

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

(1) Principal Investigator/Project Director

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

(2) Other Investigators

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

(3) Additional Personnel

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

-The specific items or expertise they will provide.

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

-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) Resumes

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

(2) Technical Evaluation

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

(3) Additional Technical Proposal Information

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

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

(4) Other Considerations

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

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

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

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

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

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

(5) Obtaining and Disseminating Biomedical Research Resources

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

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

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

(a) Sharing Research Data

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

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

(7) Information Technology Systems Security

Information Security is applicable to this solicitation and the following information is provided to assist in proposal preparation.

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

The Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, Contractor (including subcontractor), or other source. The National Institute of Standards and Technology (NIST) has issued a number of publications that provide guidance in the establishment of minimum security controls for management, operational and technical safeguards needed to protect the confidentiality, integrity and availability of a Federal information system and its information.

The Statement of Work (SOW) requires the successful offeror to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies the following requirements apply to this solicitation:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); http://csrc.nist.gov/policies/FISMA-final.pdf

(a) Information Type

Mission Based Information

(b) Security Categories and Levels

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

(c) Position Sensitivity Designations

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

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

[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 staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a federal information system(s). The Government will determine and notify the Contractor of the appropriate level of suitability investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for Contractor use at:
http://ais.nci.nih.gov/forms/Suitability-roster.xls

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

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

(d) Information Security Training

HHS policy requires Contractors/subcontractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each Contractor/subcontractor employee has completed the NIH Computer Security Awareness Training course at: (http://irtsectraining.nih.gov/) prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract. The successful offeror shall maintain a listing of all individuals who have completed this training and shall submit this listing to the Project Officer.

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

(e) Offeror's Official Responsible for Information Security

The offeror shall include in the "Information Security" part of its Technical Proposal the name and title of its official who will be responsible for all information security requirements should the offeror be selected for an award.

(f) NIST SP 800-26 Self-Assessment Questionnaire

The offeror must include in the "Information Security" part of its Technical Proposal, a completed Self-Assessment Questionnaire required by NIST Draft SP 800-26, Revision 1, Guide for Information Security Program Assessments and System Reporting Form at: (http://csrc.nist.gov/publications/drafts/Draft-sp800-26Rev1.pdf, See Appendix B for submission format.) NIST 800-26 assesses information security assurance of the offeror's internal systems security. This assessment is based on the Federal IT Security Assessment Framework and Draft NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems, at: (http://www.csrc.nist.gov/publications/drafts/800-53-rev1-ipd-clean.pdf).

Subcontracts: The offeror must include similar information for any proposed subcontractor that will perform under the SOW to (1) develop a Federal information system(s) at the offeror's/subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the offeror's/subcontractor's facility.

(g) Draft Information System Security Plan

The offeror must include a draft Information System Security Plan (ISSP) using the current template in Appendix A of NIST SP 800-18, Guide to Developing Security Plans for Federal Information Systems (http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf). The details contained in the offeror's draft ISSP must be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels.

Subcontracts: The offeror must include similar information for any proposed subcontractor that will perform under the SOW with the offeror whenever the submission of an ISSP is required.

Note to Offeror: The resultant contract will require the draft ISSP to be finalized in coordination with the Project Officer no later than 90 calendar days after contract award. Also, a Contractor is

required to update and resubmit its ISSP to NIH every three years following award or when a major modification has been made to its internal system.

(i) References

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

(8) T**echnical Questions**

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

c. BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

(2) Proposal Cover Sheet

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;

7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

(3) Information Other than Cost or Pricing Data

a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

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

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

1. Direct Labor

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

2. Materials

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

3. Subcontracted Items

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

4. Raw Materials

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

5. Purchased Parts

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

6. Fringe Benefits

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

7. Indirect Costs

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

8. Special Equipment

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

9. Travel

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

10. Other Costs

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

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

(a) Exceptions from cost or pricing data.

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

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

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

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

the proposed quantities;

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

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

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

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

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

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

(End of provision)

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

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

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

(5) Salary Rate Limitation in Fiscal Year 2006

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

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

P.L. 109-149 states in pertinent part:

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

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

*Note to Offerors: The current Fiscal Year Executive Level I Salary Rate should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year 2006 Executive Level I Salary rates.

(6) 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.

(7) Other Administrative Data

a) Property

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

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

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

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

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

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

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

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.

(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) Financial Capacity

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

d) Incremental Funding

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is

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

HHSAR 352.232-75, Incremental Funding (January 2001)

(1) 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.

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

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

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

(1) 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.

(2) 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.

(8) 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

(9) Proposer's Annual Financial Report

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

(10) Representations and Certifications

One copy of SECTION K (which includes FAR Clause 52.204-8 Annual Representations and Certifications) shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of SECTION K shall be submitted from any proposed subcontractor. SECTION K can be found at: http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

(11) Travel Costs/Travel Policy

a) Travel Costs - Commercial

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

b) Travel Policy

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

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against three factors. The factors, in order of importance are: technical, cost/price, and past performance. Although technical factors are of paramount consideration in the award of the contract, cost/price, and past performance 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. In any event, the Government reserves the right to make an award to that Offeror whose proposal provides the best overall value to the Government. The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. EVALUATION OF DATA SHARING PLAN

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

3. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the Technical Evaluation Committee when reviewing Technical Proposals. Proposals will be judged solely on the written material provided by the Offeror. The criteria listed below are in the order of relative importance with weights assigned for evaluation purposes. Sub-criteria are listed in order of descending importance. Offerors and reviewers are advised to refer to Appendix A – Additional Technical Proposal Instructions of this solicitation package for guidance and information related to the preparation and format of Technical Proposals.

CRITERIA WEIGHT

CRITERION 1: SCIENTIFIC AND PROFESSIONAL PERSONNEL 40 points

a. Principal Investigator

Adequacy and suitability of the documented education, training and availability of the Principal Investigator for planning, managing and directing the proposed activities including experience in administering a project of similar content and complexity; familiarity with past and current research in the areas of HIV and co-infections, antivirals, antimicrobials, and microbiology; doctoral degree in medicinal chemistry/biology with knowledge of microbiology and virology; and knowledge of computer science aspects of the database software/hardware to be utilized under this contract.

b. Key Scientific and Professional Staff

Adequacy and suitability of key scientific and professional staff with respect to their demonstrated qualifications, availability, experience, education and training; familiarity with past and current research in the area of HIV and co-infections, antivirals,

antimicrobials, microbiology, in vitro assays and animal models; experience in conducting on-line literature searches in appropriate databases. Capability to function as a resource to DAIDS for advice on the computer science aspects of the database software and hardware to be utilized under this contract; expertise in relational databases.

c. Data Entry and IT Personnel

Adequacy, availability and suitability of training, qualifications and experience of data entry and IT personnel with respect to chemical structures and data entry; quality control; preparation of text and graphic data in html and gif format for Web site inclusion; database management, and using and maintaining hardware and software to be utilized under this contract; e.g., Molecular Design (MDL) and Oracle software.

CRITERION 2: TECHNICAL APPROACH 40 points

a. Adequacy and feasibility of the technical approaches and proposed plans to survey the literature and select citations that contain chemical and biological information on experimental therapies for HIV and OIs; to identify and abstract relevant chemical and biological information; to determine the validity and authenticity of the data; and to update the chemical and biological databases, the literature citation database, and the publicly available Web database with the corresponding information.

b. Adequacy and appropriateness of the proposed data management procedures for updating and maintenance of the databases, quality control, disaster recovery, software development and maintenance, and security and confidentiality of the data; adequacy of the approaches for overcoming potential problems in the administration of a reliable, efficient, fully operational and responsive data management system.

c. Adequacy and feasibility of the technical approach for performing substructure and full structure preclinical information searches; adequacy and soundness of the approach and rationale for selecting the most promising chemical structures for the four sample search requests provided.

CRITERION 3: PROJECT MANAGEMENT 10 points

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

b. Appropriateness and feasibility of the plans for the prioritization of projects and procedures for the implementation and timely completion of projects; previous experience with the timely completion of comparable tasks. Organization’s ability to provide appropriate trained personnel and flexible resources for the project to meet contract requirements.

c. Demonstrated organizational experience in computerized chemical databases management, maintenance, and quality control.

d. Appropriateness and adequacy of the procedures to safeguard confidentiality and intellectual property of data and materials provided by third parties or the Government, as well as data generated by the Contractor.

