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

RFP-NIH-NIAID-DAIDS-07-45
"NIAID Specimen Repository"

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:** November 27, 2006	5. **Small Bus. Set-Aside:** [ ]Yes [X] No
September 22, 2006	**Time:** 3:00 p.m., EST	**8(a) Set-Aside:** [ ]Yes [X] No
		NAICS #: 541710
		(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 Attachment 1

9. **Issued By:**	10. [X] **NIAID reserves the right to make awards without discussions.**	
Joshua J. LaVine, Contract Specialist Office of Acquisitions, DEA NIAID, NIH, DHHS 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	11. **Options:** **[ ] No** **[X] Yes (See Part IV, Section L.)**	12. **Period of Performance:** Up to 7 years beginning on or about September 15, 2007

13. **Primary Point of Contact:**	14. **Secondary Point of Contact:**	15. **Protest Officer:**
Name : Joshua J. LaVine	**Name: Eileen Webster-Cissel**	Charles W. Grewe
Phone: 1-866-410-5758 (Ext. 27149)	**Phone:** 301-496-0349	Director, Office of Acquisitions
Fax: 301-402-0972	**Fax:** 301-402-0972	**Address (See block 9.)**
E-Mail: JLaVine@niaid.nih.gov	**E-Mail:** Webstere@niaid.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**
Joshua J. LaVine Office of Acquisitions, DEA NIAID, NIH, DHHS 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	Joshua J. LaVine 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.

DETAILED TABLE OF RFP CONTENTS

PART I - THE SCHEDULE

THE CONTRACT SCHEDULE SET FORTH IN **SECTIONS B THROUGH H**, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS **NOT** AN EXACT REPRESENTATION OF THE CONTRACT DOCUMENT THAT WILL BE AWARDED AS A RESULT OF THIS SOLICITATION. THE CONTRACT COST OR PRICE AND OTHER CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR *(i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror's proposal and requiring Contracting Officer Prior Approval)* WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The purpose of this contract is the continuation of an ongoing specimen storage and management program for HIV seropositive and negative specimens received from subjects enrolled in NIAID-sponsored multi-site clinical and epidemiological studies.

ARTICLE B.2. PRICES/COSTS

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

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

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

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated October 3, 2005, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

The Contractor shall provide the reports and deliverables specified below. All reports shall be submitted in electronic form (or hard copy form when not possible) as PC-formatted computer files in Microsoft Word and Microsoft Excel and/or searchable PDF format. Electronic versions shall be sent on CD or more current electronic data storage medium, by U.S. mail or courier service. All reports shall be archived on CD or other appropriate media for provision to the NIAID Project Officer at the expiration of the contract.

A. Quarterly Progress Reports

The Contractor shall submit copies of Quarterly Progress Reports on/before the 15th of the month following the end of each quarter. The first quarter of the contract should include the first three months of performance and any fraction of the first month in which the contract began. A Quarterly Progress Report shall not be required when providing an Annual or the Final Report. Each Quarterly Progress Report shall consist of:

1. A cover page containing:
    a. Contract number and project title
    b. Period of performance being reported upon
    c. Type of report
    d. Contractor's name and address
    e. Author(s)
    f. Date of submission

2. An introduction, covering the purpose and scope of the contract effort pertaining to the period of the report.

    a. Summaries or charts/graphs/tables of activities for the quarter being reported upon, as specified in the Statement of Work. Incoming and Outgoing shipment information and activities shall be included as follows:
        1) Summary tables and/or graphs for activities relating to shipments received, including (refer to Statement of Work, Paragraph B.2.):
            a) total number of shipments received across the Study Groups and within each Study Group by Site;
            b) specimens received versus added to inventory by Study Group and material type and by Site within each Study Group;
            c) summary of types and quantities of discrepancies by Study Group and by Site within each Study Group;
            d) turnaround times for commitment of specimen batches including NSR discrepancy reporting and Site corrective action timelines;
            e) special issues noted regarding receipt and commitment of specimen shipments such as shipment condition, discrepancies encountered or turnaround time issues, and/or others as identified; and
            f) other information and activities as may be required by the NIAID Project Officer or the Contractor.
        2) Summary tables, and/or graphs for activities relating to outgoing shipment tasks, including (refer to Statement of Work, Paragraph B.3.):
            a) number and material type(s) of shipments received by Sites within each Study Groups and by non-Sites;
            b) number of shipments requiring tasks performed on specimens such as aliquoting or blinding by Study Group or collaborators;
            c) turnaround times for shipment of outgoing specimens including types of discrepancies found by material type and Study Group as well as corrective action reporting by Sites and/or GSMs; and
            d) other information as may be required by the NIAID Project Officer.

    b. Health and Safety of Personnel (refer to Statement of Work, Paragraph B.4.)

        1) Summary of employees' training records; and
        2) Summary of documented safety issues.

    c. Storage Facilities and Equipment (refer to Statement of Work, Paragraph C.)
        1) Freezer inventory including any retirement activity and/or new purchases;
        2) Rate and number of freezers being filled, depleted, and/or re-organized (to include freezer identification information);
        3) Summary of maintenance reports for freezers, other equipment, and facilities to include out-of-range findings and corrective actions; and
        4) Summary of inspections to include problems encountered and corrective actions taken.

    d. Shipping Materials, Technical Assistance, and Site Training (refer to Statement of Work, Paragraphs D.1. and D.2.)
        1) Table of shipping materials sent to Sites and non-Sites including quantity and dates;
        2) Summary of retirement or purchases of shippers or shipping materials along with current list of inventory of shippers and associated materials;
        3) Summary of any revised SOPs, NSR policies, guidelines, and/or reference materials;
        4) Summary of site-specific issues and resolutions via NSR technical support, such as use of the SIDMS, shipping materials, and incoming and outgoing specimen shipments;
        5) Summary of NSR training activities and/or meetings attended for Study Groups, Sites, GSMs or others; and
        6) Upon request of the NIAID Project Officer, a summary of findings from questionnaires to Sites regarding NSR services.

e. Communications with the NIAID Project Officer (refer to Statement of Work, Paragraph D.3.)

1) Tracking table containing conference call issues, resolutions, and/or action items by conference call date;
2) Summary of work projected for next quarter; and
3) Summary of semi-annual meetings with the NIAID Project Officer.

f. Quality Control/Quality Assurance (refer to Statement of Work, Paragraph E.)
1) Summary of Quality Control test outcomes performed on specimen shippers;
2) Summary of operational Quality Assurance test outcomes performed on freezers, other equipment or facilities;
3) Summary of quarterly key indicator trends including corrective actions taken for any out-of-specifications, errors, or non-conformances as well as plans for reducing or maintaining the lower acceptable limit of specifications;
4) Corrective action reports generated for Study Groups and/or GSMs;
5) Summary of planned studies, interim results and/or status of ongoing studies, and/or completed study results from specimen integrity evaluations; and
6) External audit reports and responses.

g. Computerized Software (refer to Statement of Work, Paragraph F).

1) Summary of NSR website updates and/or postings
2) Summary of data management activities, including issues and solutions related to computer hardware and software; and
3) Other information as required by the NIAID Project or Contracting Officers.

4. A Personnel Report, which shall include name, title, percent effort and responsibility of key personnel, technicians, data entry operators, administrative and financial personnel working on the contract as well as subcontractors and/or consultants. For each individual provide a brief summary of tasks performed during the quarter.

5. Scientific Activities. This shall include any research not included in B.2. below; a list of scientific meetings and conferences attended; a list of manuscripts published, submitted or in preparation; and a list of abstracts submitted for presentation or in preparation.

B. Interim Reports

1. Upon request of the NIAID Project Officer, and within five business days of such a request, the Contractor shall provide an Interim Report encompassing 1-4 weeks of recent NSR activities including:
a. The specific work accomplished and in progress;
b. A summary of all incoming and outgoing shipping activity;
c. A description of any technical or performance problems encountered and corrective actions planned or taken;
d. The estimated time taken to complete the work described; and
e. Selected other items as required by the NIAID Project Officer.

2. The Contractor shall submit written or electronic reports of all research and development studies performed as specified in paragraph E of the Statement of Work as follows:
a. Within 10 working days following completion of data analysis, study results shall be reported to the NIAID Project Officer and relevant Study Group(s) as specified by the NIAID Project Officer.
b. Within 3 months of study completion, the Contractor shall provide to the NIAID Project Officer materials to support preparation of scientific manuscripts for publication in peer reviewed journals. In cases where the Contractor drafts a publication, prior to a publication submission, all manuscripts shall be provided in hard copy or electronic copy to the NIAID Project Officer and others for review and approval, as specified by the NIAID Project Officer.

C. Annual Progress Reports

Annual Reports shall include the fourth Quarterly Progress Report and an Annual Table of Contents referring to previous Quarterly Progress Reports. Annual Reports shall be provided on or before the 30th of the month after

each anniversary date of the contract. An Annual Report is not required for the period when the Final Report is due.

D. Final Progress Report and Summary of Salient Results

The Final Report shall cover the entire contract performance period and be in sufficient detail to explain comprehensively the accomplished tasks, a brief description of any unfinished projects, and a status report on transition or shut down activities. In addition, the Contractor shall provide a 200 word minimum "Summary of Salient Results" detailing the important accomplishments from the contract during the performance of the contract. A draft of the Final Report shall be submitted for review by the NIAID Project Officer 30 days prior to the completion of the contract. The Final Report shall be submitted prior to, or at the completion of the contract.

E. Other Reports/Deliverables

1. Invention Reporting Requirement

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

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

Contracting Officer
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Office of Acquisitions, RCB
6700B Rockledge Drive, Room 3214
Bethesda, MD 20892-7612

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

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

2. Source Code and Object Code

Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.
Other Deliverables

3. Manual of complete NSR SOPs (existing and in draft) subject to the NIAID Project Officer approval for all aspects of the Statement of Work within 20 business days of award date.

4. Draft User Manual for Sites and GSMs to include NSR policies, guidelines, and reference materials as noted in the Statement of Work within 20 business days of award date.

5. Draft implementation plan for the comprehensive Quality Assurance Program for the NSR, including key indicators and a Site/GSM questionnaire for feedback on provided services within 25 business days of the award date.

6. Outline of proposed experiments for specimen integrity studies within 45 business days of award date.

7. Initial Transition Plan within 10 business days of the start of the contract, that includes draft NSR SOPs, describing NSR operational procedures and policies/guidelines, including quality assurance measures for the safe and orderly relocation of all NSR-related materials from the current Contractor, as outlined in paragraph A. of the Statement of Work. This plan shall include staffing requirements and a description of work during the transition.

8. Draft plan for the secure transfer, maintenance, and upgrade of data, hardware, and software within 10 business days of the start of the contract. Draft plan for the Information Technology report and InfoSec study within 60 business days of the start of the contract. Refer to Scope of Work requirements, Section F.3 through F.9.

9. Eight months prior to the expiration date of the contract, the Contractor shall provide a draft Final Transition Plan which describes proposed procedures for an orderly transition to a subsequent Contractor or the NIAID and estimated cost as outlined in paragraph H.1 of the Statement of Work.

10. A Final Transition Plan shall be provided six months prior to the completion date of the contract.

11. Contract Completion: The Contractor, subject to NIAID Project Officer approval, shall deliver to the NIAID or its designee, by the completion date of this contract, freezers and specimens, inventory and software systems, including software programs, labeled and inventoried paper files, and Government-Furnished Property (GFP), as outlined in paragraph H. of the Statement of Work.

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, is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at, .

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. PERIOD OF PERFORMANCE

a. The period of performance for the basic requirement of this contract shall be from the date of contract award through 7 (seven) years thereafter.

b. If, and to the extent the Government exercises the option(s), the period of performance for each option will be

from the date of option exercise through one year thereafter.

ARTICLE F.2. DELIVERIES

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

a. The items specified below as described in SECTION C, ARTICLE C.2. will be required to be delivered F.O.B. Destination as set forth in FAR Clause 52.247-35, F.O.B. Destination, Within Consignees Premises (April 1984), and in accordance with and by the date(s) specified below:

Type of Report	No. of Copies	Due Date
Quarterly Progress Report	Original - Contracting Officer (CO) 1- Copy to the Project Officer (PO)	Due on/ before the 15th of the month following each quarterly reporting period. Not due when Annual or Final Reports are due.
Interim Report	1 - Original - CO 1 - Copy - PO	Due within 5 days of request.
Annual Progress Report	1 - Original - CO 1 - Copy - PO	Due on/before the 30th of the month after each Anniversary date of the contract. Not due when the Final Report is due.
Final Progress Report and Summary of Salient Results	1 - Original - CO 1 - Copy - PO	On/before the completion date of the contract. A draft of the final Progress Report shall be provided 30 days prior to the final for PO review and revision.
Transition Plan (Contract Start-up)	1 - Original - CO 1 - Copy - PO	10 business days after the effective date of the Contract.
Transition Plan (Draft)	1 - Original - CO 1 - Copy - PO	Eight months prior to completion of the Contract.
Transition Plan (Final)	1 - Original - CO 1 - Copy - PO	Six months prior to completion of the Contract.
Other Deliverables	As specified in the Statement of Work.	As specified in the Statement of Work.

If the Contractor becomes unable to deliver the reports specified hereunder within the period of performance because of unforseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer written notice at least 10 business days prior to the due date of anticipated delays with reasons therefore. The Contracting Officer and Project Officer must approve the extension in writing. A new delivery date must be established.

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

NIAID Project Officer:
National Institutes of Health, DHHS
National Institute of Allergy and Infectious Diseases
Treatment Research Program, DAIDS
6700-B Rockledge Drive, Room 5206, MSC 7624
Bethesda, MD 20894-7624

NIAID Contracting Officer: National Institutes of Health, DHHS
National Institute of Allergy and Infectious Diseases
Office of Acquisitions, DEA, OA
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

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

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

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

[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 Contracting Officer hereby delegates the Project Officer as the Contracting Officer's authorized representative responsible for signing software license agreements issued as a result of this contract.]

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL

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

NAME	TITLE
[To be specified prior to award]	

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. HHSNXXXXXXXXXXC.)

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-XXXXXC.)

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

Contracting Officer
Office of Acquisitions
National Institute of Allergy and Infectious Diseases, NIH
Office of Acquisitions, DEA
6700B Rockledge Dr., Rm 3214, MSC 7612
Bethesda, MD 20892-7612

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

b. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with P.L.- and the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H.8. 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. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property),

this ARTICLE will include applicable provisions and incorporate the HHS Publication entitled, **Contractor's Guide for Control of Government Property**, which can be found at:

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

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

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

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

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

b. Electronic Access to Contractor Performance Evaluations

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

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

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

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

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

ARTICLE H.2. HUMAN MATERIALS

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

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

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

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

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

ARTICLE H.4. 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.5. 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.6. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to clause 52.217-__ set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost [plus fixed fee] of the contract will be increased as set forth in the ESTIMATED COST [PLUS FIXED FEE Article in SECTION B of this contract.

ARTICLE H.7. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

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

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

b. Subcontracting Reports

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

(1) Individual Subcontract Reports (ISR)

Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:

April 30th
October 30th

(2) Summary Subcontract Report (SSR)

Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

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

ARTICLE H.8. 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 and Section No.*	**Fiscal Year**	**Dollar Amount of Salary Limitation**

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

ARTICLE H.9. 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

[X] Administrative, Management and Support Information:
[ ] Mission Based Information:

b. Security Categories and Levels

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

[ ] **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).

[X] **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. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: http://ais.nci.nih.gov.

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 the 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.]

Contractor/subcontractor staff shall complete the following additional training prior to performing any work under this contract:

e. Rules of Behavior

The contractor/subcontractor employees shall comply with 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.

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 90 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.10. ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS

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

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

ARTICLE H.11. ENERGY STAR REQUIREMENTS

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

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

For more information about ENERGY STAR® see http://www.energystar.gov/
For more information about FEMP see http://www.eere.energy.gov.

ARTICLE H.12. PUBLICATION AND PUBLICITY

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

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

ARTICLE H.13. PRESS RELEASES

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

b. Public Law and Section No.	**Fiscal Year**	**Dollar Amount of Salary Limitation**
[Applicable information to be included at award]		

ARTICLE H.14. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's

Hotline. The toll free number is **1-800-HHS-TIPS** (**1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

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

ARTICLE H.15. 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.

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

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

ARTICLE H.16. ANTI -LOBBYING

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

c. 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.

d.	**Public Law and Section No.**	**Fiscal Year**	**Dollar Amount of Salary Limitation**
	[Applicable information to be included at award]		

ARTICLE H.17. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

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

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

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

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

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

ARTICLE H.19. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

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

providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

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

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

General Clauses for a Cost-Reimbursement Research and Development Contract

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

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

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.

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

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

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

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.

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

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

(2) FAR Clause **52.217-8, Option to Extend Services** (November 1999).

"...The Contracting Officer may exercise the option by written notice to the Contractor within [INSERT THE PERIOD OF TIME WITHIN WHICH THE CONTRACTING OFFICER MAY EXERCISE THE OPTION].

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

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

[ ] Offeror elects to waive the evaluation preference."

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

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

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

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

(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:

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

(10) FAR Clause **52.227-19, Commercial Computer Software--Restricted Rights** (June 1987).

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

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

(12) FAR Clause **52.230-2, Cost Accounting Standards** (April 1998).

(13) FAR Clause **52.230-3, Disclosure and Consistency of Cost Accounting Practices** (April 1998).

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

(15) FAR Clause **52.237-3, Continuity of Services** (January 1991).

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

(17) FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).

(18) FAR Clause **52.245-19, Government Property Furnished "As Is"** (April 1984).

(19) FAR Clause **52.246-23, Limitation of Liability** (February 1997).
AND/OR

(20) FAR Clause **52.246-24, Limitation of Liability - High-Value Items** (February 1997).

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

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

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

(1) HHSAR Clause **352.270-5, Key Personnel** (April 1984).

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

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

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

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

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

This contract incorporates the following clauses in full text.

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

1. 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.

2. FAR Clause **52.223-11, Ozone-Depleting Substances** (May 2001)

(a) **Definition.** Ozone-depleting substance, as used in this clause, means any substance the Environmental Protection Agency designates in 40 CFR part 82 as--

(1) Class I, including, but not limited to, chlorofluorocarbons, halons, carbon tetrachloride, and methyl chloroform; or
(2) Class II, including, but not limited to, hydrochlorofluorocarbons.

