

SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1. Requisition or other Purchase Authority: Public Law 81-692, as amended		
2. Request for Proposal (RFP) Number: NIAID-DAIDS-NIHAI2012153	3. Issue Date: December 31, 2012	4. Set Aside: [X] No [] Yes See Part IV Section L
5. Title : Humanized Mouse Models for HIV Therapeutics Development		
6. ISSUED BY: Office of Acquisitions Division of Extramural Activities National Institute of Allergy and Infectious Diseases National Institutes of Health Department of Health and Human Services 6700-B Rockledge Drive, Room 3214, MSC-7612 Bethesda, Maryland 20892-7612 If using overnight delivery, use 20817		7. SUBMIT OFFERS TO: See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.
8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 3:00 PM local time on March 14, 2013. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.		
9. This solicitation requires delivery of proposals as stated in ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." If proposals are required to be delivered to two different locations, the OFFICIAL POINT OF RECEIPT for determining TIMELY DELIVERY is the address provided for the OFFICE OF ACQUISITIONS. IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH subparagraph (c)(3) of FAR Clause 52.215-1, Instructions to Offerors--Competitive Acquisition," LOCATED IN SECTION L.1. OF THIS SOLICITATION.		
10. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. Offerors must access the CCR through The System for Award Management (SAM) at http://www.sam.gov		
11. FOR INFORMATION CALL: Dena Nannetti PHONE: 301-496-6424 e-MAIL: dena.nannetti@nih.gov COLLECT CALLS WILL NOT BE ACCEPTED.		
Secondary Point of Contact: John Manouelian, Contracting Officer PHONE: 301-451-3694 e-MAIL: manouelj@mail.nih.gov COLLECT CALLS WILL NOT BE ACCEPTED.		<hr/> <hr/> <hr/> <hr/> <hr/>

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PART I - THE SCHEDULE

THE INFORMATION SET FORTH IN **SECTION A - SOLICITATION/CONTRACT FORM**, HEREIN CONTAINS IMPORTANT INFORMATION FOR ANY OFFEROR INTERESTED IN RESPONDING TO THIS SOLICITATION. ANY CONTRACT RESULTING FROM THIS SOLICITATION WILL INCLUDE IN ITS **SECTION A - SOLICITATION/CONTRACT FORM**, ACCOUNTING, APPROPRIATION AND GENERAL INFORMATION APPLICABLE TO THE CONTRACT AWARD.

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

This contract is for Humanized Mouse Models for HIV Therapeutics Development to conduct studies in vitro and in humanized mouse models, to improve the SCID-hu Thy/Liv and the second model, and to adapt other existing or newly discovered models, all for the purpose of developing novel therapies for HIV-1 disease.

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. ESTIMATED COST - OPTION

- a. The estimated cost of the Base Period of this contract is \$_____.
- b. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total estimated contract amount will be increased as follows:

	Estimated Cost (\$)
Base Period	
Option Period(s):	
Total [Base Period and Option(s)]	

ARTICLE B.4. 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) Conferences & Meetings, 2) Food for Meals, Light Refreshments & Beverages, 3) Promotional Items, 4) Acquisition, by purchase or lease, of any interest in real property; 5) Special rearrangement or alteration of facilities; 6) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 7) Travel Costs including Foreign Travel; 8) Consultant Costs; 9) Subcontract Costs; 10) Patient Care Costs; 11) Accountable Government Property; 12) Printing costs; and 13) Research Funding.

ARTICLE B.5. 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. The following Advance Understandings are applicable to this acquisition and will be included in any resultant contract.

A. Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget

1. The Contractor agrees to provide a detailed breakdown on invoices of the following cost categories:

- a. Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort, and amount claimed
- b. Fringe Benefits - Cite rate and amount
- c. Overhead - Cite rate and amount
- d. Materials & Supplies - Include detailed breakdown when total amount is over \$1,000
- e. Travel - Identify travelers, dates, destination, purpose of trip, and amount. Cite COA, if appropriate. List separately, domestic travel, general scientific meeting travel, and foreign travel
- f. Consultant Fees - Identify individuals and amounts
- g. Subcontracts - Attach subcontractor invoice(s)
- h. Equipment - Cite authorization and amount
- i. Total Cost

Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

2. The Contractor agrees to immediately notify the Contracting Officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the amount allotted to the contract, and the reasons for the variance. Also refer to the requirements of the Limitation of Cost Clauses in the contract.