CRITERION 4: FACILITIES AND RESOURCES 10 points

Adequacy and availability of all necessary facilities, equipment, and resources required to carry out the contract requirements, and if applicable, the facilities, equipment, network and computational resources of subcontractors and consultants.

a. Computational facilities and support to conduct work described in the Statement of Work including high speed Internet capability, software, hardware, and other necessary equipment.

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

TOTAL: 100 Points

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.

SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP

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

PACKAGING AND DELIVERY OF THE PROPOSAL

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

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

A. EXTERNAL PACKAGE MARKING:

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

"**RFP NO. NIH-NIAID-DAIDS-07-27**
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. PAPER COPIES and CD-Rom to:

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

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

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

C. NUMBER OF COPIES:

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

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

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

- Type size must be 10 to 12 points.
- Type spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
- Print margins must be at least one inch on each edge of the paper.

- Print setup should be single-sided on standard letter size paper (8.5 x 11" in the U.S., A4 in Europe).

CREATING AND NAMING ELECTRONIC FILES:

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

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

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

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

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

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

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

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

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

Document	Number of Copies	Page Limits
Technical Proposal and all Appendices	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** Twenty (20) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices) in a Portable Document Format (PDF)	**Not to Exceed 200 pages**
Business Proposal	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** Three (3) Compact Disks containing an electronic copy of the Business Proposal in a Portable Document Form (PDF).	N/A
Breakdown of Proposed Estimated	This Attachment to the Business Proposal should be submitted as a	N/A

Cost using Electronic Cost Proposal EXCEL Workbook	separate EXCEL file on the Business Proposal Compact Disk. **See Section J, Attachment entitled Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet to access the Excel Workbook.**	

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DAIDS-07-27
RFP Title: Management of Information Resources on Therapeutic Agents for HIV and Opportunistic Infections

Please review the attached Request for Proposal. Furnish the information requested below and return this page by no later than **November 4, 2006**. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

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

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

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

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

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

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

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

Attn: Jill Johnson
RFP-NIH-NIAID-DAIDS-07-27
FAX# (301) 402-0972
Email: JMJohnson@niaid.nih.gov

BACKGROUND

MANAGEMENT OF INFORMATION RESOURCES ON THERAPEUTIC AGENTS FOR HIV AND OPPORTUNISTIC INFECTIONS
RFP NIH-NIAID-DAIDS-07-27

The Division of AIDS (DAIDS), NIAID supports research to identify therapeutic agents for the prevention and treatment of infection with the human immunodeficiency virus (HIV), and co-infections associated with the acquired immunodeficiency syndrome (AIDS), including *Mycobacterium tuberculosis*. Lead compounds are identified through published research as well as a DAIDS-sponsored comprehensive portfolio of grant and contract resources designed to discover novel anti-HIV and AIDS-associated opportunistic infection (OI) therapies. Investigators in these and other DAIDS-sponsored pre-clinical programs are actively engaged in researching the basic biology of targeted pathogens, identifying novel therapeutic approaches to treat diseases caused by these infectious agents, and testing therapeutic strategies in animal models.

Databases containing chemical structures and biological data have been established through NIAID contract resources to track the development of chemotherapies for HIV and its associated infections, and to serve as an information resource for NIAID and the scientific community. These databases represent the most up-to-date information resources available for ongoing research in experimental therapies for HIV and OIs, and are essential for supporting the acquisition of new chemicals for biological evaluations conducted by DAIDS-supported screening and testing contractors.

A master database (see Appendix D for a full description) located and maintained at the incumbent contractor's site and which will transfer to the successful Offeror, incorporates six separate databases containing chemical and biological information on (1) anti-HIV therapeutic agents, (2) agents tested for activity against co-infections, (3) agents tested for activity against *M. tuberculosis* and (4) microbicides. The fifth database contains literature citations relevant to AIDS therapies; and the sixth is a publicly available Web database that contains non-confidential portions of the master database. In order to make it available to the public, the Web database resides on a separate server at the NIAID (http://chemdb.niaid.nih.gov). Whenever possible, compounds located on the publicly available Web database link directly to other NIH literature or chemical databases, including PubMed, PubChem and the National Library of Medicine's ChemID Plus database. The PubChem database (http://pubchem.ncbi.nlm.nih.gov) is part of an NIH-wide resource within the molecular libraries and imaging component of the NIH Director's Roadmap Initiative (http://nihroadmap.nih.gov/molecularlibraries/).

DAIDS initiated the creation of the chemical and biological databases for experimental therapies for HIV and OIs in 1988, and contract support for the management and maintenance of the databases was first provided in 1990. The contract was renewed in 1995 and again in 2000. This solicitation provides for the recompetition of a contract currently held by Cygnus Corporation (N01-AI-05422) and due to expire on September 20, 2007. NIAID anticipates awarding a single contract for a term of seven (7) years.

STATEMENT OF WORK

MANAGEMENT OF INFORMATION RESOURCES ON THERAPEUTIC AGENTS FOR HIV AND OPPORTUNISTIC INFECTIONS
RFP NIH-NIAID-DAIDS-07-27

OVERALL OBJECTIVES AND SCOPE

This contract provides for the management of chemical and biological databases which serve as tools for the rational selection and discovery of potential therapies for AIDS and opportunistic infections (OIs). The Contractor shall update the databases with pertinent published literature and NIAID confidential data and information on the chemical, virological, immunological and microbiological aspects of therapeutic agents for HIV, OIs, and TB, and on microbicides.

The chemical and biological databases which the Contractor shall maintain and update are incorporated into a master database and are described as follows:

1. Anti-HIV Therapeutic Agents Database – contains in vitro inhibitory and enzyme mechanistic data from the public literature linked to over 99,529 compounds;
2. Co-infections Database – contains data from the public literature on OI therapeutics, data on tuberculosis-associated agents, and data containing propriety information on more than 108,459 investigational compounds;
3. M. tuberculosis Database – contains data on over 94,386 compounds tested for activity against *M. tuberculosis*;
4. Topical Microbicides Database– contains experimental data on over 1,645 topical agents tested against the spread of HIV;
5. Literature Citations Database – contains over 14,634 references from published literature, patents, and meeting abstracts that can be searched by author, title, journal, patent number or year of publication, and that are linked to Medline abstracts in the PubMed database; and
6. Publicly Available Web Database – located at http://chemdb.niaid.nih.gov, contains non-confidential portions of the master database. Currently, there are over 138,703 compounds linked to over 2,908,104 lines of data on this public website. In addition to the chemical and biologic data, the public website contains links to bi-weekly Literature Surveillance Memos that identify relevant published research on pre-clinical experimental therapies for HIV, OIs, and other viral pathogens.

The scope of information resource management activities to be performed by the Contractor include literature surveillance on experimental therapeutic agents for HIV and OIs, abstraction of relevant data and updating of the chemical and biologic databases, maintenance and updating of the literature citations and publicly available Web databases, maintenance of the computer systems and provisions for quality control. The Contractor shall exercise considerable professional judgment in surveying a broad base of literature sources and in selecting citations that contain information pertinent to HIV and OI preclinical therapeutic and drug discovery efforts.

The sources of data for updating the databases are as follows:

- Public literature (including publications, patents and meeting abstracts)
- HIV and co- infections data reports from DAIDS-supported screening contractors performing in vitro and in vivo biological assays. The data reports will be provided to the Contractor by the Project Officer.

TECHNICAL REQUIREMENTS

Independently and not as an agent of the Government, the Contractor shall furnish all services, qualified personnel, materials, equipment and facilities not otherwise provided by the Government under the terms of this contract as needed to perform the work described below.

The major tasks to be carried out are as follows:

1. Initial Transition
2. Literature Surveillance
3. Abstraction of Data and Updating of Databases
4. Maintenance of a Literature Citation Database
5. Maintenance of the Publicly Available Web Database
6. Software/Hardware Maintenance, Development and Provision of Security
7. Assembly of Preclinical Information Search Requests
8. Scientific and Technical Personnel
9. Facilities, Equipment, and Other Resources
10. Project Management
11. Final Transition

1. INITIAL TRANSITION

In the event the incumbent contractor is not successful in the recompetition, the Project Officer will provide the Contractor with a copy of the incumbent contractor's Final Transition Plan concurrent with the contract award.

a) Within fifteen (15) calendar days of contract award, the Contractor shall submit for Project Officer review and approval, an Initial Transition Plan and timetable for the receipt, storage, and transfer of all items in the incumbent contractor's Final Transition Plan. This Plan shall include, but may not be limited to equipment, databases, back-up tapes, hard discs, hardware and software, source code for all developed software, documentation, and licenses.

b) Upon receipt of written approval by the Project Officer, implement the Initial Transition Plan to complete the tasks associated with the initial transition within thirty (30) calendar days.