(b) The Contractor shall label products which contain or are manufactured with ozone-depleting substances in the manner and to the extent required by 42 U.S.C. 7671j (b), (c), and (d) and 40 CRF Part 82, Subpart E as follows:

"WARNING: Contains (or manufactured with, if applicable) *, a substance(s) which harm(s) public health and environment by destroying ozone in the upper atmosphere."

*The Contractor shall insert the name of the substance(s).

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS:

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal	See Attachment Section at the end of this RFP
Attachment 2:	Proposal Intent Response Sheet SUBMIT ON OR BEFORE 11/15/2006	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 Other Deliverables	See Attachment Section at the end of this RFP
Attachment 6:	Appendix A Additional Technical Proposal Instructions	See Attachment Section at the end of this RFP
Attachment 7:	Appendix B Additional Business Proposal Instructions Uniform Budget Assumptions)	See Attachment Section at the end of this RFP
Attachment 8:	Appendix C Computer Systems	See Attachment Section at the end of this RFP
Attachment 9:	Appendix D Active Study Groups	See Attachment Section at the end of this RFP
Attachment 10:	Appendix E Current and Potential Domestic and International Sites	See Attachment Section at the end of this RFP
Attachment 11:	Appendix F Government Furnished Property/Materials	See Attachment Section at the end of this RFP
Attachment 12:	Information Technology Systems Security - Prospective Offeror Non-Disclosure Agreement	http://rcb.cancer.gov/rcb-internet/forms/IT-security-nondisclosure.pdf

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

Attachment No.	Title	Location
Attachment 13:	Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Attachment 14:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Attachment 15:	Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
Attachment 16:	Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf

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

Attachment No.	Title	Location
Attachment 17:	Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Attachment 18:	Small Business Subcontracting Plan	http://rcb.cancer.gov/rcb-internet/forms/sb-subplan-nci.pdf
Attachment 19:	Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet	http://oamp.od.nih.gov/contracts/BUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls
Attachment 20:	Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Attachment 21	Certificate of Current Cost or Pricing Data	http://rcb.cancer.gov/rcb-internet/forms/cert-current-cost.pdf
Attachment 22	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf

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

Attachment No.	Title	Location
Attachment 23	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 24	Privacy Act System of Records *System of Records No. _____ is applicable to this RFP.*	http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm
Attachment 25	Safety and Health, HHSAR Clause 352.223-70	http://www.niaid.nih.gov/contract/forms/form10.pdf
Attachment 26	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Attachment 27	Government Property Schedule	See Attachment Section at the end of this RFP
Attachment 28	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf
Attachment 29	Commitment To Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Attachment 30	Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Attachment 31	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)]

(a) *Definitions*. As used in this provision--
Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

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

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

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

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

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

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

(2) The first page of the proposal must show--
(i) The solicitation number;
(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions

included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

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

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

(*1*) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(*2*) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(*3*) It is the only proposal received.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

right to reject any proposal submitted with a nonconforming legend.

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

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

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

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

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

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

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

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

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

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

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

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

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

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 .

(2) The small business size standard is 541710.

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

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

It is anticipated that one award will be made from this solicitation and that the award will be made on/about September 15, 2007.

It is anticipated that the award from this solicitation will be a multi-year cost reimbursement type contract completion form, with a period of performance of 7 (seven) 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 12.5 FTEs (Full Time Equivalents) per annum, for the basic requirement and .5 FTEs, per annum, for the option period(s). 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

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

Contracting Officer
National Institute of Allergy and Infectious Diseases
Office of Acquisitions, DEA
6700B Rockledge Dr., Rm 3214, MSC 7612
Bethesda, MD 20892-7612

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

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.

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

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

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

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

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

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

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

(5) **Alternate Proposals**

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

(6) **Evaluation of Proposals**

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

(7) **Potential Award Without Discussions**

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

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

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

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

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

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

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

(9) **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 technical portion of each 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 subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(g) Certify, in each application/proposal for funding to which the regulations applies, that:

1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

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

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of

interests include, but are not limited to:

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

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

(12) **Past Performance Information**

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

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

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

The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort. For the purpose of this solicitation, a "major subcontract" is defined as any subcontract that exceeds $500,000.

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.

(13) **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

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003)
b) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).
c) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
d) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. TECHNICAL PROPOSAL INSTRUCTIONS

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

(1) **Technical Discussions**
The technical discussion included in the technical proposal should respond to the items set forth below:

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

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

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

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

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

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

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

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

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

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

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

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

-The specific items or expertise they will provide.

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

-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

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

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

(3) **Additional Technical Proposal Information**

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

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

(4) **Other Considerations**
Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

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

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

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

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

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

(5) **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.

(6) **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

[X] Administrative, Management and Support Information:
[ ] Mission Based Information:

(b) Security Categories and Levels

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

[ ] 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).

[X] 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. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: http://ais.nci.nih.gov.

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: [insert link for course] 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) 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.

(g) 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

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. **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.*

5. **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the

apparent successful offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, Attachment to this RFP is an example of such a plan.

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

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

c) The offeror understands that:

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

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

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

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

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

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

d) Each plan must contain the following:

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

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

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

Owned Small Business Concerns.

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

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

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

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

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

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

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

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

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

6. **HUBZone Small Business Concerns**

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

7. **Extent of Small Disadvantaged Business Participation**

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

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

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) code, and region, if any, the authorized SDB

procurement mechanisms and applicable factors (percentages). TheNAICS codes can be found at: http://www.sba.gov/size

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

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

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Subsector(s). The applicable authorized NAICS Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

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

EXAMPLE

Targets for SDB Participation - NAICS Subsector 223

	SDB Percentage of Total Contract Value	**SDB Dollars**
Total Contract Value-$1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	$150,000

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

8. **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.

9. **Other Administrative Data**

a) **Property**

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

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

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

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

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

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

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

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

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

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

HHSAR 352.232-75, Incremental Funding (January 2001)

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

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

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

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

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

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

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.

10. **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

11. **Proposer's Annual Financial Report**

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

12. **Representations and Certifications - SECTION K**

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

13. **Travel Costs/Travel Policy**

a) **Travel Costs - Commercial**

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

b) **Travel Policy**

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

SECTION M
EVALUATION FACTORS FOR AWARD

1. GENERAL

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

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

2. EVALUATION OF OPTIONS

It is anticipated that any contract awarded from this solicitation will contain option provisions and periods.

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the options.

3. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

Technical Proposals submitted in response to this RFP will be evaluated based on the factors listed below. Proposals will be judged solely on the written material provided by the Offeror and the information gathered by the NIAID Contracting Officer concerning past performance. It is anticipated that one award will be made as a result of this acquisition.

OFFEROR(S) AND REVIEWERS ARE ADVISED TO REFER TO APPENDIX A “Additional Technical Proposal Instructions and Format for Technical Proposal Table of Contents OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATON RELATED TO THE PREPARATION AND EVALUATION OF TECHNICAL PROPOSALS.

CRITERA **WEIGHT**

A. TECHNICAL APPROACH 40 POINTS

Understanding of the scope, purpose, and complexity of the Statement of Work requirements including recognition of potential problems and proposed solutions, as evidenced by the Offeror”s proposed technical plan to perform the following functions:

1. SPECIMEN MANAGEMENT (20 points)

a) Adequacy and appropriateness of the plans and operating procedures to efficiently and effectively:

i. plan and initial and final transition of the NSR (in the event the incumbent contractor is not awarded the contract);

ii. acquire, process, store, track, package, inventory, and ship domestically and internationally, human biological specimens, including use of currently acceptable standards as indicated by international, Federal, State, and local government regulations, policies, and/or guidelines such as CLIA, GLP, and ISO 9000 as well as current HHS OHRP and other guidelines for the use of stored specimens; knowledge of IATA and other transport regulations and capability to import and export diagnostic and infectious disease specimens internationally; and

iii. establish and maintain an NSR IRB for review of Study Group Sample Informed Consents (SICs) to ensure the proper use of stored specimens; and

iv. execute, maintain, and document a personnel safety and health program including training in CLIA, TDG, Biosafety Level 2, and infectious agent handling.

b) Soundness and feasibility of the overall technical approach of the Offeror and all subcontractors including proposed state-of-the-art current technologies and quality management systems including reporting.

c) Adequacy and appropriateness of the plans for providing training and technical assistance to Sites on all aspects of the NSR.

2. QUALITY ASSURANCE PROGRAM (10 points)

a) Adequacy and feasibility of the proposed Quality Assurance Program to monitor the entire specimen management process including the proposed: quality control of shipping materials, key indicators of quality, system to capture and report errors/issues including corrective actions;

b) Innovation, adequacy, and feasibility of proposed procedures for improvements in: the retrospective storage and potential discarding of specimens, and the prospective collection of specimens;

c) Adequacy, feasibility, and innovation of proposed specimen integrity studies.

3. COMPUTERIZED SOFTWARE SYSTEMS (10 points)

a) Adequacy of the proposed SIDMS to meet current and evolving specimen management needs and technologies including hardware and software requirements;

b) Adequacy of the proposed software system for data management and reporting; adequacy of the plans for interfacing and electronically communicating with other computer systems, Sites, and NIAID contractors for the exchange of data;

c) Adequacy of the proposed draft report of IT requirements including information security needs; adequacy of the plans for maintaining and updating secure internal information database systems;

d) Appropriateness of the plans for posting and tracking NSR activity-related information via the NSR web site, including incoming and outgoing specimen shipment status, NSR and SIDMS User Manuals, NSR policies and guidelines, relevant scientific data, and quarterly discrepancy rates.

B. PROJECT MANAGEMENT AND PERSONNEL/STAFFING 40 POINTS

1. PROJECT MANAGEMENT (20 points)

Appropriateness and adequacy of the proposed project organization, staffing plan, and management in relation to the implementation, conduct, monitoring and completion of the tasks identified in the Statement of Work, including the responsibilities and level of effort for all proposed personnel who will be assigned to the contract, their time commitment, as well as proposed subcontractors and consultants. Included are:

a) Adequacy, appropriateness, and quality of existing or proposed SOPs submitted for implementation and

the operation of the NSR;

b) Adequacy to develop, distribute, and maintain policies, guidelines, and user manuals;

c) Appropriateness and adequacy of the proposed administrative framework including clear lines of authority and responsibility for personnel;

d) Adequacy and feasibility of the proposed plan to operate and manage a specimen repository in accordance with the proposed time schedule for achieving contract objectives and within the negotiated budget;

e) Efficiency and soundness of procedures for maintaining quality control over the implementation and operation of the contract, including plans to keep within budget;

f) Quality and appropriateness of proposed outside consultants, as well as assurance of their availability;

g) Adequacy of procedures for managing subcontract(s);

h) Adequacy and appropriateness of the plans to communicate and coordinate with multiple, geographically diverse Sites;

i) Adequacy of proposed communications and interactions between the PI and other key personnel with the NIAID Contracting Officer and the NIAID Project Officer including reporting of schedule and budget on a regular basis as well as plans for how key personnel will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).

2. PERSONNEL/STAFFING

a) Principal Investigator (10 Points)

The proposed Principal Investigator must have a Ph.D. or its equivalence in biomedical sciences.

i. Appropriateness and adequacy of the documented availability, training, related expertise and experience of the proposed Principal Investigator in the principles and practices of repository specimen management for human biological specimens, with professional, technical and administrative competence to manage and operate the NSR;
ii. Adequacy of the demonstrated knowledge and research experience in HIV/AIDS or other infectious diseases;

ii. experience to award and effectively manage subcontracts;

iv. ability to hire staff for projects in a way that reflects flexibility and responsiveness to changing needs;

v. ability to provide technical assistance and oversight, including specific training/guidance in the safe and proper handling of infectious agents; and

vi. ability to design and oversee specimen integrity studies.

b) Project Manager: (5 Points)

Appropriateness and adequacy of the documented availability, training, related expertise and experience of the Project Manager in the principles and practices of repository specimen management for human biological specimens; and with technical and managerial competence to efficiently manage and coordinate repository operations and specimen handling and management, customer service, and trouble shooting.

c) Other Personnel (5 Points)

Relevance, extent of training and experience, and availability of other professional and research, technical, and support staff in the area of specimen management and repository operations and facilities, including quality assurance management, SIDMS, and other software system management; and adequacy of back-up staffing and the evidence that they will be able to function as a team.

C. FACILITIES AND EQUIPMENT 20 POINTS

Documented availability of adequate facilities, equipment, and organizational resources necessary for safe and secure operation and maintenance of the NSR.

a) Adequacy of facilities and equipment to ship, receive, store and maintain the activity and viability of the current biological specimen collection as well as the proposed number of specimens expected over the course of the contract.

b) Adequacy of the proposed facility as demonstrated in the detailed floor plan showing the location of equipment and resources and any facility renovations that would be accomplished prior to initiation of the contract.

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

d) Adequacy and feasibility of the proposed disaster recovery program and ability to report documented tests of the system.

e) Adequacy of the proposed freezer and facility monitoring; adequate proposal to capture and report out-of-range freezer conditions and link those data electronically to vial data.

f) Adequacy and availability of equipment proposed for the project (i.e., percentage of time equipment will be dedicated to the project).

g) Adequacy of the plan for compliance with all safety guidelines and regulations, including training and monitoring of personnel for exposure to infectious and hazardous reagents.

h) Adequacy of all proposed physical and electronic security systems to prevent unauthorized entry into the facility; adequacy of proposed security systems to prevent unauthorized access of the NSR computer databases and other computer-associated systems, programs and files; adequacy of proposed alarm systems for emergency and equipment malfunction situations, etc.

i) Evidence of the possession of any current special licenses or local permits that may be needed (e.g. infectious agents).

j) Adequacy of the proposed facility to operate under appropriate BSL2 containment conditions.

D. EXPANSION OPTION 25 POINTS

Adequacy of the proposed expansion plan including the resources, facilities, and timeliness to address expansion needs; demonstrated ability of the Principal Investigator and the Project Manager to oversee and manage the expansion; and the ability to recruit qualified personnel in a timely manner.

TOTAL POSSIBLE POINTS: 125 POINTS

4. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

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

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

Offers will be evaluated on the following sub-factors:

(a) Extent to which SDB concerns are specifically identified
(b) Extent of commitment to use SDB concerns
(c) Complexity and variety of the work SDB concerns are to perform
(d) Realism of the proposal
(e) Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
(f) Extent of participation of SDB concerns in terms of the value of the total acquisition.

5. 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.

6. EVALUATION OF DATA SHARING PLAN

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy.

If your proposal does not include a plan or if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government

holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered “unacceptable” by the Government after discussions, your proposal may not be considered further for award.

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--DAIDS-07-45 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
Joshua LaVine Contract Specialist Office of Acquisitions, DEA, , NIH 6700-B Rockledge Drive, Room 3214 Bethesda, Maryland 20817	Joshua LaVine Contract Specialist Office of Acquisitions (OA) DEA NIH, NIAID 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612

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

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Breakdown of Proposal Estimated Cost Using Electronic Cost Proposal Excel Workbook	**This Attachment should be submitted Also as a separate excel file on the Business Proposal Compact Disk.** **See Section J, Attachment entitled Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet to access the Excel Workbook**	**N/A**

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DAIDS-07-45
RFP Title: NIAID Specimen Repository

Please review the attached Request for Proposal. Furnish the information requested below and return this page by __ . Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

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Attn: Joshua Lavine
RFP-NIH-NIAID- DIADS-06-07
FAX# (301) 402-0972
Email : JLavine@niaid.nih.gov

NIAID Specimen Repository
Background

The mission of the Division of AIDS (DAIDS), the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), is to help ensure an end to the HIV/AIDS epidemic by increasing basic knowledge of the pathogenesis and transmission of the human immunodeficiency virus (HIV), supporting the development of therapies for HIV infection and its complications, and supporting the development of vaccines and other prevention strategies. This mission is carried out by three Programs: the Basic Sciences Program (BSP), the Therapeutics Research Program (TRP) and the Vaccine and Prevention Research Program (VPRP).

The purpose of this solicitation is to continue an ongoing specimen storage and management program for HIV seropositive and negative specimens received from subjects enrolled in NIAID-sponsored multi-site clinical and epidemiological studies. The NIAID Specimen Repository (NSR) is critical to the scientific integrity of on-going and future studies concerning HIV diagnosis, pathogenesis, disease progression, assessment of treatments, vaccine efficacy and other preventive measures. The NSR has been in operation since 1988 and currently stores 5 million specimens. The acquisition history of the NSR is as follows:

1988 – 1999	Series of contracts with BRI, Inc (last contract # N01-AI-45204)
1999-present	SeraCare Life Sciences, Inc., previously known as BBI Biotech Services, Inc. (contract # N01-AI-95381)

The current contract will expire on August 15, 2006. The purpose of this solicitation is to re-compete this requirement and award a single contract for a term of seven years.

The recompeted contract will continue to provide a resource designed to receive, store, catalog, retrieve, aliquot, and ship human specimens from subjects enrolled in NIAID-supported or collaborative multi-site epidemiologic, vaccine and prevention investigations, both domestically and internationally. The contract will include Quality Assurance/Quality Control requirements for prospective evaluation of short and long term specimen integrity, viability, and functionality. Data generated will aid in ongoing specimen management, including identification and removal of non-useful specimens as well as possibly refining specimen storage models.

The NSR will serve current and future NIAID-sponsored clinical trial networks and epidemiological cohort study groups referred to as Study Groups. Currently, the NSR supports the following ongoing NIAID Study Groups, noted in order of greatest to least numbers of stored specimens: the Women's Interagency HIV Study (WIHS); the Multicenter AIDS Cohort Study (MACS); the HIV Vaccine Trials Network (HVTN); the Women and Infants Transmission Study (WITS); and the HIV Prevention Trials Network (HPTN). Refer to Appendix D for information regarding active Study Groups. The NSR also maintains specimens from other NIAID-sponsored studies that either have been completed, such as the AIDS Vaccine Evaluation Group (AVEG); the HIV Transmission Network (HIVNET); the Jump Start Project; the Heterosexual HIV Transmission Study (HATS); the Division of AIDS Treatment Research Initiative (DATRI); and the San Francisco Men's Health Study (SFMHS); or from Study Groups that currently send newly-generated specimens to another repository, such as the Adult and Pediatric AIDS Clinical Trials Group (AACTG and PACTG).

The NSR supports the short, moderate, and long-term specimen storage component of the domestic and international research agendas of the Study Groups. Retrieval and distribution of specimens is guided by the scientific priorities of the Executive or Advisory Committees of the

various, respective Study Groups. These specimens include peripheral blood mononuclear cells, serum, plasma, tissue specimens, and other bodily fluids or substances such as cervicalvaginal lavage (CVL), breast milk, semen, saliva, urine, feces, mucosal, autopsy and biopsy materials, and whole blood spots dried on filter paper.