B. Intellectual Property

The purpose of this solicitation is to recomplete an existing contract for small animal models that can be used to evaluate potential therapeutics for HIV-1 infection. It is expected that in addition to the animal models, a great majority of the therapeutics will be proprietary, in part to the third party suppliers. For the purposes of this agreement, therapeutics ("material") includes compositions of matter, and associated information such as methods of making or using the compositions. It is clear from the NIAID's experience that third party suppliers ("Supplier") will not provide their proprietary materials ("Material") without assurance that the intellectual property rights associated with their Material will be protected. Accordingly, to encourage a Supplier to provide their Material for production or evaluation under this contract the Contractor agrees to this Article, which requires the Contractor and its subcontractors to provide a research use license and a commercialization license option to Subject Inventions made under the contract to the Supplier as follows:

The Contractor agrees to promptly notify the NIAID and the Supplier in writing of any Subject Inventions of the Contractor, its principal investigator and/or any other employees or agents of the Contractor, whether patentable or

not, which are conceived and/or first actually reduced to practice in the performance of work under this contract using a Supplier's Material (hereinafter "Contractor Invention"). The notice shall inform the Supplier of its right to the option set forth herein. This may be accomplished by attaching a copy of this Article to the notice.

(1) Single Supplier

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

The Contractor will allow Provider three (3) months from the date the Contractor sends written notice to the Supplier of the existence of a Contractor Invention (or such additional period as the Supplier and the Contractor may agree) to notify the Contractor in writing, whether or not it wants to obtain an exclusive license to the Contractor Invention.

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

(2) Multiple Suppliers

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

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

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

Supplier Inventions

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

Protection of Proprietary Data

Because the Contractor will be utilizing and evaluating Materials provided to the Government by third party Suppliers, it is essential to include provisions that will protect the proprietary rights of the Suppliers. These materials generally are supplied to the Government under conditions outlined in NIAID's standard Material Evaluation Agreement (MEA) or other appropriate documents. See SECTION J, LIST OF ATTACHMENTS, for a copy of the NIAID Material Evaluation Agreement. The Contractor shall be bound by the same terms and conditions as the Government in these agreements, with respect to the proprietary and confidential nature of the information provided by the Supplier. The Contractor agrees that its principal investigator and/or any other employees or agents of the Contractor will provide data generated under this contract exclusively to the NIAID or if directed by the NIAID to the Supplier and the FDA or other appropriate Federal agency. The Contractor understands that the NIAID may need to negotiate individual agreements with the various Suppliers to obtain Materials and that the terms of the agreements may vary. The Contractor agrees to enter into material transfer agreements with Suppliers when requested by the Suppliers as a condition for the Contractor to receive Materials. Such Agreements shall reference this contract by contract number and shall be consistent with any agreement the NIAID has entered into with the Supplier to obtain Materials. In the event the Contractor reasonably objects to the terms of the material transfer agreement, the Contractor shall promptly bring such objection to the attention of the Contracting Officer for an appropriate resolution.

"Confidential Information" is scientific, business, or financial information provided by the Supplier or the NIAID Contract Officer's Representative (COR) and marked "Confidential." Oral Disclosures of Confidential Information will be reduced to writing, marked "Confidential," and sent to Contractor within 10 days of disclosure to be considered Confidential Information. Confidential Information may not be revealed without written permission from the COR. Similarly, designated Materials are to be considered confidential. In cases where it is not clear whether information or Materials are to be considered confidential, the Contractor should contact the COR to obtain a determination. All materials supplied to the Contractor shall be utilized solely for contract-related research purposes and no unauthorized use or distribution of these materials shall be permitted.