2. LITERATURE SURVEILLANCE

The Contractor shall perform literature searches for graphical and text data on experimental therapeutic agents for HIV and OIs.

a) Monitor current publications (including U.S. and foreign patents) in chemistry, virology, immunology, microbiology, biochemistry and biology, and identify relevant published research findings on experimental therapies for HIV and OIs. When requested by the Project Officer, provide hard copies of designated publications. Utilize electronic access to computerized data information systems such as Web of Science, CAS-ONLINE, CAS-SciFinder, DIALOG, MEDLINE, International Pharmaceutical Abstracts and full text U.S. and European patent databases. The Contractor shall have an Internet address and send and receive files electronically via standard file transfer protocol (FTP), secure file transfer protocol (SFTP), or other NIAID preferred protocol.

b) Within fourteen (14) calendar days after contract award, provide the Project Officer with the first bi-weekly Literature Surveillance Memos containing literature citations for both HIV and OIs of potentially relevant published research works identified in paragraph 2a. Subsequent biweekly Literature Surveillance Memos, containing an average of 90

literature citations, shall be provided to the Project Officer every two weeks over the contract's period of performance. Bi-weekly Literature Surveillance Memos shall be provided as hard copies and electronic files with links to online libraries and databases that include the following elements: 1) database used to generate the citation; 2) citation title; 3) citation author(s), and 4) journal or patent number and date of publication. Within five (5) business days of receipt of the bi-weekly Literature Surveillance Memos, the Project Officer will review the literature citations, and provide the Contractor with a subset for abstracting. An average of 70 citations for abstracting is anticipated on a monthly basis.

3. ABSTRACTION OF DATA AND UPDATING OF DATABASES

The Contractor shall identify and abstract relevant chemical and biological information on experimental therapies for HIV and OIs from the public literature and from HIV and co-infections data reports from DAIDS-supported screening contractors for updating of the HIV, OI, TB and microbicides databases.

a) Identify, for inclusion into the HIV, OIs, TB and microbicides databases, relevant chemical and biological data described in paragraph 3.b) below, from a subset of the citations in the bibliography described in paragraph 2.b), and from public or confidential HIV and co- infections data reports from DAIDS-supported screening contractors performing in vitro and in vivo biological assays. The subset of citations and the public or confidential contract data reports for abstracting will be provided by the Project Officer. Exert a critical expert opinion on the validity and authenticity of the identified relevant data.

b) Abstract the following relevant chemical and biological information:

1. chemical structure, name and synonyms;
2. chemical class;
3. *in vitro* antiviral activity against HIV-1 and HIV-2, simian immunodeficiency virus (SIV), and feline immunodeficiency virus (FIV);
4. *in vitro* antimicrobial activity against M. tuberculosis, M. avium, Pneumocystis carinii, Toxoplasma gondi, Cryptosporidium parvum, Microsporidium, Cytomegalovirus, fungi (Cryptococcus, Candida, and Aspergillus), Hepatitis C, and other AIDS-related pathogens;
5. inhibitory activity against relevant isolated enzymes (e.g. reverse transcriptase, protease, integrase and dihydrofolate reductase, etc.);
6. *in vivo* biological activity in relevant animal models of AIDS-related infections;
7. possible mode(s) of action;
8. major research finding(s) if any. Such findings may include, but not be limited to, a new class of chemicals with potent biological activity, a new mode of action, or activity against resistant strains;
9. literature reference(s); and
10. NIAID contract or grant source number if applicable and available.

c) Add abstracted information specified above from the subset of literature citations and the HIV and OIs contract data reports to the corresponding HIV, OIs, TB and microbicides databases. The HIV and OIs contract data reports contain data compatible with the HIV, OIs, TB and microbicides database fields.

d) Transfer the open literature portions of the data fields from the HIV, OIs, TB, and microbicides databases to the publicly available Web database.

4. MAINTENANCE OF A LITERATURE CITATION DATABASE

The Contractor shall maintain and update a literature citation database containing bibliographic data relevant to HIV, OIs and TB therapies using ProCite software.

a) Update the literature citation database with all the biweekly literature citations contained in the Literature Surveillance Memos as described in paragraph 2.b). The literature citations database shall include author(s), title, journal, patent number, year of publication, and name of the electronic database searched.

b) Maintain and update a PDF file containing the subset of citations selected to be abstracted as described in paragraph 3.a), as an Oracle table and link each citation to the corresponding chemical structure and biological data in the HIV, OIs, TB, and microbicides databases.

c) Transfer all the biweekly literature citations in HTML format and with links to PubMed abstracts to the publicly available Web database.

d) Provide hardcopies of reprints requested by the Project Officer. All reprints shall be the property of DAIDS and shall be located in the offices of DAIDS staff in Bethesda, Maryland. Reprints requested by the Project Officer shall be delivered within two business days after the request.

5. MAINTENANCE OF THE PUBLICLY AVAILABLE WEB DATABASE

a) Maintain the availability of the public Web database without interruption by identification and correction of any problems in the system in collaboration with the NIAID Office of Technology Information Systems (OTIS) staff. Download of all updates and computer programs from the Contractor to the publicly available database server will be performed by OTIS staff.

b) Update the Web database every three (3) months through the transfer of non-confidential portions of the data fields from the HIV, OIs, TB and microbicides databases. Update the Web database biweekly with literature citations described in paragraph 2.b). All updates shall be provided to the assigned OTIS staff responsible for the download through e-mail or computer disc. The contents of the Web database are available on the web site **http://chemdb.niaid.nih.gov.**

c) Wherever possible, link compounds directly to other NIH literature or chemical databases, including PubMed, PubChem and the National Library of Medicine's ChemID Plus database.

6. SOFTWARE/HARDWARE MAINTENANCE, DEVELOPMENT AND PROVISION OF SECURITY

a) Provide software and hardware maintenance, computer update support, biweekly backups, and adequate security provisions to protect the confidentiality, integrity, and availability of the data as approved by the Project Officer. The Contractor shall perform database entry/editing/quality control, and management and maintenance of Molecular Design Limited (MDL) software ISIS/Base, ISIS/Draw, ISIS/Host, ProCite and Oracle software. The Contractor shall provide modifications to maintain and enhance effectiveness, reliability, and integration of disparate databases, and correct any identified problems in the systems.

b) Utilize industry best practices in the development of all software which includes, but is not limited to maintenance updates to fix bugs, improvements for security issues,

or enhancements (such as improved structured queries for the Oracle data) as requested by the Project Officer. Any software developed shall conform to NIAID OTIS standards and be compatible with existing NIAID infrastructure and applicable Federal Information Processing Standards (FIPS), HHS, NIH, and NIAID ADP and Information Security policies. These standards will be provided to the Contractor by OTIS staff.

c) Provide NIAID with onsite media and licensing for all required software (e.g. MDL ISIS, Oracle, etc.), documentation and source code of all developed software. All computer software, documentation and deliverables shall be the property of the U.S. Government.

d) Utilize staged deployment techniques as deemed necessary by NIAID OTIS staff; thoroughly test software in the development arena before staging on quality assurance (QA); participate in QA testing when appropriate; develop automated software installation where possible; and support deployment on production systems that would minimize adverse operational impact.

e) Assist NIAID OTIS staff with the production of security Certification and Accreditation (C&A) documents by providing information as demonstrated for testing of system security controls. Develop, with NIAID OTIS input, a Plan of Action and Milestones (POA&M), that describes the measures that have been implemented or planned: (i) to correct any deficiencies noted during the assessment of the security controls; and (ii) to reduce or eliminate known vulnerabilities in the information system. The Contractor will provide NIAID OTIS (specifically the NIAID Information System Security Officer [ISSO]) a copy of the System Security Plan (SSP).

f) Develop a Disaster Recovery Plan within six (6) months of contract award, document a detailed list of disaster recovery procedures, and provide onsite assistance for the publicly available web database in the event disaster recovery is needed. A copy of the Disaster Recovery Plan shall be submitted to the Project Officer, Contracting Officer, and NIAID OTIS staff for review and approval, be located at the NIAID and will be the property of the NIAID.

7. ASSEMBLY OF PRECLINICAL INFORMATION SEARCH REQUESTS

a) At the request of the Project Officer, the Contractor shall use literature sources, including commercially available databases and the databases maintained by the Contractor, to survey, retrieve, and assemble preclinical information on designated drugs or agents. The Contractor shall process each request utilizing appropriate expertise, and check the output for accuracy, completeness, and relevancy.

b) Within two (2) business days of receipt of the request from the Project Officer, the Contractor shall present the data to the Project Officer in a written format or as specified by the Project Officer.