The NSR currently maintains approximately 140 mechanical (-70C) freezers and 37 liquid nitrogen (-150C) freezers for NIAID specimens that will transfer with award to the successful Offeror. The specimen inventory database management system, Biological Specimen Inventory System (BSI-II), which will also be provided to the successful Offeror, was developed, maintained, and upgraded through the current NSR subcontractor, Information Management Services (IMS), Inc. Information regarding the BSI-II can be found at: www.bsi-ii.com. Information regarding IMS, Inc. can be found at: www.imsweb.com. The BSI-II contains all the data for specimens collected prior to August 1999, as well as all the associated information for arriving, stored, and shipped specimens since August 1999. Specimens are tracked at the vial level.

Currently, the NSR program supports, through receipt or shipment of specimens, over 300 domestic and international laboratories that are either part of the Study Group (referred to as Sites) or collaborating laboratories with the Study Groups (referred to as non-Sites). (See Appendices D and E for information regarding Study Groups and Sites). For receipt and storage of specimens at the NSR, the base contract is expected to support the current 29 domestic Sites and 11 international Sites. For shipment of specimens from the NSR, the base contract is expected to support the current total of 300 Sites and non-Sites at approximately 100 Sites/non-Sites per year. Through Options, the NSR may receive and/or ship specimens for as many as an additional 30 domestic and 20 international Sites. Although the structure of the Study Groups is subject to change during the contract period, the changes are not expected to result in changes to the number of participating Sites in the base contract. However, should NIAID have a need to expand the number of Sites and/or non-Sites during the course of the contract, such an increase in the Contractor's activities may be activated, at the discretion of the NIAID, by exercising one or more Options in each of the contract years. (Refer to paragraph I. in the Statement of Work for additional information regarding the Options.)

Additional information relevant to this solicitation is provided in the following Appendices:

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

APPENDIX B ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS

APPENDIX C COMPUTER SYSTEMS

All Sites are using computerized specimen management and shipment systems. The WIHS, MACS, HPTN, HVTN international Sites, and WITS utilize the same system, a study-specific, customized laboratory data management system (LDMS) developed and maintained by Frontier Sciences, that allows Sites to uniformly barcode specimens with a unique embedded identifier, and provide standardized electronic manifests. The HVTN domestic Sites utilize a different laboratory information management system (LIMS) that also provides standardized barcodes for specimens with unique, embedded identifiers and electronic shipping manifests across its laboratories and domestic Sites.

The successful Offeror may be required to provide some NSR-related information through the DAIDS Enterprise System (DAIDS-ES). While some of this may be accomplished through a link from the

DAIDS-ES to the NSR web site, some data may need to be shared by the NSR, and with the DAIDS-ES, in which case data sharing agreements, standards, etc., shall be required.

APPENDIX D ACTIVE STUDY GROUPS

A list of the active Study Groups including clinical sites, locations, mission, and web site links.

APPENDIX E CURRENT AND POTENTIAL DOMESTIC AND INTERNATIONAL SITES

A list of the current and potential domestic and international Sites including numbers of shipping and receiving labs by Study Group as well as city/state or city/country locations.

APPENDIX F GOVERNMENT-FURNISHED MATERIALS/PROPERTY

A list of all Government-furnished equipment that will be transferred to the successful Offeror.

NIAID SPECIMEN REPOSITORY
STATEMENT OF WORK

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

I. General Description of the Scope and Objectives

A. If applicable, perform an initial transition of equipment, specimens, and data from the incumbent contractor if not successful.
B. Secure, receive, catalog, process, store, and disburse human biological specimens from subjects participating in NIAID-sponsored treatment, prevention, and/or cohort studies.
C. Provide adequate cold storage facilities and equipment for clinical specimens.
D. Provide shipping materials and documents, technical assistance and training to Site personnel and study teams on specimen handling and shipping, and communicate with the NIAID Project Officer.
E. Develop, perform, and maintain Quality Assurance systems for the NIAID Specimen Repository (NSR) facility, operations, stored specimens, shipping materials, and personnel and in accordance with all applicable Federal, State, and local regulatory requirements.
F. Provide (or utilize the current) computerized Specimen Inventory Database Management System (SIDMS) that supports NSR functions.
G. Provide a technical and administrative infrastructure to ensure efficient planning, initiation, implementation, and management of NSR activities.
H. Develop and implement a Final Transition Plan at the end of the contract.
I. Expand services to include additional Sites and non-Sites, when necessary, through exercise of Options.

II. Technical Specifications

A. INITIAL TRANSITION

Specifically the contractor shall perform the following tasks as applicable:

1. Safely and efficiently assume the activities from the incumbent contractor to ensure a seamless transition without loss of time, loss of resources, or that would not pose obstacles to the conduct of ongoing research.

2. Complete the transition within the first 60 business days following the effective date of the contract. The functions of the NSR must be maintained during the transition period and receipt, storage, cataloging, processing, and distribution of specimens must not be interrupted at any time.

3. Within 10 business days of the start of the contract, develop and implement an Initial Transition Plan including the tasks that are associated with the relocation effort from the current contractor, and the type and manner of operations required by the Contractor during the transition period. This shall include safe and effective coordination with the current contractor at the start of the new contract period for transfer of contract-related materials including:

   a. Government-Furnished Property (GFP). Verification of equipment performance standards shall take place prior to and after the transfer, including installation,

operational, and performance qualifications on all freezers received from the current contractor. The successor Contractor shall verify through records of the incumbent Contractor or through testing standards that all Government-furnished equipment is acceptable for use. This data shall be provided electronically.

b. All computerized data files and software systems (with documentation and specifications) including specimen inventory files, specimen batches in queue for commitment or shipment, data entry files, and active specimen discrepancy files. Data shall be provided electronically. Meet with OTIS staff within 5 business days of the start of the contract to develop a draft plan for the HHS approved and secure transfer and re-establishment of electronic data files, hardware, and software.

c. DAIDS-specific standard operating procedures (SOPs), electronic and/or hard copy files of freezer and other equipment management and maintenance, correspondence files, and archived activity files for incoming and outgoing shipments. Electronic versions of data shall be provided where possible.

d. Re-direction of incoming shipments to the contract awardee to occur within 15 business days following the effective date of the contract.

e. Transfer of all mechanical and liquid nitrogen freezers, specimens, other equipment and materials within 20 business days following the effective date of the contract.

f. Use of the BSI-II or validated transfer of BSI-II data to a NIAID-approved SIDMS within 20 business days following the effective date of the contract.

g. Plan and execute transition meeting(s) with the NIAID Project and Contract Officers within 5 business days following the effective date of the contract.

h. Plan and execute conference calls with the NIAID Project Officer and respective Group Specimen Managers or designated Study Group representatives to discuss incoming and outgoing specimen shipment needs of the Study Groups as well as NSR policies for acceptance and withdrawal of specimens within 15 business days following the effective date of the contract award.

4. Coordinate with the Sites and Group Specimen Managers (GSMs) within the first 10 business days following the effective date of the contract to ensure an orderly transition including:

    a. Providing Sites and GSMs with contact information for the Contractor.

    b. Providing Sites with instructions for specimen shipments to the Contractor and instructions concerning any schedule changes caused by the transition.

    c. Providing Sites and GSMs with information on any changes in communications or requests, shipping, shipping materials, specimen commitment or requisition turnaround times, or other aspects of operations that will be impacted.

B. SECURE, RECEIVE, CATALOG, PROCESS, STORE, AND DISBURSE HUMAN BIOLOGICAL SPECIMENS FROM NIAID-SPONSORED STUDY GROUPS

1. INCOMING and OUTGOING SHIPMENTS

   a. Assume costs for all shipments to and from the NSR.

   b. Coordinate all shipments to preserve specimen integrity and utility.

   c. Provide safe packaging, shipping and distribution of specimens to eligible research investigators in the U.S. and abroad so that shipments are coordinated for timely receipt. A secure package tracking system must be utilized to ensure that all specimens are delivered to the intended recipient.

   d. Use shipping containers with sufficient margins of safety for maintaining appropriate environmental safeguards and desired refrigeration levels for specimens in transit, depending on the mode of transportation employed.

   e. Use shipping containers for specimens that comply with current domestic and international transport regulations and pertinent (IATA) International Air Transport Association/International Civil Aviation Organization Dangerous Goods Regulations: http://www.iata.org/dangerousgoods/about.htm.

   f. Obtain, if not already in possession, appropriate shipping licenses and permits from local, State, Federal and international authorities for the safe import, storage and distribution of diagnostic or biohazardous materials, according to current regulatory guidelines as applicable.

   g. In accordance with OHRP guidelines and 45CFR Part 46, establish or provide an NSR Institutional Review Board (IRB) to review Study Group sample informed consents and other study-related documents, as necessary, in terms of specimen acceptance for NSR storage and subsequent distribution http://www.hhs.gov/ohrp/humansubjects/guidance/reposit.htm.

   h. Operate in accordance with current acceptable standards as indicated by international, Federal, State, and local government regulations, policies, and/or guidelines in conducting the tasks outlined in the Statement of Work. Such regulations, policies and guidelines include:

      i. 49 CFR Part 100-199 Transportation

      ii. 42 CFR Part 71.54 and 72.3 Etiologic Agents, Hosts and Vectors; Interstate Shipment of Etiologic Agents

      iii. 39 CFR Part 124 Postal Services

      iv. 21 CFR Part 58 Good Laboratory Practices (GLP)

      v. 21 CFR Part Good Manufacturing Practices (GMP)

      vi. 29 CFR Part 1910.1030, Occupational Exposure to Blood Borne Pathogens, Final Rule, and; b) 29 CFR Part 1910, Occupational Exposure to hazardous chemicals in Laboratories, Final Rule

      vii. International Air Transport Association (IATA), Dangerous Goods Regulations 46th Edition 2005

      viii. International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transportation of Dangerous Good by Air 2005-2006

ix. United Nations Recommendations on the Transport of Dangerous Goods, 13th Revised Edition and amendments (ST/SG/AC.10/1/Rev.13; ST/SG/AC.10/32Add.1 dated 25 January 2005)

x. Clinical Laboratory Improvement Amendments (CLIA) including all changes through 1/24/2004) http://www.phppo.cdc.gov/clia/regs/toc.aspx

xi. Biosafety in Microbiological and Biomedical laboratories published by the Department of Health and Human Services, Centers for Disease Control and Prevention, and National Institutes of Health, 4th Edition May 1999 http://www.cdc.gov/od/ohs/biosfty/biosfty.htm; http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm

xii. International Organization for Standardization (ISO) 9001

xiii. Update: "Universal Precautions for Prevention of Transmission of Human Immunodeficiency Virus, Hepatitis B Virus, and Other Blood borne Pathogens in Health-Care Settings." Morbidity and Mortality Weekly Report, June 24, 1988, Vol. 37, No. 24.

xiv. Safety and Health (Deviation), Public Health Service Acquisition Regulation (HHSAR) Clause 352.223-70

2. INCOMING SPECIMEN SHIPMENTS

Secure, receive, catalog, and store clinical specimens from both domestic and international NIAID-sponsored Study Group Sites.

a. Arrange for the shipping of specimens to the NSR from all designated domestic Sites by overnight express shipment.

b. For designated international Sites, receive shipments within acceptable, expected shipment times, based on the country, but not longer than 72 hours.

c. Secure and utilize shipment services by established carrier(s) with a proven record for handling medical/clinical specimens in shipping containers with dry ice, liquid nitrogen, or other refrigerants, as needed.

d. Perform a 100% documented inspection and verification of all incoming shipments at the vial level. Received shipments not containing any discrepancies shall be inventoried and committed within 5 business days.

e. Track and record in a standardized format, discrepancies found with each received shipment. Electronically document, and report to the Site within 3-5 business days of shipment receipt, all discrepancies found for each shipment. Provide a summary report of shipment discrepancies in the Quarterly Progress Reports (see Reporting Requirements and Other Deliverables Section of this RFP).

f. Provide on a designated NSR web site, tracking information maintained in the SIDMS, such as status of incoming shipments; categories and numbers of discrepancies by shipment, Site and Study Group; date discrepancy report sent; date corrective actions received; and date shipment specimens committed to inventory and the SIDMS. Information should be available using real-time data in a canned report format.

g. Verify corrective actions received from Sites on specimen vial or manifest discrepancy data within 3 business days of electronic receipt.

h. Commit specimens and data within 24 hours of verification of accurate and complete corrective actions data. Guidelines shall be established by the Contractor and the NIAID Project Officer regarding acceptable data in the manifest, barcode, and readable vial label for specimen commitment.

i. After permanent storage commitment, perform, at a minimum, a 5% location quality control check on vial location for each specimen shipment.

j. A unique vial identifier will be imbedded in bar-coded vials. The Site-generated unique vial identifier shall be linked either to a unique vial identifier generated by the SIDMS for each incoming vial or utilized as the unique vial identifier within the SIDMS. Refer to Appendix C, Computer Systems, for Site-specific specimen management and shipping database systems.

3. OUTGOING SPECIMEN SHIPMENTS

Retrieve, process, inspect, package, and disburse clinical specimens to domestic and international NIAID-sponsored Study Group Sites and Study Group collaborating laboratories (referred to as non-Sites).

a. Develop or utilize an established electronic requisition process via the SIDMS to receive requests for specimens, in order to obtain all necessary information to retrieve and ship the appropriate specimens, such as specimen type, patient ID, receiving lab address and contact, requested shipment date, actual shipment data, verification of appropriate Study Group approval, and subject informed consent.

b. Post on the NSR-designated web site, requisition queue and key information for users, such as, receiving lab personnel, Group Specimen Managers (GSMs) - designated person(s) identified by the NIAID Project Officer as responsible for specimen management within their clinical trial network or study cohort, and the NIAID Project Officer to view and receive updated information on shipments.

c. Retrieve specimens from storage locations and perform any necessary discrepancy reporting and corrective action processes on vials with incongruent information.

d. Perform processing tasks on vials such as aliquoting or relabeling vials for blinding that may be required for up to 25% of the shipments.

e. Perform a 100% documented inspection and verification of all outgoing shipments at the vial level.

f. Disburse specimens to domestic and international destinations within 10 business days of electronic request by GSMs via the SIDMS. Quality-controlled shipping materials and specimen tracking while in transit shall be provided by the Contractor.

g. Provide for the return shipment of unused specimen portions and/or empty shipping containers and packing materials.

4. HEALTH AND SAFETY OF PERSONNEL

The Contractor shall provide its personnel with protective garments, equipment, training and sufficient monitoring to assure safe handling of potentially hazardous and infectious materials. Specifically, the Contractor shall comply with all applicable health and safety regulations while conducting the work set forth herein. The Contractor shall follow all safety and health regulations in accordance with HHSAR 352.223-70. Refer to paragraph B.1.h of this Statement of Work for a full list of safety and health regulations, policies, and guidelines.

C. STORAGE FACILITIES AND EQUIPMENT

There shall be sufficient freezer capacity to ultimately store and maintain approximately nine (9) million human biologic specimens by the end of the seven year contract period. This estimate includes the approximate five (5) million current specimens, which will transfer with the award, as well as the projected accumulation and storage of an additional four (4) million more specimens over the course of contract performance.

1. Provide sufficient floor space and/or a vertical storage stacking system as needed in a single facility to accommodate:
   a. Up to one hundred (100) *additional* twenty-seven cubic foot -70 C mechanical freezers (or their equivalent) for a total of two hundred and forty (240) mechanical freezers and thirty (30) *additional* liquid nitrogen freezers or their equivalent (added to those that will transfer from the incumbent contractor) for a total of sixty-seven (67) liquid nitrogen freezers.
   b. A repair and freezer validation area measuring at least 500 square feet.
   c. A spare parts storage area measuring at least 500 square feet.
   d. Designated laboratory work area(s) of sufficient size and capacity for handling NSR diagnostic and infectious specimens under Biosafety Level 2 containment conditions. The Contractor shall provide an adequate number of biosafety cabinets. The various processing areas must be sufficiently isolated from other work areas.
   e. Dedicated office spaces for record/file keeping, administrative, system, and data management activities.
2. House the equipment in a climate-controlled facility with the capacity to maintain room temperatures of 19-22° C when all equipment is operating.
3. Maintain and operate controlled freezers for the following storage conditions:
   a. -10° to -20° C, -70° to -90° C, and -150° to -196° C (vapor phase, liquid nitrogen conditions).
   b. Enough back-up freezer space to accommodate 10% of the collection. Complete transfer of the contents of a freezer shall occur within 2 hours of an initial failure.
4. Provide adequate electrical power to accommodate all mechanical freezers, the central alarm system, and the air conditioning system. Provide adequate back-up power supply on-site to handle a case of electrical power failure. All freezers, air conditioners and the central alarm system shall be electrically monitored so that should the power fail, complete back-up power (capable of continuous operation for up to 48 hours) shall be immediately available.
5. Provide a central 24-hour per day, computerized alarm system for monitoring each freezer and the storage facility conditions. Provide immediate audible alarm, beeper and cell phone

triage alert. Respond to alarm conditions within thirty minutes after notification. Provide a qualified repository technician on site at the NSR to ensure that within 30 minutes the event prompting the alarm condition shall be evaluated and corrected.

6. Perform weekly tests on the alarm system. Perform monthly tests on the back-up electrical system. Include the results of these tests in the Quarterly Progress Reports (see Reporting Requirements and Other Deliverables Section of this RFP).
7. Electronically capture out-of-range freezer conditions and link with vial data stored in the SIDMS for both emergency findings and weekly tests. Hard copy reports of issues and actions taken shall be printed, filed, and later compiled and included in the Quarterly Progress Reports (see Reporting Requirements and Other Deliverables Section of this RFP). The NIAID Project Officer will review and approve out-of-range values established at the beginning of the contract.
8. Perform regular operational quality assurance maintenance for all cold storage equipment, the central alarm system, the air conditioning system, and the back-up power system. Summaries of the maintenance shall be reported in the Quarterly Progress Reports (see Reporting Requirements and Other Deliverables Section of this RFP).
9. Maintain a log of regular inspections and provide a summary of inspection records, including problems encountered and actions taken, in the Quarterly Progress Reports (see Reporting Requirements and Other Deliverables Section of this RFP).
10. Provide security measures that ensure the facility and equipment are protected against fire, other environmental hazards, and personal intrusion.
11. Provide an established operational disaster recovery program with documentation of at least annual internal test audits.