Any Publication containing data generated under this contract ("Results") must be submitted for review by the COR and Supplier before submission for public presentation or publication. A "Publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information, for example a manuscript or abstract. The purpose of this review is to ensure that Publications do not contain any of NIAID's or Supplier's proprietary Confidential Information and to allow Supplier time to file patent applications, if so desired. Contract support shall be acknowledged in all Publications of Results. The COR and Supplier will review all Publications containing Results submitted to the COR and Supplier in a period of time not to exceed 120 calendar days from receipt of Results by both the COR and Supplier, and will either agree to the publication/disclosure, recommend changes and, as applicable, refer the document to the Supplier of the compound for their review. Publication of results earlier than 120 days after submission will require Supplier's written approval. When the Supplier does not consent to publication of the manuscript or abstract on the basis that Supplier's Confidential Information is included in the Publication, the COR shall notify the Contractor and the NIAID Contracting Officer. The COR is responsible for ensuring that all parties adhere to the terms and conditions of any existing Material Evaluation Agreement or other appropriate document between NIAID and the Supplier. NIAID will use its best efforts to assist and expedite the review process by the Supplier.

Should patents arise from this contract, they shall be subject to federal law governing inventions. Every patent applicant (individual or institutional) is required to provide the Government with a non-exclusive, irrevocable, paid-up license to the invention.

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

SECTION C - DESCRIPTION - STATEMENT OF WORK

ARTICLE C.1. DESCRIPTION - 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 November 20, 2012, attached hereto and made a part of this Solicitation (See SECTION J - Attachment 3).

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including specific checklists, by application, can be found at: <http://www.hhs.gov/web/508/index.html> under "Helpful Resources."

a. Technical Progress Reports

1. In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award. *[Note: Beginning May 25, 2008, the Contractor shall include the applicable PubMed Central or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]*

For proposal preparation purposes only, the following reports will be required as follows:

- Monthly
- Quarterly
- Semi-Annually
- Annually
- Annually (with a requirement for a Draft Annual Report)
- Final - Upon final completion of the contract
- Final - Upon final completion of the contract (with a requirement for a Draft Final Report)

2. **Summary of Salient Results**

The Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This report will be required on or before the expiration date of the contract.

b. **Other Reports/Deliverables**

1. **Information Security and Physical Access Reporting Requirements**

The Contractor shall submit the following reports as required by the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract. Note: Each report listed below includes a reference to the appropriate subparagraph of this article.

a. Roster of Employees Requiring Suitability Investigations

The Contractor shall submit a roster, by name, position, e-mail address, phone number 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 Contracting Officer's Representative (COR), with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. (Reference subparagraph A.e. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

b. IT Security Plan (IT-SP)

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, the contractor shall submit the IT-SP within thirty (30) days after contract award. The IT-SP shall be consistent with, and further detail the approach to, IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The IT-SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT-SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT-SP applies.

The Contractor shall review and update the IT-SP in accordance with NIST SP 800-53A, Guide for Assessing the Security Controls in Federal Information Systems and Organizations, on an annual basis.

(Reference subparagraph D.c.1. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

c. IT Risk Assessment (IT-RA)

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, the contractor shall submit the IT-RA within thirty (30) days after contract award. The IT-RA shall be consistent, in form and content, with NIST SP 800-30, Risk Management Guide for Information Technology Systems, and any additions or augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy.

The Contractor shall update the IT-RA on an annual basis.

(Reference subparagraph D.c.2. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

d. FIPS 199 Assessment

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, the Contractor shall submit a FIPS 199 Assessment within thirty (30) days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard.

(Reference subparagraph D.c.3. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

e. IT Security Certification and Accreditation (IT-SC&A)

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, the Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed within three (3) months after contract award.

The Contractor shall perform an annual security control assessment and provide to the Contracting Officer verification that the IT-SC&A remains valid.