8. SCIENTIFIC AND TECHNICAL PERSONNEL

The Contractor shall provide scientific and technical personnel with the expertise and experience required to manage scientific information resources on therapeutics for HIV and OIs, including:

a) A Principal Investigator with a doctoral degree in medicinal chemistry/biology, knowledge in the area of HIV and OI therapeutics research, experience in using and

maintaining software in the management of chemical and biological databases, experience with extracting and prioritizing relevant information from the scientific literature on HIV and OI experimental therapies, and experience with the administration and overall monitoring of information resource management projects.

b) Key scientific and professional staff with appropriate knowledge, training, and experience in the area of HIV and OI therapeutics research; experience with literature surveillance and on-line database searches; and expertise in relational databases.

c) Data Entry and Information Technology staff with training and experience in the entry of chemical structure and biological information into chemical and biological databases, and training and expertise in database management, and hardware and software maintenance.

9. FACILITIES, EQUIPMENT, AND OTHER RESOURCES

The Contractor shall provide and maintain the following facilities, equipment and resources to carry out the requirements set forth in the Statement of Work:

a) A central facility for literature surveillance, abstracting of chemical and biological data, and updating of the databases.
b) All computer hardware and software, computer equipment and services.
c) Dedicated space for staff and equipment.
d) Controlled access areas for secure storage of data reports, reprints, and confidential information.

10. PROJECT MANAGEMENT

a) **Overall Management**

Provide a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and management and completion of all projects carried out under this contract. This infrastructure shall include a Principal Investigator with responsibility for overall project management and communications, tracking, monitoring and reporting on project status, progress and costs.

b) **Meet with the Project Officer**

Meet with the Project Officer and appropriate DAIDS staff every two months for one day at NIAID offices in Bethesda, Maryland, to review progress, discuss anticipated or existing problems, and the work to be performed in the near future.

c) **Communicate Effectively with the Project Officer**

1) Establish electronic communication with the Project Officer sufficient to support exchange of e-mail and the submission of data files and reports when requested.
2) Provide periodic updates of project status, at a frequency to be scheduled after contract award, via telephone or e-mail.
3) Submit, Technical Reports, and Other Reports/Deliverables in a timely fashion in accordance with the Reporting Requirements and Deliverables Section of this contract.

11. FINAL TRANSITION

The Contractor shall ensure an orderly and efficient transition of contract-related materials to a successor contractor or to the Government by the expiration date of the contract, if required by the NIAID:

a) Prepare and submit, for review and approval by the Project Officer and the Contracting Officer, a written Final Transition Plan three (3) months prior to the expiration of this contract. The Final Transition Plan shall detail the transfer of all or part of this project to a subsequent contractor or the Government.

b) Implement the Final Transition Plan as approved by the Project Officer and the Contracting Officer for the transfer of data, back-up tapes, hard discs, software, source code of all developed software, documentation, and related licenses. Complete documentation shall accompany all software. Any software, licensing, intellectual rights, source code, and documentation developed by the Contractor for these systems shall become the property of the Government.

c) Provide the successor contractor with all acquired publications, reprints, abstracts and any other documents, results of all searches, database entries, and files necessary for the continuation of this contract.

REPORTING REQUIREMENTS AND DELIVERABLES

MANAGEMENT OF INFORMATION RESOURCES ON THERAPEUTIC AGENTS FOR HIV AND OPPORTUNISTIC INFECTIONS
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A. TECHNICAL REPORTS

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit technical progress reports covering the work accomplished during each reporting period. These shall be factual and prepared in accordance with the following format (refer to paragraph B, Technical Reports Delivery Schedule, for distribution and submission requirements).

1. Weekly Progress Reports

a. The Contractor shall submit one copy of a 1-2 page Weekly Progress Report to the Project Officer and one copy to the Contracting Officer that shall contain: a) number of compounds entered in each database (i.e., HIV, OI, TB, and microbicide) and b), brief description of overall activities and highlights of accomplishments during the week.

2. Semi-Annual Progress Reports

a. The Contractor shall submit three (3) copies of a Semi-Annual Progress Report that shall include:
b. Aims, objectives and rationale
c. Highlights of accomplishment during the reporting period
d. Assessment of computer support activity
e. Narrative discussion of work accomplished during the reporting period
f. Narrative evaluation of data entered in databases during the reporting period that shall include the number of compounds (synthetic or natural products) related to biological target, chemical classes, and source of data
g. Results of efforts, both positive and negative
h. Discussion of any special activities to be undertaken during the next reporting period

i. A Semi-Annual Progress Report shall not be required when the Final Report is due.

3. Final Report

a. The Contractor shall submit three (3) copies of a draft Final Report thirty (30) days prior to the expiration date of the contract, which documents and summarizes the work accomplished during the entire contract period of performance. The Final Report shall not include detailed copies of information previously submitted in the Weekly Progress Reports or Semi-Annual Progress Reports, but shall include enough detail to document the contract's accomplishments. The Final Report shall be submitted by the expiration date of the contract.

4. Summary of Salient Results (Form 1688-1)

The Contractor shall submit, with the Final Report, a brief summary (not to exceed 200 words) of salient results achieved during the contract period of performance.

Report Format

All reports shall contain a title page, which includes:

a. Contract number and title
b. Type of report (Weekly, Semi-Annual or Final)
c. Period of performance being reported
d. Contractor's name and address
e. Author(s)
f. Date of submission

B. TECHNICAL REPORTS DELIVERY SCHEDULE

If the Contractor is unable to deliver the reports specified above within the established due dates because of unforeseen difficulties, not withstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of anticipated delays with reasons therefore and a proposed revised due date. The Contracting Officer with the advice of the Project Officer will notify the Contractor regarding the appropriate action to be taken.

Type of Deliverable	**Initial Report Due**	Recipients & Copies	**Subsequent Reports Due**
Weekly Progress Reports	1 Week after effective date of contract	1 electronic copy – PO, CO	Weekly, due no later than each Monday
Semi-Annual Progress Reports	Six months after effective date of contract	2 hard copies and electronic copy- PO 1 hard copy and electronic copy – CO	Semi-annually, due no later than 15 days after the end of each 6 month period. Semi- Annual Progress Report is not due when a Final Report is due.
Draft Final Report	30 days prior to the expiration date of contract	2 hard copies and electronic copy - PO 1 hard Copy and electronic copy– CO	An edited/corrected Final Report is due on the expiration date of the contract
Form 1688-1	On the expiration date of the contract	hard and electronic copy – PO, CO	NA

C. OTHER REPORTS/DELIVERABLES

The Contractor, subject to Project Officer approval, shall deliver to the Government or its designee by the expiration date of the contract, all government-owned property including computer hardware/software and reprints and citation lists related to different databases.

1. **Biweekly Literature Surveillance Memos**

As referenced in SOW paragraph 2b, prepare and submit to the Project Officer Biweekly Literature Surveillance Memos that include citation lists for both HIV and OIs of potentially relevant published research works. The Biweekly Literature Surveillance Memos shall include the following elements:

A title page which includes:

(1) Contract number and title
(2) Type of literature report, HIV or OIs
(3) Period of performance being reported
(4) Contractor's name and address
(5) A brief introduction describing the subject list
(6) Database used to generate the citation
(7) Citation title
(8) Citation author(s)
(9) Journal or patent and Date of publication

2. Scientific Manuscripts

Scientific manuscripts and/or reports of the studies to be submitted for publication in the peer-reviewed literature and/or presentation of the study results at relevant scientific meetings must be pre-approved by the Project Officer. Manuscripts, abstracts, poster presentations and other publications/presentations shall be submitted to the Project Officer for approval at least 30 days prior to submission for public presentation or publication. The Project Officer will respond within two weeks, when possible. Permission to publish data from third parties (e.g. academic investigators or private drug sponsors) will be obtained from those parties by NIAID prior to Project Officer approval and could delay Project Officer approval.

3. Data

Upon completion of this contract, all data and archived citations/reports collected and maintained under this contract shall be delivered to the Government and/or successor contractors, if any.

4. Initial Transition Plan

Within 15 calendar days after contract award the Contractor shall provide an Initial Transition Plan and timetable for the receipt, and storage of all items potentially being transferred from the incumbent contractor. This shall include equipment, databases, back-up tapes, hard discs, hardware and software, source code for all developed software, documentation, and licenses.