D. SHIPPING MATERIALS, TECHNICAL ASSISTANCE, SITE TRAINING, AND COMMUNICATONS WITH NIAID PROJECT OFFICER

1. SHIPPING MATERIALS
   a. Provide to shipping Sites, IATA-approved packaging materials, associated shipping forms and shipment tracking services to maintain appropriate environmental safeguards and desired refrigeration levels for specific specimens in transit.
   b. Perform validation studies and quality assurance procedures on shipping containers per manufacturer and international, Federal, State, and local regulations, as applicable.
2. TECHNICAL ASSISTANCE AND SITE TRAINING
   a. Develop, distribute, post, and maintain on a designated web site an NSR User Manual for Sites and GSMs that describes NSR use policies, guidelines, and reference materials such as:
      1) shipping procedures to and from the NSR, including a list of NSR-provided shipping materials, vial and manifest format and content requirements, and specimen acceptance and return criteria;
      2) data discrepancy reconciliation procedures and expected turnaround times for Site corrective actions; turnaround times for shipment inventory and commitment, as well as Site and non-Site request and receipt of outgoing shipments;
      3) recommended supplies, vendors, and material-specific specimen processing for

short, moderate, and long term storage; and

4) planning procedures for new material types or studies for specimen acceptance at the NSR, including expected short, moderate and long term storage as well as specimen discard criteria.

b. Provide advice to Sites and GSMs via telephone, teleconference, and electronic communications on NSR policies, procedures, and guidelines required for all necessary activities that involve the receipt, storage, and shipment of specimens to and from the NSR.

c. Provide technical advice to the NIAID Project Officer regarding current advances in repository specimen management.

d. Provide training, instruction and oversight for all aspects of interactions between the NSR, Study Group Sites, and GSMs such as:

1) All components of the NSR User Manual, including shipping, labeling, bar-coding, specimen handling, on-site processing and storage;

2) Initial training for the SIDMS and training whenever the system is updated or new versions are released; and

3) At the request or approval of the NIAID Project Officer, provide operational information; participation at Study Group meetings (and other related Study Group meetings); training through telephone conference calls; on-site instruction; training sessions at Study Group meetings; and consultation.

e. Design, and upon review and approval of the NIAID Project Officer, distribute Study Group questionnaires on an annual basis for the NIAID Project Officer to receive feedback from users of the NSR on quality and usefulness of NSR services such as: timely delivery of shipping materials, turnaround times for specimen commitments and shipments, access to information on stored specimens, training sessions, and other services provided under the Contract.

3. COMMUNICATIONS WITH THE NIAID PROJECT OFFICER

a. Provide updates, reports and/or information regarding NSR progress on tasks as well as emerging issues during weekly conference calls that include the NIAID Project Officer, Principal Investigator, the Project Manager and other NSR personnel specified by the Contractor or the NIAID Project Officer.

b. Meet with the NIAID Project Officer at least twice per year to review progress, and to discuss anticipated or existing problems, and work to be performed. The schedule and location of such meetings shall be determined by the NIAID Project Officer and will be in addition to the no-less-than-annual NIAID audits of the NSR.

E. QUALITY ASSURANCE SYSTEMS

A comprehensive Quality Assurance Program (QAP) as outlined below, shall be present within existing operations or be enhanced and implemented within the first 90 days of the contract for the NSR facility, its operations, equipment, and personnel.

1. QUALITY ASSURANCE PROGRAM

a. Provide a comprehensive QAP to monitor the entire specimen management process, including specimen receipt and inspection at the vial, box and shipment level; specimen processing; monitoring of storage conditions at the box and freezer level; inspection of

shipping containers and storage facilities including the central alarm system, air conditioning systems, and the back-up power system; specimen data management; requisitioning; and shipping of all requested specimens.

b. Operate the QAP in an autonomous manner, separate from the technical staff, and report results directly to the contract Principal Investigator and/or other senior corporate management.

c. Identify a number of key indicators or measures to monitor the specimen management process to include facilities, equipment, operations, and personnel. Examples of such indicators are: unidentified and identified vial versus manifest discrepancies; total number of discrepancies; data entry or technician processing errors; turn-around times; numbers of incoming and outgoing shipments; overall productivity (e.g., numbers of published papers using NSR specimens); and feed-back from user questionnaires (as described under paragraph D.2.e of this Statement of Work).

d. Provide acceptable and non-acceptable (upper and lower limits), and achievable specification limits for all key indicators.

e. Follow and trend key indicators quarterly. Implement corrective actions as soon as specification limits are not met.

f. Issue and review corrective action reports and provide appropriate follow-up action. Monitor out-of-specification and error rates and implement a program to reduce these rates to as low as reasonably achievable.

g. Provide an internal audit process no less than semi-annually throughout the facility that produces reports summarizing the current status of repository operations and listing any non-conformances with repository SOPs, repository policies, and Federal, State, or local regulations.

h. Provide a process for document version control.

i. Follow, where applicable, CLIA 1988 and subsequent amendments, GLP, GMP, and/or ISO 9001 guidelines.

j. An external audit of the facility and operations will be performed by the NIAID at least annually to review the repository operations and the QAP.

2. SPECIMEN INTEGRITY EVALUATION

a. Provide or develop a program for the periodic assessment of the biological integrity and viability of the various types of stored specimens, in order to correlate storage period and storage conditions with specimen degradation and loss of activity. NIAID staff and Study Group representatives will work with the Contractor to finalize a program.

b. Evaluate every six months a selected group of analytes, for example, HIV RNA quantification; peripheral blood mononuclear cell (PBMC) culture infectivity with HIV and Epstein-Barr Virus (EBV); PBMC antigen, mitogen, or growth factor stimulation; apoptosis assays or other unique enzyme indicators of cell death or proliferation; and/or common clinical chemistry panels.

c. Design innovative experimental studies and provide data to assist in guidance for improving future specimen storage, as well as determining scientific utility of the long term storage of current specimens and the introduction of bias due to processing and storage conditions.

d. Include both physical storage conditions and biological and/or chemical variables in

experimental study designs. Such evaluations shall require that the repository send appropriate specimens, such as duplicate or mock representatives to designated testing laboratories. These laboratories may belong to the repository, be a subcontractor(s), or be a collaborative effort with Study Groups.

e. Obtain results of the specimen integrity evaluations and:

1) include them in Interim and the Quarterly Progress Reports (see Reporting Requirements and Other Deliverables Section of this RFP);

2) prepare materials and write and/or support the preparation of scientific manuscripts for publication in peer reviewed journals; and

3) at the NIAID Project Officer's request, present or support the presentation of the data at scientific and Study Group meetings.

F. SOFTWARE SYSTEMS

1. SPECIMEN INVENTORY DATABASE MANAGEMENT SYSTEM

The NIAID owns a license to the Biological Specimen Inventory System (BSI-II) developed and maintained by Information Management Services, Inc (IMS). Information regarding the BSI-II and IMS, Inc. can be found at www.bsi-ii.com and www.imsweb.com. Use of the BSI-II system will be required during the first 4 to 12 months of the new contract and either (a) throughout the remainder of the contract or (b) until a replacement system, accepted by the NIAID, is fully implemented to allow for a validated transfer of the NIAID data from the BSI-II to a different SIDMS.

Approximately 4% of the existing NSR specimens stored are bar-coded. Approximately 75% of the shipments received after February 2005 are bar-coded and will continue to be bar-coded prospectively with the objective to ultimately receive bar-coded specimens for all incoming shipments.

a. Provide the minimum requirements or their equivalents for hardware and software for the BSI-II and other software applications to include:

i. IBM Compatible computer (PC), with a processor speed of 2 GHz, 512 MB RAM, CD R/W drive, 3.5 floppy drive, 40 GB hard drive, 1600 x 1200 – 16 bit color (8 meg) PCI or AGP, 19" CRT or 17" flat screen monitor, 10/100 Mbps Ethernet card, 4 USB ports;

ii. Hewlett Packard (HP) Compatible Laser Jet Printer or other laser printer;

iii. Internet service provider and high speed connection to the internet (cable modem, DSL, ISDN, Ethernet); and

iv. Software packages, which include Microsoft Windows 2000 or XP, Microsoft Office Suite, Symantec PC Anywhere-Version 10.5 or higher, Backup Software (e.g. Colorado Backup or Iomega), anti-virus software with up-to-date virus definitions (e.g. McAfee or Norton Anti-virus).

b. Provide and maintain a computer facility and SIDMS to track specimens and activities in the NSR. The BSI-II or SIDMS shall be maintained and updated on a Government-furnished or approved central automated data processing system to integrate specimen information received from all Sites and collected by the NSR. At a minimum, the system shall include the following capabilities and compiled data:

   i. print and scan bar-coded specimen labels;

   ii. import and export bar-coded and study-specific electronic manifest information;

   iii. capture data associated with received and requisitioned specimens, including primary specimen data from Sites; data collected upon inspection of vial receipt; and any activity associated with specimen processing before permanent storage, during storage, during requisitioning, and subsequent shipment;

   iv. participant Site contact information;

   v. data associated with key tasks performed in receipt, commitment and shipment of specimens including contract personnel identification performing the tasks;

   vi. data associated with relevant dates for receipt, commitment, and shipment of specimens and associated intermediate processes such as when specimen requests are created, and when aliquoting or other specimen processing tasks are performed; and

   vii. freezer and box storage conditions linked to vial data when out-of-range findings occur.

c. Generate standard reports for the Quarterly Progress Reports (see Reporting Requirements and Other Deliverables Section of this RFP), as well as ad hoc reports requested by the NIAID Project Officer for subsets of the data collected in the SIDMS.

d. Provide for the security of the SIDMS with confidential access codes. Use of industry-standard security access codes is required.

e. Provide the NIAID Project Officer and designees user access to the SIDMS. The NIAID Project Officer will determine the level of information to be disseminated and to whom it shall be made available.

f. Perform daily back-up of database files and programs and store on-site. Perform complete weekly back-up of database files and programs and store in an off-site location from the computer facility.

g. Provide and maintain a SIDMS User Manual for NSR data entry and technician staff as well as GSMs. The SIDMS User Manual shall be posted and updated on a designated NSR website.

h. Maintain a copy of the National AIDS Repository Database System (NARDS) as a historical and accessible record of specimen information collected prior to transferring the data to the BSI. Refer to Appendix C for additional information regarding the NARDS.

i. If a different SIDMS other than the BSI-II is utilized by the Contractor, a copy of the BSI-II database shall be retained and accessible. Additionally, prior to full implementation of the new SIDMS, transfer of the NSR data from the BSI-II to a different SIDMS must be validated and approved by the NIAID Project Officer.

2. NSR WEB SITE

Maintain and update an interactive, user-friendly and secure internet web site for posting relevant NSR information such as NSR and SIDMS User Manuals, NSR policies and guidelines, relevant scientific data or publications, monthly incoming shipments, monthly outgoing shipments with in queue or shipped status, and quarterly discrepancy rates by Study Group and Site. Paragraphs B.2.f. and F.1.f.of this Statement of Work provide examples of relevant NSR information to be posted on the web site.

3. DAIDS-ENTERPRISE SYSTEM INTERFACE

Upon request of the NIAID Project Officer, provide NSR information through the DAIDS-Enterprise System (see Appendix C for information on the DAIDS – Enterprise System) such as:

a) Site and NSR contact information;
b) total numbers of committed specimens by Study Group and predominant specimen type;
c) total numbers of specimens requisitioned by Study Group; and
d) integrity, stability, and/or functional data on stored specimens.

4. ELECTRONIC COMMUNICATION

a. Provide the capability to receive manifest data files electronically from the Laboratory Data Management System (LDMS) and HVTN Laboratory Information Management System (LIMS) for import into the SIDMS and to communicate electronically via secure e-mail with all Sites, GSMs, the DAIDS Enterprise System, and the NIAID Project Officer. See Appendix C for a description of databases and software systems.

b. Provide a state-of-the-art software system for data management for expedited processing of selected high-priority information (e.g., received shipment status, vial discrepancies, weekly specimen batch commitments and shipments, freezer failures, vial status, data audit trails) and for ready transferal of data, and complete system and data documentation to NIAID or others at any point during the contract. The system shall provide sufficient flexibility and accessibility to answer any inquiries in a timely manner, typically no more than one business day.

5. SYSTEM SECURITY

Provide security needs to meet NIH requirements. Develop a system security plan and submit it through the NIAID Project Officer to the NIAID Office of Technology and Information Systems

(OTIS) for approval. Implement and maintain security requirements for the SIDMS and other database and hard copy systems to provide security against anticipated risks including loss of specimen data or important software, and access of records by unauthorized personnel or outside entities. A comprehensive plan and its intended use can be found at http://irm.cit.nih.gov/security/secplantemp.doc.

6. SYSTEM MAINTENANCE AND UPGRADES

a. Maintain and upgrade software programs that are compatible with current software in use at NIAID and with changes made in NIAID systems. Any computer system for data management or new software must meet OTIS standards and shall be developed with the software, Operating System's (OS), languages and tools recommended by OTIS in order to ensure integrated operability with the rest of NIAID databases and infrastructure. Prior to any software purchase or development, consultation must occur with the NIAID Project Officer and OTIS staff to determine the direction, software, OSs, languages and tools to be used.

b. Maintain and upgrade reliable and secured electronic communication linkages with NIAID, Sites, and SGMs that facilitate sending e-mail and sharing text and data files.

c. Management tools, computer systems, databases, documentation, data, and any other electronic or hard copy files or items developed via this contract will remain the property of the NIAID.

7. INTERACTION WITH OTHER NIAID CONTRACTORS

At the request of the NIAID Project Officer, perform data entry or interact with other NIAID contractors for the exchange of data, movement of specimens and investigational products. The Contractor may be asked to download or transfer data to other NIAID or DAIDS- supported software systems.

8. INFORMATION TECHNOLOGY REPORT

With input from NIAID subject matter experts, study the Information Technology (IT) hardware, software, networking and security needs for the entire project and develop a report of the IT requirements (including a complete IT security assessment). Part of this process shall include interaction with, and review by, OTIS staff to ensure alignment with NIAID IT operations, business processes, and documentation deliverables for the proposed IT infrastructure. The study and final recommendations shall include: IT architecture (network, security, server, application, and database), schemas, run books, processes, procedures, disaster recovery, failover, troubleshooting, application/system monitoring, and change control/management.

9. INFORMATION SECURITY (InfoSec)

InfoSec consists of:

i. Confidentiality -- the prevention of unauthorized disclosure/use of information;

ii. Integrity -- the prevention of unauthorized modifications to information; and

iii. Availability -- ensuring the reliable and timely access to data or computing resources.

With input from the NIAID Project Officer and OTIS staff, conduct a study of the InfoSec requirements of the entire project including: the privacy requirements of clinical data; physical and electronic security for both hardware, software and communications; and whether all participants involved in the contract (subcontractors, NIAID staff, study Site investigators, etc.) need to have a secure capability for communication and exchange of information in the case of a national disaster that may disrupt the ability to interact and exchange needed information. The study shall include a definition of the entire system, such as the physical and logical description of the entire planned system, including hardware, software, communications, InfoSec and other considerations.

G. PROJECT MANAGEMENT

Provide a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and management of all activities carried out under this contract and effective communications with the NIAID Project Officer and the NIAID Contracting Officer. This infrastructure shall include a Principal Investigator with responsibility for overall project management and communications, tracking, monitoring and reporting on project status and progress, and recommending modifications to project requirements and timelines, including projects undertaken by subcontractors. This infrastructure shall also include a Project Manager to coordinate repository activities conducted under this contract; and administrative staff with responsibility for financial management and financial reporting on all activities conducted by the Contractor and any subcontractors.

H. FINAL TRANSITION

The Contractor shall ensure an orderly transition to a possible successor contractor prior to expiration of this contract.

1. TRANSITION OF ACTIVITIES UPON COMPLETION OF THE CONTRACT

    a. Eight months prior to the completion of this Contract, provide to the NIAID Project Officer a draft Final Transition Plan that details the transition to a possible successor contractor of all contract-related materials. These materials shall be organized and catalogued in sufficient detail to support an orderly transition to a possible successor contractor. The Contractor shall work with the NIAID Project Officer and the NIAID Contracting Officer to refine and complete this plan, with a Final Transition Plan to be provided 6 months prior to the expiration date of the contract. The Final Transition Plan shall include recommended steps with a detailed cost estimate to sustain the activities provided for in the contract during transition and shall include delivery to the NIAID or its designee, by the expiration date of this contract, all contract-related items including:

        1) Specimen Freezers and contents. The Contractor shall perform operational and performance qualifications on freezers to be transferred to the successor Contractor;

        2) All computerized data files and software systems (with documentation and specifications) including specimen inventory files, specimen batches in queue for commitment or shipment, data entry files, active specimen discrepancy files (information shall be provided in electronic format and transferred in a secure manner as determined by NIAID IT and the contractor);

        3) DAIDS-specific SOPs, hard copy files of freezer management and maintenance, correspondence files, archived activity files for incoming and outgoing shipments; and

4) Government-Furnished Property (GFP). Verification of equipment performance standards shall take place prior to the transfer.

b. Notify all Sites as early as possible of the transition. Provide to the Sites and GSMs the schedules for the transition and instructions concerning any changes in repository activities, including schedules anticipated during the transition period.

I. EXPANDED SERVICES THROUGH EXERCISE OF OPTION(S)

In addition to the services outlined above to be provided for the basic requirement, Options(s) for additional services under the contract are defined as follows:

If and to the extent the Option is exercised, the services provided will support up to five (5) additional sites, which may be any combination of domestic or international Sites/non-Sites. Each contract year will provide for the potential exercise of up to three (3) options which will provide for the support of up to fifteen (15) additional sites, per year. The services required will be of the same scope as outlined for the basic requirement.

It will not be known at the time of contract award which sites will be included in the option(s). While these options will be evaluated prior to contract award, it will be necessary for the contractor to submit a brief technical plan and cost proposal once the sites to be supported are identified, and prior to the exercise of each option(s).

[END OF STATEMENT OF WORK]

Reporting Requirements and Other Deliverables
NIAID Specimen Repository

The Contractor shall provide the reports and deliverables specified below. All reports shall be submitted in electronic form (or hard copy form when not possible) as PC-formatted computer files in Microsoft Word™ and Microsoft Excel™ and/or searchable PDF format. Electronic versions shall be sent on CD or more current electronic data storage medium, by U.S. mail or courier service. All reports shall be archived on CD or other appropriate media for provision to the NIAID Project Officer at the expiration of the contract.