5. Final Transition Plan

Three (3) months prior to the expiration date of the contract, the Contractor shall provide for the Project Officer's approval: (1) a Final Transition Plan, which shall include: transfer of data, back-up tapes, hard discs and software to a successor contractor; and (2) plans for the shipping of acquired publications, reprints, abstracts and any other documents, results of all searches, database entries, and files

necessary for the continuation of this contract to the successor contractor, including a cost estimate for packing and shipping.

6. Plan of Action and Milestones

Within six (6) months of contract start provide a Plan of Action and Milestones (POA&M) to be developed by the Contractor with OTIS input, to address security deficiencies that are demonstrated in the Security certification and accreditation (C&A) process.

7. Disaster Recovery Plan

Within six (6) months of contract award provide a document containing a detailed list of disaster recovery procedures.

8. System Security Plan (SSP)

Within six (6) months of contract award, the Contractor will provide NIAID OTIS (specifically the NIAID Information System Security Officer [ISSO]) a copy of the SSP.

9. NIST SP 800-26 Self-Assessment Questionnaire

The contractor shall annually update and re-submit its Self-Assessment Questionnaire required by NIST Draft SP 800-26, Revision 1, Guide for Information Security Program Assessments and System Reporting Form (http://csrc.nist.gov/publications/drafts/Draft-sp800-26Rev1.pdf

D. OTHER REPORTS DELIVERY SCHEDULE

Item	Type of Deliverable	Initial Report Due	Recipients & Number Copies	**Subsequent Reports Due**
1.	Biweekly Surveillance Memos	14 days after contract award	1 hard and electronic copy each: PO and CO	Biweekly
2.	Scientific Manuscripts	30 days prior to submission	1 electronic copy: PO	As required
3.	Data/citations/ reports	By contract expiration date	1 hard and electronic copy each: PO and CO	N/A
4.	Initial Transition Plan (if required)	15 days after contract award	1 hard and electronic copy each: PO and CO	N/A
5.	Final Transition Plan	3 months prior to contract expiration	1 hard and electronic copy each: PO and CO	N/A
6.	Plan of Action and Milestones	Within 6 months of contract award	1 hard and electronic copy each: PO , CO and NIAID-OTIS	N/A
7.	Disaster Recovery Plan	Within 6 months of contract award	1 hard and electronic copy each: PO , CO and NIAID-OTIS	N/A
8.	SSP	Within 6 months after contract award	1 hard and electronic copy each to ISSO and CO	N/A
9.	NIST SP 800-26 Self-Assessment	Yearly	1 paper and e-Copy to PO	No later than 30 days after contracts

	Questionnaire		1 paper and e-Copy to CO	anniversary date

E. COPIES OF REPORTS SHALL BE SENT TO THE FOLLOWING ADDRESSES:

Project Officer
Drug Development and Clinical Sciences Branch, TRP
Division of AIDS, NIAID, NIH
Room 5149
6700-B Rockledge Drive MSC 7624
Bethesda, MD 20892-7624 (20817 for overnight deliveries)
(Email address to be provided at time of contract award)

Contracting Officer
DAIDS Research Contracts Branch
Office of Acquisitions
Division of Extramural Affairs, NIAID, NIH
6700-B Rockledge Drive MSC 7612
Bethesda, MD 20892-7612 (20817 for overnight deliveries)
(Email address to be provided at time of contract award)

NIAID Information System Security Officer
Office of Technology Information Systems (OTIS)
NIAID, NIH
10401 Fernwood Road
Bethesda, MD 20892
(Email address to be provided at time of contract award)

F. Packaging, Marking and Shipping

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

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APPENDIX A - ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS FORMAT FOR TECHNICAL PROPOSAL – TABLE OF CONTENTS

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

The following additional Technical Proposal instructions reflect the requirements of the RFP and are meant to provide additional instructions as well as a uniform format for Technical Proposals. The information requested in these instructions shall be used as a guide for formatting and preparing the Technical Proposal. Offerors shall follow the instructions in Section L of the solicitation, and include the information requested in this appendix.

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

Offerors who propose subcontracts to perform portions of the Statement of Work shall clearly identify the specific tasks for which they plan to utilize subcontractors, as well as the method and level of integration between the prime and subcontractor(s), and the expected advantages of such an approach.

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

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1

1. **PROPOSAL TITLE PAGE. Include RFP title and number, name of organization, DUNS number, proposal part, and identify if the proposal is an original or a copy.**
2. **PROJECT OBJECTIVES (NIH FORM 1688-1)**
3. **GOVERNMENT NOTICE FOR HANDLING PROPOSALS**
4. **PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)**
5. **TABLE OF CONTENTS**

SECTION 2 – SCIENTIFIC AND PROFESSIONAL PERSONNEL

The Technical Proposal should include all information relevant to document education, training, accomplishments, and relevant experience of all proposed personnel, as well as the percentage of time each will be committed to the project. This includes staff of the Offeror and all proposed subcontractors and consultants. Resumes, endorsements, and explanations of previous efforts should reflect length and variety of experience in similar tasks and should clearly demonstrate specific accomplishments. Documentation should include all previous and current projects of a

similar nature, including the contract number or grant number, the sponsoring agency, the Project Officer, and a description of the project. Limit CVs to three (3) pages for the Principal Investigator and two (2) pages for all other key personnel. Provide selected references for publications relevant to the scope of the RFP.

1. Principal Investigator: Describe the experience, training, expertise, and qualifications, and percentage of effort of the proposed Principal Investigator to lead and direct the activities to be carried out under this contract. The Principal Investigator shall have a doctoral degree in medicinal chemistry/biology and demonstrate knowledge of microbiology, virology and technical aspects of computerized chemical databases. Describe the capacity to monitor progress, assess performance, identify performance problems and implement corrective actions. Describe experience in leading and directing projects of similar size and complexity and familiarity with past and current research in the areas of HIV and co-infections, antivirals, antimicrobials, and microbiology.

2. Key Scientific and Professional Personnel: Describe the experience, training, expertise and qualifications, as well as percentage of effort, for all proposed key scientific and professional personnel, including subcontractors and consultants. This includes scientific and technical expertise and knowledge and familiarity in: past and current research in the area of HIV and co-infections, antivirals, antimicrobials, microbiology, in vitro assays and animal models; conducting on-line literature searches in appropriate chemical and biological databases; qualifications to serve as a resource to DAIDS for advice on the computer science requirements of the contract; and expertise in relational databases and preparation/formatting of text and graphic data for Web site inclusion.

3. Data Entry and IT Personnel: Describe the experience, training, expertise and qualifications, as well as percentage of effort, for all proposed data entry and IT personnel, including subcontractors and consultants. This includes scientific and technical expertise and knowledge in: chemical structures and data entry, quality control and database management. Describe previous experience in preparation of text and graphic data in html and gif format for Web site inclusion and with the use and maintenance of ORACLE and MDL software for database management.

SECTION 3 - TECHNICAL APPROACH

Technical Proposals shall describe specifically how the Offeror shall fulfill each of the items in the SOW.

Literature Surveillance (SOW Task 2)

Provide a plan/technical approach to survey a broad base of literature sources and for selection of citations that contain chemical and biological information on experimental therapies for HIV and OIs. Describe previous experience with the preparation of citation lists containing references related to the mission of DAIDS.

Abstraction of Data and Updating of Databases (SOW Task 3)

Describe the approach for identifying and abstracting relevant chemical and biological information related to HIV and OI experimental therapies, and for updating the corresponding chemical and biological databases**.** Delineate the process to be used to determine the validity and authenticity of the identified relevant data.

Maintenance of a Literature Citation Database (SOW Task 4)

Provide a plan/technical approach for maintaining and updating the literature citation database.

Maintenance of the Publicly Available Web Database (SOW Task 5)

Describe how the Offeror will maintain the availability of the public Web database to the public without interruption. Describe procedures to update the Web database through the transfer of information from the chemical and biological databases.

Software/Hardware Maintenance, Development and Provision of Security (SOW Task 6)

Describe the software/hardware maintenance and development procedures to be used for updating and for maintenance of the databases, quality control, disaster recovery, security and confidentiality of the data. Describe procedures to ensure industry best practices are followed in the development and maintenance of software. Discuss potential problems/obstacles and solutions/approaches to be used to ensure a reliable, efficient, fully operational and responsive data management system.

Assembly of Preclinical Information Search Requests (SOW Task 7)

Describe the technical approach for performing preclinical information search requests requiring substructure or full structure chemical searches. For each of the following search requests, provide the search strategy including the literature sources, the rationale for selecting the most promising chemical structure, the chemical structure, and mode of action if any, and a reference citation.

1. A fused quinoline ring system with anti-HIV activity
2. A fused quinoline ring system with anti-TB activity
3. A fused benzoquinone natural product with anti-HIV activity
4. A fused isoquinoline ring system with anti-HIV activity

SECTION 4 – PROJECT MANAGEMENT

1. Provide a plan for project organization, staffing, and management in relation to the implementation, conduct, monitoring and completion of the tasks identified in the Statement of Work. Describe in detail the responsibilities and level of effort of all proposed personnel who will be assigned to the contract, including proposed subcontractors and consultants and an administrative framework (including an organization chart) indicating clear lines of authority and responsibility for all proposed personnel.

2. Provide a detailed work plan with proposed time schedules satisfactory for achieving contract objectives and procedures for maintaining quality control over the implementation and operation of the contract.

3. Describe the organization's ability to provide appropriate trained personnel, and timely, flexible resources for the project to meet contract requirements. Discuss organizational experience in computerized chemical databases management, maintenance, and quality control. Discuss how projects are prioritized within the Offeror's organization, the level of priority this contract would receive, and procedures for initiation of contract requirements in a timely manner. Provide documentation of prior success in the timely completion of comparable tasks.

4. Discuss how the Principal Investigator will communicate contract progress and interact with the Project Officer and Contracting Officer to effectively monitor and manage the contract.

5. Describe the procedures that will be employed to safeguard confidentiality and intellectual property of data and materials provided to you by third parties or the Government, as well as data generated, during the performance period of the contract.

SECTION 5 - FACILITIES AND RESOURCES

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

a. a description of the location and features of the proposed facilities including a detailed floor plan and a list of equipment and resources dedicated to the project (lease or ownership information shall be provided evidencing availability for the period of performance of the contract); and

.

b. identification and description of all support resources (including IT systems) which will be required to effectively complete the contract requirements.

SECTION 6 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

Data Sharing Plan

Section L of the RFP specifies the minimum documentation requirements for Data Sharing. All related documentation shall be included in the proposal in this clearly marked section.

IT Systems Security

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

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APPENDIX B - ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS

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

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

BUSINESS PROPOSAL – TABLE OF CONTENTS

SECTION 1 – PROPOSAL COVERSHEET

SECTION 2 – COST OR PRICE SUPPORT

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

SECTION 3 – UNIFORM COST ASSUMPTIONS

Literature Surveillance (SOW Task 2)

It is anticipated that on a biweekly basis, for the entire contract period of performance, the Contractor shall provide the Project Officer with a report containing an average of 90 literature citations on relevant HIV and OI chemotherapies.

Abstraction of Data and Updating of Databases (SOW Task 3)

Assume a biweekly citation list of 90 references of which 35 citations will be selected by the Project Officer for abstracting. For the purpose of preparing a cost estimate it is anticipated that 3,500 anti-HIV compounds, 2,500 compounds against OIs, and 2,000 anti-TB experimental drugs shall be entered into the databases on a yearly basis. It is anticipated that seven (7) DAIDS contractors will be submitting reports containing biological data for inclusion into the databases.

Literature Citation Database (SOW Task 4)

For the purpose of preparing a cost estimate, assume that 2,000 citations in PDF version will be added to the literature citation database and about 120 reprints archived per year. Currently 90% of the literature citations are downloaded via modem from the NLM MEDLINE database directly into the ProCite software hosting the literature citation database. Examples of reprints to be

archived are publications that describe the chemistry, biology and therapies for HIV and OIs. Information on the remaining citations is entered manually.

Assemble Preclinical Information Search Requests (SOW Task 7)

Assume that 60 information search requests will be requested annually by the Project Officer. Thirty of the requests will include substructure or full structure chemical searches. Assume 15 of the substructure searches and 15 of the non-substructure searches will require written responses and the remainder will be communicated to the Project Officer via electronic mail.

Meet with the Project Officer (SOW Task 10b)

Assume visits every two (2) months, for one day, by the Principal Investigator and one key person to meet with the Project Officer in Bethesda, MD.

Estimated Level of Effort

Offerors shall assume an overall staffing requirement of approximately six (6) full time equivalents (FTEs) per year. This information is furnished to Offerors for information purposes only and is not to be considered restrictive for proposal purposes.

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

Past Performance Data, including references

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

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APPENDIX C - ADVANCE UNDERSTANDINGS

Confidentiality of Information and Intellectual Property

Confidentiality of Information

Information and data provided to or generated by the Contractor under this contract shall be treated confidentially and protected by an Advance Understanding to be included in the resulting contract and worded as follows:

"Because there is a likelihood that the Contractor will be utilizing and evaluating materials provided to the Government by a third party Provider, it is essential to include provisions that will protect the proprietary rights of the Provider. These materials generally are supplied to the Government as proprietary and confidential. The Contractor shall be bound by the same terms and conditions as the Government in these agreements, with respect to the proprietary and confidential nature of the information provided by the Provider.

All information provided by the Provider or Project Officer shall be assumed to be confidential unless specifically identified as non-confidential in writing by the Project Officer. Confidential information may not be revealed without written permission. All materials supplied to the Contractor and all test results similarly are to be considered confidential. All materials supplied to the Contractor shall be utilized solely for contract-related research purposes and no unauthorized use or distribution of these materials will be permitted.

Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted for review and written approval by the Project Officer before submission for public presentation or publication. Contract support shall be acknowledged in all such publications. A "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information. The Project Officer will review all manuscripts/abstracts in a period of time not to exceed 20 calendar days from receipt, and will either grant clearance for publication/disclosure, recommend changes or, as applicable, refer the document to the Provider of the drug substance for their review. When the Provider does not consent to publication of the manuscript or abstract, the Project Officer shall withhold approval to publish in accordance with the terms and conditions of any existing Evaluation Agreement or Material Transfer Agreement between NIAID and the Provider. NIAID will use its best efforts to assist and expedite the review and approval process by the Provider."

Intellectual Property

Contractors acknowledge that:

* If needed for the project, Contractor is solely responsible for the timely acquisition of any proprietary rights, including intellectual property rights, and all materials appropriate for Contractor to perform the project;

* Contractor acknowledges that prior to, during, and subsequent to the award, the U.S. Government is not required to obtain for Contractor any proprietary rights, including intellectual property rights, or any materials needed by Contractor to perform the project;

* Contractor acknowledges the requirement to report to the U.S. Government all inventions made in the performance of the project, as specified at 35 U.S.C. Sect. 202 (Bayh-Dole Act).

Contractor is encouraged to reach early consensus with any proposed partners regarding any appropriate intellectual property or other legal issues that may arise during the project. In addition, Contractors are expected to exercise their Bayh-Dole rights in a manner that does not conflict with the goals of this award or the intent of the Bayh-Dole Act to promote the utilization, commercialization and availability of U.S. Government-funded inventions for public benefit. Finally, Contractor is expected to make new information and materials known to the research community in a timely manner through publications, web announcements, and reports to the NIAID or other mechanisms consistent with laws, regulations, and NIH policies.

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

Division of Acquired Immunodeficiency Syndrome, NIAID
Non-Clinical Evaluation Agreement

NIAID Non-Clinical Evaluation Agreement

This Agreement is made and entered into between the National Institute of Allergy and Infectious Diseases ("NIAID"), having offices at Bethesda, Maryland 20892, and <insert institution>, having offices at <insert institution's city, state zip> ("Provider").

Provider has requested to participate in one or more of the anti-infective or other non-clinical evaluation programs funded by the Division of Acquired Immunodeficiency Syndrome (DAIDS), part of the National Institute of Allergy and Infectious Diseases (NIAID), an institute of the National Institutes of Health (NIH), which is a component of the Department of Health and Human Services (HHS), an agency of the U.S. Government.

Provider may request to submit without charge patented or unpatented drugs, compounds or other products to NIAID. Through its contract testing laboratories or contract coordinating facilities, NIAID may evaluate the submitted material for possible activity against infectious organisms or perform other non-clinical evaluations.