A. Quarterly Progress Reports

The Contractor shall submit copies of Quarterly Progress Reports on/before the 15th of the month following the end of each quarter. The first quarter of the contract should include the first three months of performance and any fraction of the first month in which the contract began. A Quarterly Progress Report shall not be required when providing an Annual or the Final Report. Each Quarterly Progress Report shall consist of:

1. A cover page containing:

    a. Contract number and project title
    b. Period of performance being reported upon
    c. Type of report
    d. Contractor's name and address
    e. Author(s)
    f. Date of submission

2. An introduction, covering the purpose and scope of the contract effort pertaining to the period of the report.

3. Summaries or charts/graphs/tables of activities for the quarter being reported upon, as specified in the Statement of Work:

    a. Incoming and Outgoing shipment information and activities shall be included as follows:
        1) Summary tables and/or graphs for activities relating to shipments received, including (refer to Statement of Work, Paragraph B.2.):
            a) total number of shipments received across the Study Groups and within each Study Group by Site;
            b) specimens received versus added to inventory by Study Group and material type and by Site within each Study Group;
            c) summary of types and quantities of discrepancies by Study Group and by Site within each Study Group;
            d) turnaround times for commitment of specimen batches including NSR discrepancy reporting and Site corrective action timelines;
            e) special issues noted regarding receipt and commitment of specimen shipments such as shipment condition, discrepancies encountered or turnaround time issues, and/or others as identified; and
            f) other information and activities as may be required by the NIAID Project Officer or the Contractor.
        2) Summary tables, and/or graphs for activities relating to outgoing shipment tasks, including (refer to Statement of Work, Paragraph B.3.):

a) number and material type(s) of shipments received by Sites within each Study Groups and by non-Sites;
b) number of shipments requiring tasks performed on specimens such as aliquoting or blinding by Study Group or collaborators;
c) turnaround times for shipment of outgoing specimens including types of discrepancies found by material type and Study Group as well as corrective action reporting by Sites and/or GSMs; and
d) other information as may be required by the NIAID Project Officer.

b. Health and Safety of Personnel (refer to Statement of Work, Paragraph B.4.)
   1) Summary of employees' training records; and
   2) Summary of documented safety issues.

c. Storage Facilities and Equipment (refer to Statement of Work, Paragraph C.)
   1) Freezer inventory including any retirement activity and/or new purchases;
   2) Rate and number of freezers being filled, depleted, and/or re-organized (to include freezer identification information);
   3) Summary of maintenance reports for freezers, other equipment, and facilities to include out-of-range findings and corrective actions; and
   4) Summary of inspections to include problems encountered and corrective actions taken.

d. Shipping Materials, Technical Assistance, and Site Training (refer to Statement of Work, Paragraphs D.1. and D.2.)
   1) Table of shipping materials sent to Sites and non-Sites including quantity and dates;
   2) Summary of retirement or purchases of shippers or shipping materials along with current list of inventory of shippers and associated materials;
   3) Summary of any revised SOPs, NSR policies, guidelines, and/or reference materials;
   4) Summary of site-specific issues and resolutions via NSR technical support, such as use of the SIDMS, shipping materials, and incoming and outgoing specimen shipments;
   5) Summary of NSR training activities and/or meetings attended for Study Groups, Sites, GSMs or others; and
   6) Upon request of the NIAID Project Officer, a summary of findings from questionnaires to Sites regarding NSR services.

e. Communications with the NIAID Project Officer (refer to Statement of Work, Paragraph D.3.)
   1) Tracking table containing conference call issues, resolutions, and/or action items by conference call date;
   2) Summary of work projected for next quarter; and
   3) Summary of semi-annual meetings with the NIAID Project Officer.

f. Quality Control/Quality Assurance (refer to Statement of Work, Paragraph E.)
   1) Summary of Quality Control test outcomes performed on specimen shippers;
   2) Summary of operational Quality Assurance test outcomes performed on freezers, other equipment or facilities;
   3) Summary of quarterly key indicator trends including corrective actions taken for any out-of-specifications, errors, or non-conformances as well as plans for reducing or maintaining the lower acceptable limit of specifications;
   4) Corrective action reports generated for Study Groups and/or GSMs;
   5) Summary of planned studies, interim results and/or status of ongoing studies, and/or completed study results from specimen integrity evaluations; and
   6) External audit reports and responses.

g. Computerized Software (refer to Statement of Work, Paragraph F.)
    1) Summary of NSR website updates and/or postings;
    2) Summary of data management activities, including issues and solutions related to computer hardware and software; and
    3) Other information as required by the NIAID Project or Contracting Officers.

4. A Personnel Report, which shall include name, title, percent effort and responsibility of key personnel, technicians, data entry operators, administrative and financial personnel working on the contract as well as subcontractors and/or consultants. For each individual provide a brief summary of tasks performed during the quarter.

5. Scientific Activities. This shall include any research not included in B.2. below; a list of scientific meetings and conferences attended; a list of manuscripts published, submitted or in preparation; and a list of abstracts submitted for presentation or in preparation.

B. Interim Reports

1. Upon request of the NIAID Project Officer, and within five business days of such a request, the Contractor shall provide an Interim Report encompassing 1-4 weeks of recent NSR activities including:
    a. The specific work accomplished and in progress;
    b. A summary of all incoming and outgoing shipping activity;
    c. A description of any technical or performance problems encountered and corrective actions planned or taken;
    d. The estimated time taken to complete the work described; and
    e. Selected other items as required by the NIAID Project Officer.

2. The Contractor shall submit written or electronic reports of all research and development studies performed as specified in paragraph E of the Statement of Work as follows:
3.
    a. Within 10 working days following completion of data analysis, study results shall be reported to the NIAID Project Officer and relevant Study Group(s) as specified by the NIAID Project Officer.
    b. Within 3 months of study completion, the Contractor shall provide to the NIAID Project Officer materials to support preparation of scientific manuscripts for publication in peer reviewed journals. In cases where the Contractor drafts a publication, prior to a publication submission, all manuscripts shall be provided in hard copy or electronic copy to the NIAID Project Officer and others for review and approval, as specified by the NIAID Project Officer.

C. Annual Progress Reports

Annual Reports shall include the fourth Quarterly Progress Report and an Annual Table of Contents referring to previous Quarterly Progress Reports. Annual Reports shall be provided on or before the 30th of the month after each anniversary date of the contract. An Annual Report is not required for the period when the Final Report is due.

D. Final Progress Report and Summary of Salient Results

The Final Report shall cover the entire contract performance period and be in sufficient detail to explain comprehensively the accomplished tasks, a brief description of any unfinished projects, and a status report on transition or shut down activities. In addition, the Contractor shall provide a 200 word minimum “Summary of Salient Results” detailing the important accomplishments from the

contract during the performance of the contract. A draft of the Final Report shall be submitted for review by the NIAID Project Officer 30 days prior to the completion of the contract. The Final Report shall be submitted prior to, or at the completion of the contract.

E. Other Deliverables

1. Manual of complete NSR SOPs (existing and in draft) subject to the NIAID Project Officer approval for all aspects of the Statement of Work within 20 business days of award date.

2. Draft User Manual for Sites and GSMs to include NSR policies, guidelines, and reference materials as noted in the Statement of Work within 20 business days of award date.

3. Draft implementation plan for the comprehensive Quality Assurance Program for the NSR, including key indicators and a Site/GSM questionnaire for feedback on provided services within 25 business days of the award date.

4. Outline of proposed experiments for specimen integrity studies within 45 business days of award date.

5. Initial Transition Plan within 10 business days of the start of the contract, that includes draft NSR SOPs, describing NSR operational procedures and policies/guidelines, including quality assurance measures for the safe and orderly relocation of all NSR-related materials from the current Contractor, as outlined in paragraph A. of the Statement of Work. This plan shall include staffing requirements and a description of work during the transition.

6. Draft plan for the secure transfer, maintenance, and upgrade of data, hardware, and software within 10 business days of the start of the contract. Draft plan for the Information Technology report and InfoSec study within 60 business days of the start of the contract. Refer to Scope of Work requirements, Section F.3 through F.9.

7. Eight months prior to the expiration date of the contract, the Contractor shall provide a draft Final Transition Plan which describes proposed procedures for an orderly transition to a subsequent Contractor or the NIAID and estimated cost as outlined in paragraph H.1 of the Statement of Work.

8. A Final Transition Plan shall be provided six months prior to the completion date of the contract.

9. Contract Completion: The Contractor, subject to NIAID Project Officer approval, shall deliver to the NIAID or its designee, by the completion date of this contract, freezers and specimens, inventory and software systems, including software programs, labeled and inventoried paper files, and Government-Furnished Property (GFP), as outlined in paragraph H. of the Statement of Work.

F. **REPORT DISTRIBUTION**

Type of Report	No. of Copies	Due Date
Quarterly Progress Report	Original – Contract Officer (CO)	Due on/before the 15th of the month following each quarterly reporting period.

	1 copy – Project Officer (PO)	Not due when Annual or Final Reports are due.
Interim Report	Original – PO	Due within 5 days of request
Annual Progress Report	Original –CO 1 copy – PO	Due on/before the 30th of the month after each Anniversary date of the contract. Not due when the Final Report is due.
Final Progress Report and Summary of Salient Results	Original –CO 1 copy – PO	On/before the completion date of the contract. A draft of the Final Progress Report shall be provided 30 days prior to the Final for PO review and revision.
Transition Plan (Contract start-up)	Original – CO 1 copy – PO	10 business days after the effective date of the contract.
Transition Plan (Draft)	Original –CO 1 copy – PO	Eight months prior to completion of the Contract.
Transition Plan (Final)	Original –CO 1 copy – PO	Six months prior to completion of the Contract.

If the Contractor becomes unable to deliver the reports specified hereunder within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer written notice at least 10 business days prior to the due date of anticipated delays with reasons therefore. The Contracting Officer and Project Officer must approve the extension in writing. A new delivery date must be established.

G. Addressees:

NIAID Project Officer:
National Institutes of Health, DHHS
National Institute of Allergy and Infectious Diseases
Treatment Research Program, DAIDS
6700-B Rockledge Drive, Room 5206, MSC 7624
Bethesda, MD 20892-7624

NIAID Contracing Officer:

National Institutes of Health, DHHS
National Institute of Allergy and Infectious Diseases
Contract Management Program, DEA
6700-B Rockledge Drive, Room 3214**,** MSC 7612
Bethesda, MD 20892-7612

APPENDIX A - ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS and FORMAT for:

TECHNICAL PROPOSAL – TABLE OF CONTENTS

THE BELOW TEMPLATE MUST BE USED AS THE TABLE OF CONTENTS FOR YOUR TECHNICAL PROPOSAL AND ALL INFORMATION IN YOUR TECHNICAL PROPOSAL SHOULD BE PRESENTED IN THE ORDER SPECIFIED BELOW.

OFFERORS ARE REMINDED THAT THE TOTAL PAGE LIMITATION FOR THE ENTIRE TECHNICAL PROPOSAL PACKAGE IS 150 PAGES INCLUDING APPENDICES AND ATTACHMENTS, BUT EXCLUDING KEY SOPS. PLEASE REFER TO THE FOLLOWING LINK FOR SPECIFIC PROPOSAL PREPARATION INSTRUCTIONS REGARDING PAGE LIMITATIONS: http://www.niaid.nih.gov/contract/eproposal.htm#electronic

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

OFFERORS ARE ADVISED TO GIVE CAREFUL CONSIDERATION TO THE STATEMENT OF WORK, ALL REFERENCE MATERIAL PROVIDED AS APPENDICES AND ATTACHMENTS, AND THE TECHNICAL EVALUATION CRITERIA IN THE DEVELOPMENT OF YOUR PROPOSAL.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

GENERAL NOTES:

1. All Offerors must adhere to the following page limitations:

   a. TECHNICAL PROPOSAL: Not-to-exceed a total of 150 pages
   b. APPENDICES AND ATTACHMENTS: Not-to-exceed 50 pages of the 150 total pages
   c. STANDARD OPERATING PROCEDURES: NO PAGE LIMITATIONS FOR ALL KEY SOPS INCLUDING OPERATIONS, PERSONNEL TRAINING, AND QUALITY ASSURANCE

2. A detailed technical plan must be submitted in the Offeror's Technical Proposal indicating how each aspect of the Statement of Work is to be accomplished. Your technical approach should be in as much detail as 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.

3. It is recognized that a single institution may not have the expertise and facilities required to perform all requirements of the Statement of Work. Therefore, the Offeror may propose to subcontract a portion of the work. If a subcontractor is proposed, similar technical information must be provided in the Technical Proposal as that required for the Offeror, i.e., technical approach, methods, experience, personnel qualifications, facilities, resources, etc. The relationship between the proposed subcontractor and the Offeror must be clearly delineated.

SECTION 1. TECHNICAL APPROACH – STATEMENT OF WORK

A. INITIAL TRANSITION

Describe your plan for transition of the current NSR from the incumbent Contractor, including movement of freezers containing specimens, all other Government-furnished property and all data and data systems. Currently, the NSR is housed in Frederick, Maryland. Describe all coordination efforts required between the incumbent Contractor and the Offeror for the relocation tasks. Include plans for the conduct of ongoing operation and coordination with Sites and non-Sites for transition of the NSR. Provide timelines for the transition.

Provide an outline for developing a draft plan to address the secure movement and maintenance of data and data systems (i.e., security plan).

The NIAID owns ten (10) LN2 shippers (holding 324 vials) and thirty (30) FSSU-24 shipping containers holding 24 boxes of 81 specimens with reusable outer containers and disposable inner liners. These, as well as other commercially purchased shippers, will be transferred to the successful Offeror upon award of a contract. The FSSU-24 shipping containers were developed through the DoD and manufactured by SkyDyne, Inc. For more information regarding these shippers, visit the website: http://www.skydyne.com/FSSU24.html

Refer to Appendix F for a list of Government-Furnished Property to be transferred.

B. SECURE, RECEIVE, CATALOG, PROCESS, STORE, AND DISBURSE HUMAN BIOLOGICAL SPECIMENS FROM NIAID-SPONSORED STUDY GROUPS

1. INCOMING AND OUTGOING SPECIMEN SHIPMENTS

a. Discuss your plans and procedures including state-of-the-art technologies for managing incoming shipments, providing Sites with shipping materials and instructions; logistics and procedures for receiving (including a tracking mechanism for shipment receipt and condition of shipment upon receipt), internal tracking and inventorying specimens; identifying, reporting, and correcting shipment discrepancies; identifying types of incoming specimen data tracked in the SIDMS; and implementing expected turnaround times.
b. Discuss your plans and procedures including state-of-the-art technologies for managing outgoing shipments, including providing Sites with instructions; logistics and procedures for retrieving specimens; identifying, reporting, and correcting discrepancies; storing, packaging and shipping specimens (including a shipment tracking mechanism while in transit) both domestically and internationally; identifying data elements to be tracked in the SIDMS; and implementing expected turnaround times.
c. Discuss your knowledge regarding IATA and other relevant regulations regarding domestic as well as the import and export of specimens internationally; provide documentation of any permits or licenses currently held.
d. Discuss your knowledge and use of current international, Federal, State, and local regulations, policies, and/or guidelines in your repository operations, such as CLIA, ISO 9000, GLP, and OHRP for stored specimens.
e. Discuss your personnel health and safety program.
f. Discuss your plans to form and maintain an NSR IRB according to current regulations and guidelines for the use of stored biological specimens.

2. HEALTH AND SAFETY OF PERSONNEL

   Provide a safety and health plan and a summary of your safety and health operating procedures manual; training certificates from Transport of Dangerous Goods training courses for key personnel; documentation of ongoing programs and plans for programs for adequate training of personnel handling infectious biological material, including: decontamination procedures, accident procedures and monitoring for infection; evidence of training and compliance with applicable guidelines or regulations for a Biosafety Level 2 facility; and, draft SOPs for acquiring, storing, processing, and disbursing diagnostic and potentially infectious biological specimens.

C. STORAGE FACILITIES AND EQUIPMENT

1. Include in your proposal the following: ability to monitor and maintain current NSR freezers, purchase new freezers, and retire aging freezers; existing or planned security systems; and ability or proposal to capture out-of-range freezer conditions and electronically link those data to vial data.
2. Discuss your existing or proposed operational disaster recovery program and ability to report documented tests of the system.

D. SHIPPING MATERIALS, TECHNICAL ASSISTANCE, SITE TRAINING, AND COMMUNICATIONS WITH THE NIAID PROJECT OFFICER

1. SHIPPING MATERIALS

   a. Discuss your plans for procuring, maintaining, and performing quality control on shipping materials.

2. TECHNICAL ASSISTANCE, SITE TRAINING, AND COMMUNICATIONS WITH THE NIAID PROJECT OFFICER

   a. Discuss your ability and experience in developing, distributing, and updating policies, user manuals, and guidelines via hard copy, electronic mail and web site.

   b. Discuss your ability and experience in preparing and presenting data at national and international meetings.

   c. Discuss plans to communicate with the NIAID Project Officer, staff at Sites, GSMs and others specified by the NIAID Project Officer through conference calls and meetings. Indicate personnel to be included in regularly scheduled conference calls and personnel to be included in regularly scheduled meetings with the NIAID Project Officer.

   d. Describe plans for providing training and technical assistance to Sites on all aspects of the NSR including shipping, labeling, bar-coding, specimen handling, on-site processing and storage, and use of the SIDMS.

E. QUALITY ASSURANCE SYSTEMS

1. QUALITY ASSURANCE PROGRAM

   Propose a draft QAP describing in detail, current quality assurance systems in place, organization and staffing, as well as plans for additional improvements. Propose key

indicators or measures to sufficiently monitor the specimen management process.

2. SPECIMEN INTEGRITY EVALUATION

The Offeror shall use its management experience to propose a draft plan to address issues concerning the possibility of a maximum capacity for the repository; basic points which may be used in deciding which categories of specimens might be collected, stored, or discarded; ways to effectively manage the availability/accessibility of specimens to the scientific community; and how to institute and maintain quality control standards throughout the plan. Included in the draft plan should be proposed experimental study designs to evaluate specimen integrity and viability. Upon award the successful Offeror's draft plan will be refined in collaboration with NIAID Study Groups and policy-makers.