NIAID and Provider therefore agree as follows:

1. Definitions.

1.1 "Confidential Information" is scientific, business or financial information the Provider or NIAID deem to be proprietary or confidential and which information is identified in writing on submitted materials.
1.2 "Contractors" are NIAID approved non-profit and for-profit testing laboratories with contractual obligations to NIAID that NIAID represents to be consistent with the terms of this Agreement.
1.3 "Evaluations" will include the testing of the Materials by the protocols.
1.4 "Invention" means any invention or discovery which is or may be patentable or otherwise protected under title 35, United States Code, or any novel variety or plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).
1.5 "Materials" means chemical matter and compositions submitted by the Provider.
1.6 "Results" means all recorded data, results, and technical information first produced from the Evaluations of the Materials under this Agreement and not previously disclosed by the Provider.

2. Evaluations of Materials.

2.1 NIAID has the right to decline to conduct Evaluations of any Materials. Provider understands that not all Evaluations offered by NIAID are available at all times. Evaluations will be approved jointly by NIAID and the Provider.
2.2 At Provider's request and with the prior approval of NIAID, Material to be evaluated may be submitted to Contractors under code. NIAID must be provided with the key to the code and the chemical structures of the encoded material to prevent duplication of evaluations.

2.3 Under the direction of NIAID, Provider will forward to NIAID the Materials and data sheets of the Materials which contain pertinent available data as to chemical composition, purity, solubility, toxicity, previous biological efficacy and any precautions that need to be followed in the handling, storing, and shipping of Materials.

2.4 NIAID will work in conjunction with Contractors to ensure rapid ongoing communication of Results to the Provider, and Provider will in turn use reasonable efforts to keep NIAID informed of Provider's own concurrent studies with the Materials that may affect Evaluations or Results.

2.5 Materials are to be used by Contractors for Evaluations under this Agreement only and for no other purpose. In addition, the Materials will not be chemically modified, replicated, derived or reverse engineered unless specifically necessary for the performance of the Evaluations. Upon completion of Evaluations, all unused Materials will be returned to Provider or destroyed as directed by Provider.

3. Confidentiality.

3.1 Provider may provide Confidential Information relevant to the Evaluation of the Materials to NIAID and the Contractors. NIAID represents that the Contractors are required by their NIAID contracts to protect such Confidential Information with reasonable efforts as specified in 3.3 below.

3.2 To the extent permitted by law, Confidential Information disclosed to NIAID or the Contractors will remain confidential for five (5) years after the effective date of this Agreement unless the information:

a) Is known by the public or becomes known by the public through no fault of NIAID or the Contractors;

b) Was obtained by NIAID or the Contractors, without restriction, from a third party having no confidentiality obligation to the Provider;

c) Has been independently developed by NIAID or the Contractors without reference to the Provider's Confidential information; or

d) Is required to be disclosed by law, regulation or court order provided that Provider has been notified and NIAID or the Contractors has taken reasonable efforts to minimize the extent of the required disclosure.

3.3 NIAID will ensure that Confidential Information is kept in restricted-access files. Only personnel directly involved in the Evaluations will have access to the files containing Confidential Information. Provider acknowledges that Results are not Confidential Information, unless deemed otherwise by NIAID, and may be disclosed by NIAID and the Contractors in accordance with Article 4 below.

4. Disclosure of Results.

4.1 NIAID and the Contractors may publish or otherwise publicly disclose Results after a period of six (6) months from the date of transfer of Results to Provider. After this period of time NIAID will consult with Provider, and will require the Contractors to consult with Provider, whenever Results are included in any publication or other public disclosure such as a press release. The six month delay in disclosure is intended to allow Provider time to file patent applications if desired.

4.2 Publication of Results earlier than the six (6) month period by NIAID or Contractors will require Provider's prior written consent, which will not be unreasonably withheld.

4.3 Provider will not be identified in NIAID or Contractor publications as the source of Materials without Provider's prior written approval.

4.4 Provider will allow NIAID fourteen (14) days to review and comment of any proposed press releases, paper, or abstract for publication relating to the Evaluations or Results. Provider will not construe the involvement of NIAID in Evaluations as an endorsement of Materials by the U.S. Government or any of its agencies, employees or Contractors.

4.5 Provider will include acknowledgement of NIAID and the contracts providing support in any publication or press release.

5. Intellectual Property.

5.1 NIAID acknowledges that this Agreement may not be construed as a grant by the Provider of a license or any other right or interest to the Materials beyond those expressly set forth herein.

5.2 Provider acknowledges that the Contractors have the right to elect to retain title to any new Invention(s) made under NIAID sponsored contracts [37 CFR 401.14(b)]. However, Contractors have agreed to an "Intellectual Property Option" as part of their contracts with NIAID. Under the Intellectual Property Option the Contractors are required to:

a) Promptly notify NIAID and the Provider of any new Invention(s) made by the Contractors in the performance of the Evaluations under this Agreement;

b) Grant Provider a paid-up, nonexclusive, nontransferable, royalty-free, world-wide license to all such new Invention(s) for research purposes only; and

c) Grant Provider a time-limited first option to negotiate an exclusive, world-wide royalty-bearing license to Contractor's interest in all such new Invention(s) for all commercial purposes, including the right to grant sub-licenses, on terms to be negotiated in good faith by Provider and the Contractor.

6. Warranty and Limitation of Liability.

6.1 NIAID acknowledges and agrees that the Materials are experimental in nature. PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTY OF ANY KIND, EITHER EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR WARRANTY THAT THE USE OF MATERIALS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK OR OTHER PROPRIETARY RIGHT.

6.2 It is the intention of NIAID that Provider not be liable for any claims or damages arising from use of the Material by NIAID; however, no indemnification for any loss, claim, damage, or liability is intended or provided by NIAID under this Agreement. NIAID shall be liable for any loss, claim, damage, or liability that NIAID incurs as a result of its activities under this Agreement, except that NIAID, as part of an agency of the United States, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. §§ 2671 et seq.

7. Term and Termination.

7.1 This Agreement will be in effect for five (5) years from the date of the last signature below.

7.2 Either NIAID or Provider may terminate this Agreement at any time by giving written notice at least thirty (30) days prior to the desired termination date.

8. Amendments.

8.1 If NIAID or Provider desires an extension of, or other modification to this Agreement they will, upon reasonable notice to the other, confer in good faith to determine the desirability of the modification. No modification is effective until a written amendment is signed by authorized representatives of NIAID and Provider.

8.2 If Provider desires to add Materials or Evaluations not originally agreed to, prior approval from NIAID is required and an amendment to this Agreement must be made. All terms and conditions of this Agreement will remain in full force and effect.

9. Governing Law.

The construction, validity, performance and effect of this Agreement shall be governed by Federal law, as applied by the Federal Courts in the District of Columbia. Federal law and regulations will preempt any conflicting or inconsistent provisions in this Agreement. The illegality or invalidity of any provisions of this Agreement shall not impair, affect, or invalidate the other provisions of this Agreement.

10. Survivability.

The provisions of Articles 3, 4, 5, 6, 9 and 10 will survive the termination or expiration of this Agreement.

11. Points of Contact.

NIAID Agreement POC

Name:
Title:
Organization:
Street/Bldg:
City: State: Zip:
Phone:
Fax:
Email:

NIAID Scientific POC

Name:
Title:
Organization:
Street/Bldg:
City: State: Zip:
Phone:
Fax:
Email:

Provider Agreement POC

Name:
Title:
Organization:
Street/Bldg:
City: State: Zip:
Phone:
Fax:
Email:

Provider Scientific POC

Name:
Title:
Organization:
Street/Bldg:
City: State: Zip:
Phone:
Fax:
Email:

Accepted and agreed by the Parties through their duly authorized representatives as of the last date of signature below.

FOR NIAID:

_____

Name: Edmund C. Tramont, MD Date:

Title: Director, DAIDS, NIAID

Address:

Phone/Fax:

FOR PROVIDER:

_____

Name: Date:

Title:

Organization:

Address:

Phone/Fax:

Intellectual Property Option to be offered to NIAID's Third Party Providers of Proprietary Material *and* Protection of Resultant Proprietary Data.

This Article Must be Included In Any Subcontract for Evaluation of Material. The Subcontractor Shall Then Have All the Obligations of the Contractor.

The goal of this contract is to promote the development of critical biological information by evaluating various materials for anti-microbial activity. For the purposes of this agreement, "material" includes compositions of matter, and associated information such as methods of making or using the compositions. It is expected that the great majority of materials will be proprietary to third parties. It is clear from the NIAID's experience that third party providers ("Provider") will not provide their proprietary material ("Material") without assurance that the intellectual property rights associated with their Materials will be protected. Accordingly, to encourage Providers to provide their Materials for evaluation under this contract the Contractor agrees to the Article pertaining to the Intellectual Property Option to the Provider, which requires the Contractor and its subcontractors to provide a research use license and a commercialization license option to Subject Inventions made under the contract to the Providers as follows:

The Contractor agrees to promptly notify the NIAID and the Provider in writing of any Subject Inventions of the Contractor, its Principal Investigator and/or any other employees or agents of the Contractor, whether patentable or not, which are conceived and/or first actually reduced to practice in the performance of work under this contract using a Provider's Material (hereinafter "Contractor Invention"). The notice shall inform the Provider(s) of its right to the option set forth herein. This may be accomplished by attaching a copy of the Article to the notice.