F. COMPUTERIZED SOFTWARE SYSTEMS

1. SIDMS

The Offeror shall assume that the Government will provide the existing software for the specimen inventory database management system, namely the Biological Specimen Inventory System (BSI-II) to the successful Offeror, but the hardware shall be provided by the successful Offeror. The BSI-II is an inventory system for all specimens that are stored at, and distributed from, the repository, with the ability to track complete specimen information received from the Sites as well as information collected in the NSR, including specimen aliquots and the freeze/thaw cycle(s) of the parent and child vials.

a. In responding to this RFP, the Offeror may include suggestions (with specific information) regarding the hardware and specimen inventory management software that is potentially more adaptable, comprehensive, and contemporary than the BSI-II.

2. NSR WEB SITE

Discuss plans to establish, maintain and update an interactive, user-friendly and secure internet web site for posting relevant NSR information including proposed mechanism(s) for interfacing the web site with the SIDMS in order to display data on the web site in real-time. Target audiences will be Study Group Principal Investigators, Site and non-Site laboratory personnel, GSMs, and DAIDS. A more restricted form of the website may be considered for the general scientific community.

3. DAIDS-ENTERPRISE SYSTEM INTERFACE

Discuss plans for interfacing with the DAIDS-Enterprise System (see Appendix C for information on the DAIDS – Enterprise System) for transfer of data specified in the Statement of Work.

4. ELECTRONIC COMMUNICATION

a. Discuss your plans to receive and transmit data files electronically via the SIDMS and to communicate electronically via secure email with all Sites, potentially other laboratory

specimen database management systems such as the LDMS and LIMS, the DAIDS Enterprise System, and the NIAID Project Officer. See Appendix C for a description of databases and software systems. Include plans for ready transferal of data and complete system and data documentation to the NIAID Project Officer or others at any point during the contract.

b. Discuss plans to provide a software system(s) to track data relating to NSR operations as stated in the Statement of Work.

5. SYSTEM SECURITY

Discuss plans to provide for computer system security needs to meet NIH requirements. The successful Offeror will be required to develop a plan and submit it through the NIAID Project Officer to the NIAID Office of Technology and Information Systems (OTIS), for approval, as specified in the Statement of Work.

A comprehensive plan and its intended use can be found at http://irm.cit.nih.gov/security/secplantemp.doc

Additional information is also available at:

- NIH System Certification and Accreditation
- NIST 800-26 Security Self Assessment Tool (SSAT)
- Assigning Security Level Designations

  Table 1: Categories of Safeguarded Agency Information

  Table 2: Security Level Designations for Agency Information

  Table 3: Position Sensitivity Designations for Individuals Accessing Agency Information

- NIST Guide for Developing Security Plans
- Security Advice for Application Developers
- System Security Plan Template
- System Development Life Cycle Activities Matrix
- Security and the System Development Life Cycle (SDLC) Class Presentation
- The Ten Most Critical Web Application Security Vulnerabilities

6. SYSTEM MAINTENANCE AND UPGRADES

a. Discuss plans to maintain and upgrade software programs that are compatible with current software in use at NIAID and with changes made in NIAID systems.

b. Discuss plans to maintain and upgrade reliable and secured electronic communication linkages with NIAID, GSMs, and Sites that facilitate sending e-mail and sharing text and data files.

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7. INTERACTION WITH OTHER NIAID CONTRACTORS

Discuss plans for potential interaction with other NIAID contractors for the exchange of data.

8. INFORMATION TECHNOLOGY (IT) REPORT

   Propose a draft report of the IT requirements (with a complete IT security assessment), including personnel who will interact with NIAID IT staff.

9. INFORMATION SECURITY (INFOSEC)

   Discuss plans to conduct a study of the InfoSec requirements of the entire project including: physical and electronic security for both hardware, software and communications; and whether all participants in the contract (subcontractors, NIAID staff, study Site investigators, etc.) need to have a secure capability for communication and exchange of information in the case of a national disaster that may disrupt the ability to interact and exchange needed information.

G. FINAL TRANSITION PLANS

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Describe general plans for transition of the program to another Offeror at the end of the contract.

H. EXPANSION OPTION(S)

The NIAID anticipates a need to provide the services outlined in this Statement of Work to additional Sites and non-Sites. The base contract covers 41 Sites shipping specimens to the NSR and 300 Sites and non-Sites receiving specimens from the NSR with an estimated increase through exercise of Options to approximately 90 Sites shipping specimens to the NSR and approximately 350 Sites and non-Sites receiving specimens from the NSR. Over the term of the contract, the number of Sites may expand to approximately 60 domestic Sites and 30 international Sites shipping specimens to the NSR. Domestic Sites will be located within the continental United States, Puerto Rico and Hawaii. Most of the international Sites will be located in South America, the Caribbean Islands, Africa, and Asia. A small number of Sites may be located in other areas (currently, one Site is located in Canada, one in Europe and one in Australia). It is important to note that not all clinical sites within a given Study Group will ship directly to the NSR. Such an increase in the Contractor's activities may be required at the discretion of the NIAID, through exercise of an Option under the terms of this contract. Each Option shall cover the addition of up to 5 Sites/non-Sites. A range of one to three Options may be exercised in any contract year.

Propose a plan for implementing up to three (3) Options per year, with each option including up to five (5) additional Sites/non-Sites. Discuss the ability of the Principal Investigator and Project Manager to oversee and manage the expansion. Discuss plans to increase the required staff, facilities and other resources necessary to provide the services called for in the Statement of Work to provide additional domestic and international Sites. This shall include the timelines for all tasks involved in implementing the expansion, proposed modifications in organizational structure, management procedures, and other Contractor functions that may be required to carry out such an expansion.

SECTION 2. PROJECT MANAGEMENT AND PERSONNEL/STAFFING

A. PROJECT MANAGEMENT

1. Management Plan

   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 for all proposed personnel who will be assigned to the contract, including proposed subcontractors and consultants, and an administrative framework indicating clear lines of authority and responsibility for personnel. Propose time schedules for achieving contract objectives, and procedures for maintaining quality control over the implementation and operation of the contract, including plans to keep within budget. Describe the extent to which outside consultants will be used, as well as assurance of their availability. Discuss the adequacy of the staffing plan to efficiently and appropriately execute the Statement of Work including the time commitment of the professional and technical staff.

2. Communication

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

B. KEY PERSONNEL

   Several high-level or Key Personnel will be required for this contract.

   Describe the experience and qualifications of Key Personnel including subcontractors, to perform the Statement of Work, as well as the percentage of the total time each will be committed to the project. Identify the composition of the task or work group, its general qualifications and recent experience with similar efforts. Provide documentation to describe:

   - Key Personnel; limit curriculum vitae (CVs) to 2-3 pages.
   - Qualifications and experience as supported by academic degree(s), specialized training, and expertise (refer to Technical Evaluation Criterion B).
   - Availability for the proposed project.
   - Previous and current projects of a similar nature, including the contract number or grant number, the sponsoring agency, the name of the Project Officer and contact information, and a description of the project.
   - Managerial ability to achieve delivery or performance requirements as demonstrated by the proposed use of management and other personnel resources and to successfully manage the Project as demonstrated by the management plan and previous relevant experience.

C. OTHER PERSONNEL

   Offeror(s) should discuss the qualifications, experience, education, competence, and role of other personnel.

SECTION 3. FACILITIES AND EQUIPMENT

Describe the facilities, equipment and other resources to be made available for this project. Include a plan for compliance with safety guidelines and regulations including the availability and

description of BSL-2 conditions for containment/safety practices for handling NSR diagnostic and infectious specimens. Include a detailed floor plan of the proposed facility showing the location of equipment and other resources. Provide a list of equipment and resources dedicated to the project including availability and systems for monitoring, back-up, and security. Provide a copy of any ownership or lease agreements for space and address the availability of the facility at the time of award. Include information on any renovations that may be necessary prior to start-up. A list of Government-supplied equipment is provided as Appendix F.

APPENDIX B

ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS

UNIFORM BUDGET ASSUMPTIONS

Offerors shall assume the following for cost estimating purposes:

1. Assume costs for all shipments to and from the NSR including all materials and tracking shipments while in transit.

2. The Repository currently contains five (5) million specimens, collected from 40 sites. The Offeror shall expect to accrue approximately four (4) million additional specimens, collected from those 40 sites, during the term of the contract. The Offeror shall assume receiving, on an average, approximately 80,000 specimens per quarter in the first year with an expansion to 100,000 specimens per quarter in the second year and up to 120,000 specimens per quarter for years 3-7. Approximately 60% of quarterly shipments are -70^0C (serum/plasma, etc.) and approximately 40% of quarterly shipments are -195^0 C (cells).

3. The Offeror shall assume that disbursement of approximately 150,000 specimen tubes will occur the first year. Disbursement of all specimens (aliquoted and non-aliquoted) during the first year will occur at a rate of approximately 37,000 specimens per quarter. For years 2-4 the Offeror shall assume the disbursement of approximately 240,000 specimen tubes (aliquoted and non-aliquoted) with a quarterly rate of 60,000 specimens. For years 5-7 the Offeror shall assume the disbursement of approximately 280,000 specimen tubes (aliquoted and non-aliquoted) will occur at a quarterly rate of 70,000 specimens. Approximately 95% of these monthly specimens are non-aliquoted, 5% are aliquoted serum and plasma, and all specimens are disbursed across approximately 100 Sites and non-Sites per year. Aliquoted plasma and serum specimens result in an additional 3-7 child vials requiring storage.

4. The Offeror shall assume the cost to establish and maintain an NSR Institutional Review Board (IRB) according to Health and Human Services Office for Human Research Protections (OHRP) as well as other Federal, State, and Local regulations and guidelines. Assume review of study-, substudy-, or cohort-specific Sample Informed Consents (SICs) or revisions on a quarterly basis.

5. The Offeror shall assume the costs of quality assurance study planning and execution to assess biological integrity and viability of specimens stored within the NSR. Assume the conduct (in house or through a sub-contractor) and data generation for semi-annual sets of studies.

6. The Offeror shall include the procurement cost of adequate numbers of non-reusable shipping materials, FSSU-24 replacement parts and service maintenance, smaller shipping containers (for example, STP-310s) for incoming and outgoing shipments outlined in 2.and 3. above.

7. The Offeror shall assume the transfer, upon award, of 140 mechanical freezers and 37 liquid nitrogen freezers presently in use.

8. The Offeror shall assume the purchase of 100 *additional* twenty seven cubic foot -70 mechanical freezers (or their equivalent) and 30 *additional* large capacity, liquid nitrogen freezers.

9. Approximately 20% of the existing freezer inventory will need to be retired and replaced during the contract period. The Offeror shall assume the purchase of 25 mechanical and 4 liquid nitrogen freezers to replace retired freezers during the 7 years at a rate of approximately 3-4 mechanical freezers each year and 1 liquid nitrogen freezer the first year and 1 every other year thereafter.

10. The Offeror shall assume the Government license fee for the BSI-II software for at least one year or until a different SIDMS is implemented. The current annual license fee for the BSI-II software is approximately $20,000.

11. The Offeror shall assume the cost to develop and maintain an NSR website. Assume connection with the SIDMS to maintain real-time updates for some data as well as additional content updates monthly.

12. The Offeror shall assume conducting 6 training sessions per year for domestic and international Sites. Include 2 of the 6 training sessions as teleconference or videoconference lasting 2 hours each, 1 of the 6 training sessions as a full-day at the Contractor's site, with up to 10 participants (Contractor will not be responsible for participant travel support), and 3 of the 6 training sessions as presentations at Study Group meetings.

13. The Offeror shall assume 2 visits per year of 2 Contractor personnel, each lasting 1 day, to Bethesda, Maryland to meet with the NIAID Project Officer and to attend DAIDS-sponsored meetings. Also, assume travel for 2 Contractor personnel for participation in 6 domestic meetings, 3 days duration, per year.

14. The Offeror shall assume two, 4-day NIAID external audits of the NSR per year and two 1-day site visits per year of the NIAID Project Officer to the Contractor's site (Contractor will not be responsible for NIAID Project Officer or NIAID audit team travel support).

15. A detailed cost proposal must also be provided for any proposed subcontractor(s).

16. Assume the following minimum requirements for hardware and software to be provided by the Contractor:

    a) IBM Compatible computer (PC), with a processor speed of 2 GHz, 512 MB RAM, CD R/W drive, 3.5 floppy drive, 40 GB hard drive, 1600 x 1200 – 16 bit color (8 meg) PCI or AGP, 19" CRT or 17" flat screen monitor, 10/100 Mbps Ethernet card, 4 USB ports
    b) Hewlett Packard (HP) Compatible Laser Jet Printer or other laser printer
    c) Internet service provider and high speed connection to the internet (cable modem, DSL, ISDN, Ethernet)
    d) Software packages, which include Microsoft Windows 2000 or XP, Microsoft Office Suite, Symantec PC Anywhere-Version 10.5 or higher, Backup Software (e.g. Colorado Backup or Iomega), anti-virus software with up-to-date virus definitions (e.g. McAfee or Norton Anti-virus)

17. **Expansion Option**: A separate cost proposal must be submitted detailing the cost of each Option. The Offeror shall assume up to three (3) Options per year, with each option including up to five (5) additional Sites/non-Sites. Assume a ratio of 2 international to 3 domestic Sites/non-Sites. Assume relevant increases in the organizational structure, management procedures, and other Contractor functions that may be required to carry out such an expansion outlined in the Statement of Work, Section I. as well as Appendix A, Section 1.H. Assume an additional 2,000 specimens per Site per quarter for incoming shipments and an additional 500 specimens per Site/non-Site per quarter for outgoing shipments.

APPENDIX C

COMPUTER SYSTEMS

BSI-II, LDMS, LIMS, NARDS, and DAIDS-ES

The NIAID may have a necessity within the period of the awarded contract to convert existing systems, databases, and applications to a functionally equivalent and compatible environment.

BSI-II

The BSI-II will be provided to the successful Offeror through a license that the NIAID owns. The BSI-II has the following specifications and minimum hardware/software requirements.

Requirements for the client: PC with 512 MB RAM, 800x600 monitor, 10 MB Disk space, JRE 1.5

Requirements for the transaction server: hi speed multi-processor unix/linux/windows box, JRE 1.5, firewall and backup software

Requirements for the transaction server: Sybase 11.9.2 or Postgres on a multi-processor box, firewall and backup software.

Requirements for a web server/web services: Apache & Tomcat and associated hardware to run them

Description of the BSI-II System:

The Client, Transaction Server, and Database

The system uses a three-tiered client/server architecture backed by a Sybase SQL database to provide access to information on more than nine million specimens. The first tier is the client which executes on the users local machine, and provides the user interface for the BSI-II system. The client is written in Java and is optimized for the Microsoft Windows environment. The client connects to the second tier, the transaction server, via the Internet. The transaction server is written in non-GUI Java and executes on a Linux machine located at IMS. The transaction server implements the interface between the client and the third tier, the SQL database. For the third tier the BSI-II system uses the Sybase Adaptive Server Enterprise SQL database executing on a SPARC station located at IMS inside a firewall. (Note: this will be changing to a Postgres database and Linux during 2005).

Capabilities

The BSI-II client interface is a tabbed panel window consisting of a general information page and the most frequently accessed managers. This main screen includes managers for incoming shipments, data entry, reporting, and requisitions. Each manager is displayed on an individual tab and can be used to launch multiple editor windows. Once the editor is launched, the user can return to the main window at any time. The main window also has drop-down menus to access other managers and dialogs. The capabilities of the three main editors and other system functions are detailed below.

The incoming shipments editor allows the repository to track new specimens sent to the database, as well as tracking any discrepancies that might exist between the physical shipment and the electronic manifest. Viewing of manifest data and observed data values are permitted.

Automatic transfer to data entry batches for committing to the database is supported.

The data entry editor has a spreadsheet interface for entering new and modifying existing data. The editor provides for automatic syntax formatting of data; context sensitive code lists; templates to automate repetitive data entry tasks; data generation; data import; and two levels of data validation. In addition, the BSI Translate program will assist the user in translating data from external systems to the BSI data language. BSI Translate also provides support for label scanning and automatic generation of data.

The system has an extensive reporting capability, and currently supports five types of reports: standard, listing, frequency, requisition, and system reports. All of the reports use the same report editor, a tabbed window where each page is used to collect different information about the report. Reports can be produced in PDF, HTML, CSV, or interactive table format. While there are over 45 standard reports and 20 lab/shipment reports available, the dynamic reports are the most utilized by the current user base.

Requisitions are used to request and track work performed on specimens in the inventory. The work tracked by BSI-II encompasses a wide range of tasks, including: aliquot, re-label, destroy, shipment, return to inventory, and other processes.

There are also modules to provide reservation of sample IDs, user administration, code list management, data entry template management; multi-specimen container (MSC) support; label printing; contact management; as well as views for server locks, system status, and the job queue.

Data transfer from NARDS to BSI-II

A conversion plan and program was written for each of the studies imported from the NARDS database. The database was validated during the transfer to the BSI, with defined checkpoints. An analysis of the data was performed and the transferred data were deemed acceptable prior to use of the data in the BSI.

LDMS and LIMS

Most, but not all, Sites are currently linked through an electronic network which is used to manage specimens and/or generate data from the Sites to a remote Central Database. The MACS, WIHS, HPTN, HVTN (international Sites) and WITS sites are also using a customized laboratory data management system (LDMS) that tracks specimens, provides assay templates, calculates derived quantities, produces reports, creates barcoded labels with a unique identifier, and generates data files for export from the Site. The domestic HVTN Sites are utilizing a different, customized laboratory information management system (LIMS) that performs the same tasks as the LDMS. The LIMS software is developed by LabWare, Inc (www.labware) and maintained by a group that includes HVTN, LabWare, Inc, and other commercial consultant representatives.

The Central Database for the MACS and WIHS is maintained by the Data Management and Statistical Center (DMSC) at the Johns Hopkins School of Public Health and the LDMS is maintained and updated by the Frontier Science Foundation (www.fstrf.org). The Central Database for the HVTN and HPTN is maintained by the DMSC located at the Fred Hutchinson Cancer Research Center in Seattle, Washington (www.fhcrc.org). The Central Database for the WITS is maintained by the DMSC located at Clinical Trials and Surveys Corporation (C-TASC; www.c-tasc.com). Specimen data acquired by all Sites for the NSR are currently generated by the Sites through an electronic manifest that is sent directly to the Contractor.

NARDS

The NARDS database was utilized during previous NIAID Repository contracts held prior to September 1999. The NARDS data set is currently stored as a SAS database. It includes 12 tables for inventory, aliquots, withdraws, deletes, etc. Beyond September 1999, the NARDS data set has only been utilized to confirm that the data transfer was correct (performed at the time the current contract was awarded in September 1999).

Division of AIDS – Enterprise System (DAIDS-ES)

The successful Offeror may be required to provide some NSR-related information through the DAIDS-ES. While some of this may be accomplished through a link from DAIDS-ES to the NSR web site, some data may need to be shared by the NSR, with DAIDS-ES, in which case data sharing agreements, standards, etc., will be required.

The DAIDS-ES is a comprehensive system that supports the business functions, management and oversight responsibilities of the Division of AIDS. The current components of the DAIDS-ES include:

DAIDS Master Contact System
The DAIDS Master Contact System is a centralized system for all address and contact information for stakeholders engaged in clinical research, such as investigators, participating institutions, laboratories, agencies, pharmaceutical sponsors, manufacturers, etc.

DAIDS Expedited Adverse Event Reporting System (DAERS)
The DAERS is a web-based application for expedited reporting of adverse events in DAIDS-sponsored clinical trials. DAERS is a 21 CFR Part 11 compliant system for use in therapeutic, vaccine and prevention trials.

DAIDS Protocol Management System
The DAIDS Protocol Management System supports end-to-end clinical trials processes, including: protocol development, registration, conduct, accrual, oversight, site monitoring, tracking and closeout. The system is CDISC and HL7 compliant with full auditing capabilities.

Successful Offerors may be required to interface, integrate or adapt their information system(s) to interact with these and future components of the DAIDS-ES, as necessary.

To achieve compatibility, DAIDS and its collaborators (contractors, cooperative agreement holders, grantees, etc.) will implement applications or data exchange mechanisms using platform technology standards such as: Web Services, eXtensible Markup Language (XML), XML Schema Definitions (XSD), RDBMS, .NET Framework, UDDI, IIS, Internet Explorer, Service Oriented Architecture (SOA), Design Patterns, Frameworks and Templates as defined by the DAIDS-ES. Collaborators shall adhere to these guidelines and standards on a continual basis.

This requirement will include the need to utilize DAIDS-ES-specified software Application Programming Interfaces (APIs) or XML and XSD, where appropriate, in all relevant applications that affect specific types of transactions, Graphical User Interfaces (GUI) and other software-based tasks that interact with or become part of the DAIDS-ES.

Depending upon the architecture and implementation of Offerors' data management system(s), the

following activities may be required to be compatible with the DAIDS-ES:

Build Interface:

Using DAIDS-ES-specified data standards, collaborators shall provide access to data in their local system(s). Standards shall either be industry data exchange standards such as those specified by NIH, CDISC, HL7 or adapted versions of these as defined by DAIDS.

System Adaptation:

Collaborators may need to adapt or modify their data management system(s) to receive and store data from the DAIDS-ES. For example, DAIDS is establishing a standardized naming and numbering convention for its awardee institutions. The DAIDS shall provide collaborators with a single set of institution or laboratory names and identifiers for all of its research participants. Collaborator's data system(s) may have to be adapted or modified to accommodate the DAIDS standard(s).

System Integration:

Collaborators may be required to dynamically obtain data from the DAIDS-ES to perform specific job functions. This will require the integration of collaborator's system(s) with the DAIDS-ES via data linkages using the appropriate latency factor or through Web Services. For example, the DAIDS-ES will serve as the central repository for investigator and protocol status information. Collaborators whose work requires information from the DAIDS-ES must dynamically integrate it into their respective data system(s).

APPENDIX D

ACTIVE STUDY GROUPS – The following is a list of the active Study Groups. NIAID is currently reviewing applications for the restructuring of the NIAID- sponsored HIV/AIDS clinical trials networks through the award of Leadership and Clinical Trial Units grants. Additional information on this restructuring is available at: http://www.niaid.nih.gov/daids/rfa/network06/default.htm.

Study Groups and Clinical Sites	Description	Website
Women's Interagency HIV Study **Sites**: Chicago(4); Bronx(2); Brooklyn(2); Los Angeles(5); San Francisco(5); Washington D.C.(5) **Total:** 23	An ongoing, domestic multi-center, prospective study to carry out comprehensive investigations of the impact of HIV infection in women; established in 1993	https://statepiaps.jhsph.edu/wihs/
Multi-center AIDS Cohorts Study **Sites:** Baltimore(1); Chicago(3); Los Angeles(3); Pittsburgh(1) **Total:** 8	An ongoing, domestic, multi-center prospective study of the natural and treated histories of HIV-1 infection in homosexual and bisexual men; established in 1984	http://statepi.jhsph.edu/macs/macs.html
HIV Vaccine Trials Network **Sites:** Boston(1); Baltimore(1); Birmingham(1); Chicago(1); Nashville(1); New York City(3); Philadelphia(1); Providence(1); Rochester(1); St. Louis(1); Seattle(1); San Francisco(1); Africa(4); Asia(2); Caribbean(4); South America(4) **Total:** 29	An ongoing international collaboration of scientists and educators searching for an effective and safe HIV vaccine. The The HVTN mission is to facilitate the process of testing preventive vaccines against HIV/AIDS. All phases of clinical trials, from evaluating experimental vaccines for safety and the ability to stimulate immune responses, to testing vaccine efficacy are being conducted; established in 1999	http://www.hvtn.org/
Women and Infants Transmission Study **Sites:** Boston(1); Brooklyn(1); Chicago(1); Houston(2); New York City(2); San Juan(1) **Total:** 8	A domestic, multi-site observational study designed to examine the impact of HIV infection on HIV infected women and their infants; established in1989 and completed in 2005	http://www.niaid.nih.gov/daids/wits.htm
HIV Prevention Trials Network **Sites:** Baltimore(1); Birmingham(1); Boston(2); Durham(1); Los Angeles(1); New York City(3); Philadelphia(1); Providence(1);	An international collaborative clinical trials network that develops and tests the safety and efficacy of primarily non-vaccine interventions designed to prevent the transmission of HIV;	http://www.hptn.org/index.htm

APPENDIX E

***CURRENT AND POTENTIAL DOMESTIC AND INTERNATIONAL SITES**

Current Domestic Sites	Number of Shipping Labs***	City/State
MACS	4	Baltimore, MD; Chicago, IL; Pittsburgh, PA; Los Angeles, CA
WIHS	6	Brooklyn, NY; Chicago, IL; Honolulu, HI; Los Angeles, CA; San Francisco, CA; Quest Diagnostics, Baltimore, MD
HVTN	12	Birmingham, AL; Boston, MA (2 labs); Durham, NC; Nashville, TN; New York NY; Richmond, CA; Rochester, NY; Seattle, WA; San Francisco, CA; St. Louis, MO; Baltimore, MD (2 labs)
HPTN	1	Richmond, CA
WITS	6	Boston, MA; Chicago, IL; Houston, TX (2 labs); New York, NY; San Juan, PR
Current International Sites	**Number of Shipping Labs*** **	**City/Country**
HVTN	11	Iquitos and Lima, Peru; Gabarone, Botswana; Rio de Janiero and San Paulo, Brazil; Kingston, Jamaica; Port-au-Prince, Haiti; Chiang Mia, Thailand; Johannesburg, Capetown, and KOSH, South Africa
Study Groups	**Number of Site and Non-Site Labs Receiving Shipments****	**Locations**
MACS, WIHS, WITS, HPTN, HVTN, AVEG, SFMHS	Approximately 300	Across all regions of the United States and several international countries such as France
Potential Domestic/International Sites	**Potential Additional Shipping Labs*** **	**City/State/Country**
Across current and potentially new or evolving Study Groups	estimated 30 within U.S. and 20 internationally	All regions of the United States and across all continents internationally including the countries Russia and Canada

*Sites in this table include shipping and/or receiving labs that are either part of a network or cohort (Sites) or are collaborating with the network/cohort (non-Sites)
**These numbers include labs that have received a one-time shipment and/or multiple shipments during the history of the NSR.
***Shipping labs refer to Site Study Group labs sending specimens to the NSR.

APPENDIX F
GOVERNMENT-FURNISHED MATERIALS/PROPERTY

Contract #: **144, DAIDS Repository**

Chest Freezers

Piece#	Rm#	Gfp/Cap	Category #	Description	Mfr	Model	Serial No	Date Rcv	Cost
601	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36L586-AR-E	T02E208247-TE		$5,000.00
602	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36L586-AR-E	T02E208248-TE		$5,000.00
603	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36L586-AR-E	T02E208251-TE		$5,000.00
604	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36L586-AR-E	T02E208252-TE		$5,000.00
610	Frederick	GFP	CHFR	-70oC Mechanical Freezer	So-low	SE-27-120	92931063		$5,000.00
611	Frederick	GFP	CHFR	-70oC Mechanical Freezer	So-low	SE-27-120	92931062		$5,000.00
621	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36L586-AR-E	T02E208249-TE		$5,000.00
634	Frederick	GFP	CHFR	-70oC Mechanical Freezer	So-low	SE-27-120	92931061		$5,000.00
652	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36LS86-AR-E	T1Oh-386367-TH		$5,000.00
653	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36LS86-AR-E	T12H-386847-TH		$5,000.00
654	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36LS86-AR-E	TO9H-386183-TH		$5,000.00
655	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36LS86-AR-E	T11H-386647-TH		$5,000.00
656	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36LS86-AR-E	T15H-387047-TH		$5,000.00
657	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36LS86-AR-E	TO8H-385998-TH		$5,000.00
658	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36lS86-AR-E	Y21G-359779-ZG		$5,000.00
659	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36LS86-AR-E	Z19F-321193-ZF		$5,000.00
660	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36LS86-AR-E	Z19F-321194-ZF		$5,000.00
661	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36LS86-AR-E	Z19F-321190-ZF		$5,000.00
663	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36LS86-AR-E	Z19F-321189-ZF		$5,000.00
664	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36LS86-AR-E	Z19F-321191-ZF		$5,000.00
665	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36LS86-AR-E	Z09D-192818-ZD		$5,000.00
666	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36LS86-AR-E	Z09D-192817-ZD		$5,000.00
667	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36LS86-AR-E	Z09D-192816-ZD		$5,000.00
668	Frederick	GFP	CHFR	-70oC Mechanical Freezer	Harris	HLT-36L586-AR-E	T02E208250-TE		$5,000.00
680	Frederick	CAP	CHFR	-70oC Mechanical Freezer	So-Low	C80-27	9900225		$5,000.00
681	Frederick	CAP	CHFR	-70oC Mechanical Freezer	So-Low	C80-27	9900117		$5,000.00
682	Frederick	CAP	CHFR	-70oC Mechanical Freezer	So-Low	C80-27	9900222		$5,000.00
683	Frederick	CAP	CHFR	-70oC Mechanical Freezer	So-Low	C80-27	9900227		$5,000.00
684	Frederick	CAP	CHFR	-70oC Mechanical Freezer	So-Low	C80-27	9900224		$5,000.00
685	Frederick	CAP	CHFR	-70oC Mechanical Freezer	So-Low	C80-27	9900226		$5,000.00
686	Frederick	CAP	CHFR	- 70 Chest Freezer	So-Low	C80-27S	0001004	10/6/2000	$7,695.00
687	Frederick	CAP	CHFR	- 70 Chest Freezer	So-Low	C80-27S	0001003	10/6/2000	$5,000.00
688	Frederick	CAP	CHFR	- 70 Chest Freezer	So-Low	C80-27S	0001001	10/6/2000	$5,000.00
689	Frederick	CAP	CHFR	- 70 Chest Freezer	So-Low	C80-27S	0001002	10/6/2000	$7,695.00
690	Frederick	CAP	CHFR	-70 Chest Freezer	So-Low	C80-27S	0001007	11/22/20	$7,695.00

Piece#	Rm#	Gfp/Cap	Category #	Description	Mfr	Model	Serial No	Date Rcv	Cost
691	Frederick	CAP	CHFR	-70 Chest Freezer	So-Low	C80-27S	0001008	11/22/20	$7,695.00
692	Frederick	CAP	CHFR	-70 Chest Freezer	So-Low	C80-27S	0001005	11/22/20	$7,695.00
693	Frederick	GFP	CHFR	SO-LOW CHEST FREEZER W/ TEMP.	SO-LOW	C80-27	102634	4/12/2002	$7,995.00
694	FREDERI	GFP	CHFR	SO-LOW CHEST FREEZER W/ TEMP.	SO-LOW	C80-27	0102632	4/12/2002	$7,995.00
695	Frederick	CAP	CHFR	Chest Freezer w/recorder	So-Low	C80-27S	0102844	6/26/2002	$7,895.00
696	Frederick	CAP	CHFR	Chest Freezer w/recorder	So-Low	C80-27S	0102849	6/26/2002	$7,895.00
697	Frederick	CAP	CHFR	Chest Freezer w/recorder	So-Low	C80-27S	0102845	6/26/2002	$7,895.00
698	Frederick	CAP	CHFR	Chest Freezer w/recorder	So-Low	C80-27S	0102843	6/26/2002	$7,895.00
699	Frederick	CAP	CHFR	Chest Freezer w/recorder	So-Low	C80-27S	0102852	6/26/2002	$7,895.00
700	Frederick	CAP	CHFR	Chest Freezer w/recorder	So-Low	C80-27S	0102848	6/26/2002	$7,895.00
701	Frederick	CAP	CHFR	Chest Freezer w/recorder	So-Low	C80-27S	0102847	6/26/2002	$7,895.00
702	Frederick	CAP	CHFR	Chest Freezer w/recorder	So-Low	C80-27S	0102851	6/26/2002	$7,895.00
703	Frederick	CAP	CHFR	Chest Freezer w/recorder	So-Low	C80-27S	0102846	6/26/2002	$7,895.00
705	Frederick	CAP	CHFR	Chest Freezer w/recorder	So-Low	C80-27S	0102842	6/26/2002	$7,895.00
710	Frederick	CAP	CHFR	Chest Freezer	So-Low	C80-27S	0203570	4/9/2003	$7,895.00
711	Frederick	CAP	CHFR	Chest Freezer	So-Low	C80-27S	0203571	4/9/2003	$7,895.00
712	Frederick	CAP	CHFR	Chest Freezer	So-Low	C80-27S	0203572	4/9/2003	$7,895.00
713	Frederick	CAP	CHFR	Chest Freezer	So-Low	C80-27S	0203573	4/9/2003	$7,895.00
BU10	Frederick	CAP	CHFR	-70 Chest Freezer	So-Low	C80-27S	0001006	11/22/20	$7,695.00
M704D	Frederick	CAP	CHFR	Chest Freezer w/recorder	So-Low	C80-27S	0102850	8/21/2002	$7,895.00
M706D	Frederick	CAP	CHFR	Chest Freezer w/racking system	SoLow	C80-27S	0203153	12/4/2002	$11,718.73
M707D	Frederick	CAP	CHFR	Chest Freezer w/racking system	SoLow	C80-27S	0203154	12/4/2002	$11,718.72
M708D	Frederick	CAP	CHFR	Chest Freezer w/racking system	SoLow	C80-27S	0203155	12/4/2002	$11,718.72
M709D	Frederick	CAP	CHFR	Chest Freezer w/racking system	SoLow	C80-27S	0203156	12/4/2002	$11,718.72
M714D	Frederick	CAP	CHFR	Chest Freezer	So-Low	C80-27S	0203574	4/9/2003	$7,895.00
M715D	Frederick	GFP	CHFR	Chest Freezer	So Low	C80-27S	0304673	5/4/2004	$7,995.00
M716D	Frederick	GFP	CHFR	Chest Freezer	So Low	C80-27S	0304674	5/4/2004	$7,995.00
M717D	Frederick	GFP	CHFR	Chest Freezer	So Low	C80-27S	0304675	5/4/2004	$7,995.00
M718D	Frederick	GFP	CHFR	Chest Freezer	So Low	C80-27S	0304677	5/4/2004	$7,995.00
M719D	Frederick	GFP	CHFR	Chest Freezer	So Low	C80-27S	0304678	5/4/2004	$7,995.00
M720D	Frederick	GFP	CHFR	Chest Freezer	So Low	C80-27S	0304679	5/4/2004	$7,995.00
M721D	Frederick	CAP	CHFR	Chest Freezer	So Low	C80-27S	0304680	5/4/2004	$7,995.00
M727D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405537	3/31/2005	$8,395.00
M728D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405540	3/31/2005	$8,395.00
M729D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405541	3/31/2005	$8,395.00
M730D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405543	3/31/2005	$8,395.00
M731D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405544	3/31/2005	$8,395.00
M732D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405547	3/31/2005	$8,395.00
M733D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405535	3/31/2005	$8,395.00

Piece#	Rm#	Gfp/Cap	Category #	Description	Mfr	Model	Serial No	Date Rcv	Cost
M734D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405539	3/31/2005	$8,395.00
M735D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405545	3/31/2005	$8,395.00
M736D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405550	3/31/2005	$8,395.00
M737D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405548	3/31/2005	$8,395.00
M738D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405549	3/31/2005	$8,395.00
M739D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405552	3/31/2005	$8,395.00
M740D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405553	3/31/2005	$8,395.00
M741D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405555	3/31/2005	$8,395.00
M742D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405556	3/31/2005	$8,395.00
M743D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405557	3/31/2005	$8,395.00
M744D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405558	3/31/2005	$8,395.00
M745D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405560	3/31/2005	$8,395.00
M746D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405562	3/31/2005	$8,395.00
M747D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405532	3/31/2005	$8,395.00
M748D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405536	3/31/2005	$8,395.00
M749D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405538	3/31/2005	$8,395.00
M750D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405554	3/31/2005	$8,395.00
M751D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405559	3/31/2005	$8,395.00
M752D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405567	3/31/2005	$8,395.00
M753D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405568	3/31/2005	$8,395.00
M754D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405551	3/31/2005	$8,395.00
M755D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405561	3/31/2005	$8,395.00
M756D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405563	3/31/2005	$8,395.00
M757D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405564	3/31/2005	$8,395.00
M758D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405565	3/31/2005	$8,395.00
M759D	Frederick	GFP	CHFR	Chest Freezer	So-Low	C80-27S	0405566	3/31/2005	$8,395.00
M760D	Frederick	CAP	CHFR	Chest Freezers	So-Low	C80-27S	0405987	7/13/2005	$8,775.00
M761D	Frederick	CAP	CHFR	Chest Freezer	So-Low	C80-27S	0405988	7/13/2005	$8,775.00
M762D	Frederick	CAP	CHFR	Chest Freezer	So-Low	C80-27S	0405989	7/13/2005	$8,775.00
M763D	Frederick	CAP	CHFR	Chest Freezer	So-Low	C80-27S	0405990	7/13/2005	$8,775.00
M764D	Frederick	CAP	CHFR	Chest Freezer	So-Low	C80-27S	0405991	7/13/2005	$8,775.00
M765D	Frederick	CAP	CHFR	Chest Freezer	So-Low	C80-27S	0405992	7/13/2005	$8,775.00
M766D	Frederick	CAP	CHFR	Chest Freezer	So-Low	C80-27S	0405993	7/13/2005	$8,775.00
M767D	Frederick	CAP	CHFR	Chest Freezer	So-Low	C80-27S	0405994	7/13/2005	$8,775.00
MBU1	Frederick	CAP	CHFR	-70oC Mechanical Freezer	So-Low	C80-27	9900107		$5,000.00
MBU11	Frederick	CAP	CHFR	Chest Freezer w/racking system	SoLow	C80-27S	0203157	12/4/2002	$11,718.72
MBU2	Frederick	CAP	CHFR	-70oC Mechanical Freezer	So-Low	C80-27	9900110		$5,000.00
MBU3	Frederick	CAP	CHFR	-70oC Mechanical Freezer	So-Low	C80-27	9900108		$5,000.00
MBU4	Frederick	CAP	CHFR	-70oC Mechanical Freezer	So-Low	C80-27	9900109		$5,000.00