(1) Single Provider

With respect to Contractor Inventions resulting from the use of Material provided by one Provider, the Contractor agrees to grant to the Provider: (i) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Contractor Inventions for research purposes only; and (ii) a time-limited first option to negotiate an exclusive, world-wide royalty-bearing license for all commercial purposes, including the right to grant sub-licenses, to any Contractor Invention on terms to be negotiated in good faith by the Provider and the Contractor, subject to the following conditions:

The Contractor will allow Provider three (3) months from the date the Contractor sends written notice to the Provider of the existence of a Contractor Invention (or such additional period as the Provider and the Contractor may agree) to notify the Contractor in writing, whether or not it wants to obtain an exclusive license to the Contractor Invention. If the Provider fails to notify the Contractor, in a timely fashion then the Contractor's obligation to offer Provider a license option with respect to that Contractor Invention will expire, and the Contractor will be free to dispose of its interests in such Contractor Invention in accordance with the Contractor's policies. If the Contractor and the Provider fail to reach agreement within ninety (90) days, (or such additional period as the Provider and the Contractor may agree) on the terms for an exclusive license for a particular Contractor Invention, then for a period of six (6) months thereafter the Contractor will not offer to license that Contractor Invention to any third party on materially better terms than those last offered to the Provider without first offering such terms to the Provider, in which case the Contractor will offer the Provider a period of thirty (30) days in which the Provider can accept or reject the offer.

(2) Multiple Providers

With respect to a Contractor Invention resulting from the use of Materials provided by multiple Providers, but which is an improvement only to a Material of a specific Provider, the Contractor agrees to grant to that Provider the rights described above in (1).

With respect to any Contractor Inventions resulting from the use of Material from multiple Providers, but that are not improvements to or specific to a single Material, the Contractor agrees to grant to each Provider who provided Material: (i) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Contractor Inventions for research purposes only; and (ii) a time-limited first option to negotiate a co-exclusive, world-wide royalty-bearing license for all commercial purposes, including the right to grant sub-licenses, to all such Contractor Inventions on terms to be negotiated in good faith by each Provider and the Contractor subject to the following conditions:

The Contractor will allow each Provider three (3) months from the time the Provider is sent written notice by the Contractor of the existence of a Contractor Invention (or such additional period as each Provider and the Contractor may agree) to notify the Contractor, in writing, whether or not the Provider wants to obtain a co-exclusive license to the Contractor Invention. If a Provider fails to notify the Contractor, in a timely fashion then Contractor's obligation to offer that Provider a license option with respect to that Contractor Invention will expire and the Contractor will continue to offer an option to a co-exclusive license to the other Providers as set forth herein. If there is a single other Provider, it shall be offered an option to an exclusive license as though it were a single Provider. If no Provider notifies the Contractor in a timely fashion the Contractor will be free to dispose of its interests in such Contractor Invention in accordance with the Contractor's policies.

Provider Inventions

The Contractor agrees that notwithstanding anything herein to the contrary, any invention or discovery, whether patentable or not, which is not a Subject Invention as defined in **35 USC 201(e)**[1] but arises out of an intentional and unauthorized use or modification of the Provider's Material by the Contractor and/or any other employees or agents of the Contractor, will be the property of the Provider (hereinafter "Provider Invention"). The Contractor will promptly notify the Provider in writing of any such Provider Inventions and, at the Provider's request and expense, the Contractor will cause to be assigned to the Provider all right, title and interest in and to any such Provider Inventions and give Provider any assistance reasonably necessary to obtain patents (including causing the execution of any invention assignment or other documents). The NIAID recognizes that the Contractor may also be conducting other research using the Provider's Material under the authority of a separate agreement with the Provider during the term of this contract; any invention arising under such separate agreement will not be subject to the terms of this provision entitled, **"Provider Inventions."**

Protection of Proprietary Data

All Materials, data and other information supplied by the Provider or the Project Officer shall be assumed to be confidential unless specifically identified as not confidential in writing by the Project Officer. The Contractor agrees that its Principal Investigator and/or any other employees or agents of the Contractor will provide the data generated under this contract exclusively to the NIAID or if directed by the NIAID, to the Provider and the FDA or other appropriate Federal agency. The Contractor understands that the NIAID must negotiate individual agreements with the various Providers to obtain Materials and that the terms of the agreements may vary. The NIAID intends that these agreements will provide for the Contractor's right to publish results generated by the Contractor under this contract after a reasonable period of time to allow the Provider to file patent applications and to protect its proprietary information. The Contractor agrees to enter into confidentiality agreements with Providers when required by the Providers as a condition for the Contractor to receive Materials. Such agreements shall reference this contract by contract number and shall be consistent with any agreement the NIAID has entered into with the Provider to obtain Materials. In the event the Contractor reasonably objects to the terms of the confidentiality agreement, the Contractor shall promptly bring such objection to the attention of the Contracting Officer for an appropriate resolution.

[1]35 USC 201(e): The term "subject invention" means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: Provided, That in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act (7 U.S.C. 2401(d)) must also occur during the period of contract performance.

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APPENDIX D - MASTER DATABASE

The Master Database developed and maintained by a previous contractor for NIAID incorporates six separate databases with 299 data fields containing chemical and biological information on (1) anti-HIV therapeutic agents, (2) agents tested for activity against co-infections, (3) agents tested for activity against M. tuberculosis, (4) agents tested in topical microbiocide assays, (5) a bibliographic literature citations database (DB), and (6) publicly available Web database. The Anti-HIV Therapeutic Agents DB contains published literature information, is subdivided into the Anti-HIV Cellular DB and the Anti-HIV Enzyme DB. The Anti-HIV Cellular DB contains over 148,927 lines of in vitro inhibitory data (EC50, TC50, TI, viral resistance, etc.) linked to over 73,985 compounds. The Anti-HIV Enzyme DB contains over 48,443 lines of data (IC50, Ki, etc.) linked to more than 25,544 compounds. The Co-infections DB is composed of three components; public literature, TB-associated agents and a separate proprietary database of data generated by NIAID-supported contract screening laboratories. The public literature-associated co- infections DB contains over 229,149 lines of data (enzyme, cellular cytotoxicity, in vitro organism assays, and in vivo animal model efficacy) linked to more than 58,189 compounds; about one-third of this data is related to viral pathogens. There are 94,386 compounds with over 127,599 lines of data for agents tested for activity against M. tuberculosis in the M. tuberculosis DB. The proprietary co-infections data, only accessible to NIAID staff, is maintained in 17 Oracle tables. These tables contain over 378,749 lines of data linked to more than 108,459 investigational compounds. The fourth database, Topical Microbiocide DB contains experimental data on topical agents being developed to prevent the spread of HIV. There are over 1,645 compounds linked to more than 8,764 lines of data. The fifth database, Literature Citation DB, contains over 14,634 references from literature, patents, and meeting abstracts that can be searched by author, title, journal, patent number or year of publication. These references are linked to Medline abstracts in the PubMed database. The sixth database contains the public portions of the databases listed above, referred to as the publicly available Web database and resides on a Website located at http://chemdb.niaid.nih.gov. This website offers a searchable, publicly available, chemical/biological database, of published information pertaining to compounds tested against HIV, OI's, TB and other viruses. Currently, there are 138,703 compounds linked to over 2,908,104 lines of data on this public website. The web database contains 208 fields for the chemical and biological data. One additional feature of this website is the Literature Memos DB that contains links to bi-weekly literature surveillance memos that identify relevant published research on pre-clinical experimental therapies for HIV, OIs and other viral pathogens. Overall the Master DB contains data derived from the open literature, patents and NIAID-supported contract-screening laboratories.

The chemical databases are currently managed using ISIS™/Base and ISIS/Host 4.0 (Window 2000 server/IIS5), ISIS/Direct 2.0, and ISIS/QSAR 2.2 software (MDL Information Systems, Inc., San Leandro, CA) for chemical structures. ORACLE and PROCITE™ software version 5.0.3 (ISI, Philadelphia, PA) are utilized for data management and for the literature citations database.