Piece#	Rm#	Gfp/Cap	Category #	Description	Mfr	Model	Serial No	Date Rcv	Cost
MBU5	Frederick	CAP	CHFR	-70oC Mechanical Freezer	So-Low	C80-27	9900104		$5,000.00
MBU6	Frederick	CAP	CHFR	-70oC Mechanical Freezer	So-Low	C80-27	9900106		$5,000.00
MBU7	Frederick	CAP	CHFR	-70oC Mechanical Freezer	So-Low	C80-27	9900103		$5,000.00
MBU8	Frederick	CAP	CHFR	-70oC Mechanical Freezer	So-Low	C80-27	9900105		$5,000.00
TEMP1	FREDERI	GFP	CHFR	SO-LOW CHEST FREEZER W/ TEMP.	SO-LOW	C80-27	0102633	4/12/2002	$7,995.00
TEMP2	FREDERI	GFP	CHFR	SO-LOW CHEST FREEZER W/ TEMP.	SO-LOW	C80-27	0102631	4/12/2002	$7,995.00
Computers & Computer Related									
001	Frederick	GFP	COMP	AX 2400 Modem	Microcom	AX/2400	1203126216	11/22/19	$0.00
002	Frederick	GFP	COMP	AX 2400 Modem	Microcom	AX/2400	1203126218	11/22/19	$0.00
003	Frederick	GFP	COMP	Compac Deskpro 286E	Compaq	Model 40	4001HZ3H0323	11/22/19	$0.00
004	Frederick	GFP	COMP	Compaq VGA monochrome monitor	Compaq	VGA 12 monochrome	004KC0434TY2	11/22/19	$0.00
005	Frederick	GFP	COMP	DEC Model VT 320 Terminal	Digital Equip Cor	VT 320-CA	SZ05046110	11/22/19	$0.00
006	Frederick	GFP	COMP	DEC Model VT 420 terminal	Digital Equip Corp	VT 420-C2	TA231N2103	11/22/19	$0.00
007	Frederick	GFP	COMP	Canon Fax phone (FAX)	Canon	Faxphone.50	45861	11/30/19	$0.00
009	Frederick	GFP	COMP	DEC VT 420 Terminal	Digital Equip Corp	VT 420-J4	HK23800838	11/22/19	$0.00
010	Frederick	GFP	COMP	1 GB Hard disk drive	Hewlett Packard	None	None	11/22/19	$0.00
010	Frederick	GFP	COMP	HP 9000/800 Business server	Hewlett Packard	HP9000/G40	3335A36991	11/22/19	$0.00
011	Frederick	GFP	COMP	1 GB disk drive	Hewlett Packard	HP9000/G40	N/A	11/22/19	$0.00
012	Frederick	GFP	COMP	Laser Printer/with cassette	Hewlett Packard	Laser Jet 4	USTC069437	11/22/19	$0.00
013	Frederick	GFP	COMP	Cassette for printer, spare	Hewlett Packard	none	none	11/22/19	$0.00
014	Frederick	GFP	COMP	HP-UX KEYBOARD	Hewlett Packard	none	none	11/22/19	$0.00
014	Frederick	GFP	COMP	X- terminal with software	Hewlett Packard	A1097C	3310J00685	11/22/19	$0.00
015	Frederick	GFP	COMP	Cartridge tape drive, external, 7 GB	Iomega	DittoMax IO 1000	UC0831DOGA	11/30/19	$0.00
015	Frederick	GFP	COMP	Personal Computer	Gateway 2000	4DX -33	1823076	11/30/19	$0.00
015	Frederick	GFP	COMP	650 VA Uninteruptable Power Supply	APC	VS650	FS9712764730	11/30/19	$0.00
016	Frederick	GFP	COMP	Power surge protector	Trippe	Isobar 4	none	11/22/19	$0.00
017	Frederick	GFP	COMP	Modem - Mini Tower	Practical Peripherals	PM1400FAMT	A1028700	11/22/19	$0.00
018	Frederick	GFP	COMP	HP-UX KEYBOARD	Hewlett Packard	none	none	11/22/19	$0.00
018	Frederick	GFP	COMP	HP ENVIZEX W/ MONITOR	Hewlett Packard	D1196A	KR40600455	11/22/19	$0.00
019	Frederick	GFP	COMP	HP ENVIZEX W/ MONITOR	Hewlett Packard	D1196A	KR40600647	11/22/19	$0.00
019	Frederick	GFP	COMP	HP-UX KEYBOARD	Hewlett Packard	none	none	11/22/19	$0.00
020	Frederick	GFP	COMP	HP-UX KEYBOARD	Hewlett Packard	none	none	11/22/19	$0.00
020	Frederick	GFP	COMP	HP ENVIZEX W/ MONITOR	Hewlett Packard	D1196A	KR40600446	11/22/19	$0.00
021	Frederick	GFP	COMP	HP-UX KEYBOARD	Hewlett Packard	none	none	11/22/19	$0.00
021	Frederick	GFP	COMP	HP ENVIZEX W/ MONITOR	Hewlett Packard	D1196A	KR40600461	11/22/19	$0.00
022	Frederick	GFP	COMP	64 MB Internal Memory	Hewlett Packard	None	None	11/22/19	$0.00
023	Frederick	GFP	COMP	Upgrade WordPerf v.6.0 to Perf. Office v3.0	Novell Corp.	v3.0	none	11/22/19	$0.00
024	Frederick	GFP	COMP	5.25 in floppy drive	Teac	FD-55GFR	BV75491	11/30/19	$0.00
024	Frederick	GFP	COMP	650 VA Uninteruptable Power Supply	APC	VS650	FS9704542223	11/30/19	$0.00

Piece#	Rm#	Gfp/Cap	Category #	Description	Mfr	Model	Serial No	Date Rcv	Cost
024	Frederick	GFP	COMP	Compaq 1725 17-in Color Monitor	Compaq	320A	717CDO2DA721	11/30/19	$0.00
024	Frederick	GFP	COMP	Compaq pc w/Pent P200,modem, etc.	Compaq	Presario	A711BKNBE210	11/30/19	$0.00
025	Frederick	GFP	COMP	HP ENTRA Workstation w/8 MB RAM	Hewlett Packard	C3264A	CA74264104	11/22/19	$0.00
028	Frederick	GFP	COMP	Printer, Eltron Delta Plus	Eltron	TLP2642PSA	47048312	11/22/19	$0.00
030	Frederick	GFP	COMP	Color Laser Jet Printer	Hewlet-Packard	5M	JPHF157259	11/30/19	$0.00
031	Frederick	GFP	COMP	Docs. for HP-UX v11.01 Sys Admin &	Hewlett-Packard	B3921EA		11/22/19	$0.00
032	Frederick	GFP	COMP	Oracle 8.0.4 Server Docs. Library Set	Oracle Corp.	A58405		11/22/19	$0.00
	Frederick	GFP	LN2	LN2 Freezer and Racks	Cryo	1830 HE	CEMZ05A110	5/10/2005	$54,016.24
Liquid Nitrogen Freezers									
801	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	Taylor- Wharton	38K	576-OO1-P4		$15,000.00
802	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	Taylor- Wharton	38K	576-OO4-P4		$15,000.00
803	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	Taylor- Wharton	38K	576-OO3-P5		$15,000.00
804	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	Taylor- Wharton	38K	576-OO4-P5		$15,000.00
805	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	Taylor- Wharton	38K	576-001-R2		$15,000.00
806	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	Taylor- Wharton	38K	576-002-R2		$15,000.00
808	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	MVE	A4500	476-B		$15,000.00
813	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	MVE	XLC1840	DOB91F101		$15,000.00
820	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	MVE	XLC1840	DOB91F102		$15,000.00
821	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	MVE	XLC1840	DOB91F103		$15,000.00
824	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	Taylor-Wharton	33 K	557-001-L5		$15,000.00
825	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	Taylor-Wharton	33 K	557-002-L5		$15,000.00
826	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	Taylor-Wharton	33 K			$15,000.00
827	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	Taylor-Wharton	33 K	557-005-L5		$15,000.00
828	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	Taylor-Wharton	33 K	576-001-N1		$15,000.00
829	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	Taylor-Wharton	33 K	576-002-M9		$15,000.00
830	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	Taylor-Wharton	33 K	576-005-M9		$15,000.00
831	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	Taylor-Wharton	33 K	576-005-N1		$15,000.00
832	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	Taylor-Wharton	38KM2l	576-001-M5		$15,000.00
833	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	Taylor-Wharton	38KM2l	576-001-M6		$15,000.00
834	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	Taylor-Wharton	38KM2l	576-004-M5		$15,000.00
835	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	Taylor-Wharton	33K	557-001-JB		$15,000.00
836	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	Taylor-Wharton	33k	557-002-JB		$15,000.00
837	Frederick	GFP	LNFR	Liquid Nitrogen Freezer	Taylor-Wharton	33k	557-003-JB		$15,000.00
838	Frederick	CAP	LNFR	Liquid Nitrogen Freezer	MVE	XLC1830HE	CMER99K102		$15,000.00
839	Frederick	CAP	LNFR	Liquid Nitrogen Freezer	MVE	XLC1830HE	CEMR99K103		$15,000.00
840	Frederick	CAP	LNFR	LN2 Freezer	Cryo	XLC 1830 HE	CEMU0IA101	10/17/20	$27,243.30
841	Frederick	CAP	LNFR	LN2 Freezer	Cryo	XLC 1830 HE	CEMU01G106	2/20/2001	$37,069.71

Piece#	Rm#	Gfp/Cap	Category #	Description	Mfr	Model	Serial No	Date Rcv	Cost
842	Frederick	CAP	LNFR	Liquid Nitrogen Freezer w/racks	MVE	XLC1830HE-F	CVBU02G104	12/1/2002	$23,270.79
843	Frederick	CAP	LNFR	LN2 Freezer	MVE	XLC1830HE	CEMV01J110	6/12/2002	$23,045.00
844	Frederick	CAP	LNFR	LN2 Freezer	MVE	XLC1830HE	CEMV02D107	6/12/2002	$23,045.00
847	Frederick	CAP	LNFR	LN2 Freezer & Racks	MVE	XLC1830HEF-2004	CEMZ04L102	1/15/2005	$23,705.00
848	Frederick	CAP	LNFR	LN2 Freezer & Racks	MVE	XLC1830HEF-2004	CEMZ04L104	1/15/2005	$23,705.00
849	Frederick	CAP	LNFR	LN2 Freezer & Racks	MVE	XLC1830HEF-2004	CEMZ04M101	1/15/2005	$23,705.00
850	Frederick	CAP	LNFR	LN2 Freezer & Racks	MVE	XLC1830 HEF-2004	CEMZ04M103	1/15/2005	$23,705.00
851	Frederick	CAP	LNFR	LN2 Freezer & Racks	MVE	XLC1830HEF-2004	CEMZ04M104	1/15/2005	$23,705.00
852	Frederick	CAP	LNFR	LN2 Freezer & Racks	MVE	XLC1830 HEF-2004	CEMZ04M105	1/15/2005	$23,705.00
853	Frederick	CAP	LNFR	LN2 Freezer & Racks	MVE	XLC1830HEF-2004	CEMZ04M107	1/15/2005	$23,705.00
854	Frederick	CAP	LNFR	LN2 Freezers & Racks	MVE	XLC1830HEF-2004	CEMZ04M107	1/15/2005	$23,705.00
L845DS	Frederick	CAP	LNFR	LN2 Freezer and racks	Cryo	XLC 1830	CEMV03B101	6/1/2003	$38,577.00
L846DS	Frederick	CAP	LNFR	LN2 Freezer	MVE	XLC 1830 HEF	CEMX04C101		
LBU1	Frederick	CAP	LNFR	Liquid Nitrogen Freezer	MVE	XLC1830HE	CMER99K104		$15,000.00
LBU2	Frederick	CAP	LNFR	Liquid Nitrogen Freezer	MVE	XLC1830HE	CEMR99K101		$15,000.00
LTMPDS	Frederick	CAP	LNFR	LN2 Freezer	MVE	XLC1830HEF-2004	CEMZ04M108	1/15/2005	$18,327.58
Liquid Nitrogen Shippers									
	Frederick	GFP	LNSH	LN 2 Shipping Containers	MVE	CryoshipEXT	GPB99D1031Y	11/22/19	$0.00
	Frederick	GFP	LNSH	LN 2 Shipping Containers	MVE	CryoshipEXT	AOB00E1063Y	11/22/19	$0.00
	Frederick	GFP	LNSH	LN 2 Shipping Containers	Taylor-Wharton	CP 65	578-003-KI	11/22/19	$0.00
	Frederick	GFP	LNSH	LN 2 Shipping Containers	Custom Biogenic	DS-3	12503	11/22/19	$0.00
	Frederick	GFP	LNSH	LN 2 Shipping Containers	MVE	CryoshipEXT	GPB98G1031Y	11/22/19	$0.00
	Frederick	GFP	LNSH	LN 2 Shipping Containers	Taylor-Wharton	CP 65	578-016-KI	11/22/19	$0.00
	Frederick	GFP	LNSH	LN 2 shipping containers	Custom Biogenic Sys	DS-3	PCS-11-93-0571	11/22/19	$0.00
	Frederick	GFP	LNSH	LN 2 shipping containers	MVE	TA-60	870-B	11/22/19	$0.00
	Frederick	GFP	LNSH	LN 2 shipping containers	MVE	TA-60	869-B	11/22/19	$0.00
	Frederick	GFP	LNSH	LN 2 shipping containers	Taylor-Wharton	CP65	578-043-J7	11/22/19	$0.00
	Frederick	GFP	LNSH	LN2 Shipping container	Custom Biogenic Sys	DS-3	1477	11/22/19	$0.00
	Frederick	GFP	LNSH	LN 2 shipping containers	Taylor-Wharton	CP65	578-049-J8	11/22/19	$0.00
Liquid Nitrogen Tanks									
	Frederick	GFP	LNTK	Bulk Liquid Nitrogen tank	MVE	VVXC-3000-NC-175	2569	11/30/19	$0.00
Miscellaneous Other									
	Frederick	GFP	MISC	Biological Safety Cabinet	CCI	740	19431	11/30/19	$0.00
	Frederick	GFP	MISC	Vertical Freezer Racks	Cryo	1830HE	0	2/28/2005	$53,346.78
	Frederick	CAP	MISC	Freezer Racks	Cryo	V-12(3)-2L-C-81	n/a	6/12/2002	$38,688.80
	Frederick	GFP	MISC	Racks	Cryo	V-13-2L	N/A	8/12/2005	$49,633.50
	Frederick	GFP	MISC	Biological Safety Cabinet	CCI	740	17566	11/30/19	$0.00

Piece#	Rm#	Gfp/Cap	Category #	Description	Mfr	Model	Serial No	Date Rcv	Cost
	Frederick	GFP	MISC	Freezer Racks	Cryo	V-8-3L	0	6/29/2005	$30,653.00
	Frederick	GFP	MISC	Vacuum jacketed pipe	MVE	none	none	11/30/19	$0.00
	Frederick	GFP	MISC	Water H20 BATH	ELEMCO	MODEL 70	134-84	11/30/19	$0.00
008	Frederick	GFP	MISC	Minolta photocopier	Minolta	EP 2121	36219639	11/30/19	$500.00
027	Frederick	GFP	MISC	Bar Code Scanner	Amer. Microsystems	5310HP4342	348747	11/22/19	$0.00
029	Frederick	GFP	MISC	Fax Machine	Murata	F-86	f8600077080030	11/30/19	$0.00
	Frederick	GFP	SCAN	Barcode Scanner	Brady	CR2010-03	10006921	8/5/2004	$894.45
	Frederick	GFP	SHIP	LN2 Dry Shipper	MVE	Cryoshipper	GPB98H1051Y	3/4/2004	
	Frederick	GFP	SHIP	LN2 Dry Shipper	MVE	Cryoshipper	AOB01K1313Y	3/4/2004	
	Frederick	GFP	SHIP	LN2 Dry Shipper	MVE	Cryoshipper	GPA95F1051Y	3/4/2004	
	Frederick	GFP	SHIP	LN2 Dry Shipper	MVE	Cryoshipper	GPB00E1043Y	3/18/2004	
	Frederick	GFP	SHIP	LN2 Dry Shipper	MVE	Cryoshipper	GPB98E1021Y	3/4/2004	
	Frederick	GFP	SHIP	LN2 Dry Shipper	MNE	Cryoshipper	AOB00D1033Y	3/4/2004	
	Frederick	GFP	SHIP	LN2 Dry Shipper	MVE	Cryoshipper	AOB01D1333Y	3/4/2004	
	Frederick	GFP	SHIP	LN2 Dry Shipper	MVE	Cryoshipper	GPB98E1051Y	3/4/2004	
	Frederick	GFP	SHIP	LN2 Dry Shipper	MVE	Cryoshipper	AOB02G1233Y	3/4/2004	
	Frederick		MISC	Vertical Filing Cabinets (10) containing equipment records					
	Frederick		MISC	Vertical Filing Cabinets (145) containing incoming and outgoing batch records					

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