(Reference subparagraph D.c.4. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

f. Reporting of New and Departing Employees

The Contractor shall notify the Contracting Officer's Representative (COR) and Contracting Officer within five working days of staffing changes for positions that require suitability determinations as follows:

- a. **New Employees who have or will have access to HHS Information systems or data:** Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the Government will determine the appropriate security level.
- b. **Departing Employees:** 1) Provide the name, position title, and security clearance level held by or pending for the individual; and 2) Perform and document the actions identified in the "Employee Separation Checklist", attached in Section J, ATTACHMENTS of this contract, when a Contractor/Subcontractor employee terminates work under this contract. All documentation shall be made available to the COR and/or Contracting Officer upon request.

(Reference subparagraph E.2.a-c. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

- g. **Contractor - Employee Non-Disclosure Agreement(s)** The contractor shall complete and submit a signed and witnessed "Commitment to Protect Non-Public Information - Contractor Agreement" form for each contractor and subcontractor employee who may have access to non-public Department information under this contract. This form is located at: <http://ocio.nih.gov/docs/public/Nondisclosure.pdf>.

(Reference subparagraph E.3.d. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

2. Section 508 Annual Report

The contractor shall submit an annual Section 508 report in accordance with the schedule set forth in the ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY Article in SECTION H of this contract. The Section 508 Report Template and Instructions for completing the report are available at: <http://www.hhs.gov/od> under "Vendor Information and Documents."

3. Other Deliverables Required by the Statement of Work(SOW)/Contract

Item	Deliverables	SOW/Contract Reference	Recipient	Delivery Schedule
1.	Draft Protocols of <i>in vivo</i> studies	SOW, paragraph 3. B.2.a	1 elec. copy to COR	At least one week before initiation of the evaluation
2.	Reports of Completed Studies	SO, paragraph 3.G.2.b	1 elec. copy to COR	Within 30 days of study completion
3.	Data from animal studies	SOW, paragraph 3.G.2.a	1 elec. copy to COR	Within 24 hours of the COR request
4.	A cumulative list of drugs or therapies studied	SOW, paragraph 3.G.3	1 elec. copy to COR	Within 24 hours of COR request
5.	A cumulative list of oral presentations and published materials	SOW, paragraph 3. G.4	1 elec. copy to COR	Within 24 hours of COR request
6.	Draft Transition Plan	SOW, paragraph 3. J.1	1 elec. copy to COR and CO	6 months prior to the expiration date of the contract
7.	Final Transition Plan	SOW, paragraph 3. J.1	1 elec. copy to COR and CO	3 months prior to the expiration date of the contract
8.	Annual Utilization Report	ARTICLE C.3.	1 elec. copy to COR and CO	On or before the 30th day following the anniversary date of the contract
9.	"Protection of Human Subjects Assurance Identification/ Declaration of Exemption", Optional Form OMB 0990-0263 (or a self-designated form) certifying IRB review and approval of the protocol from which the human materials were obtained	SOW, paragraph 3.I.	1 elec. copy to COR and CO	Must be received from the contractor/subcontractor before research or collection involving human materials may be conducted under the contract

4. Report Submission

Technical Reports and Other Deliverables listed above shall be delivered to the following addresses as specified below:

Addressee:	Deliverable Item No.:	Number of Copies:
Contracting Officer's Representative BSP, TIB, Division of AIDS National Institute of Allergy and Infectious Diseases National Institutes of Health, DHHS 6700B Rockledge Drive, Room 5207, MSC 7624 Bethesda, Maryland 20892-7624	Annual Progress Report, Draft Final Report, Final Report, and item numbers 1-9 of the Other Deliverables listed in paragraph 3 above.	1 electronic copy of each report
Contracting Officer Office of Acquisitions, Division of Extramural Activities National Institute of Allergy and Infectious Diseases	Annual Progress Report, Draft Final Report, Final Report, and item numbers 6,7, 8 and 9 of the Other Deliverables listed in paragraph 3 above.	1 electronic copy of each report

Addressee:	Deliverable Item No.:	Number of Copies:
National Institutes of Health, DHHS 6700B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612		

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Division of Extramural Inventions and Technology Resources (DEITR), OPERA, OER, NIH, 6705 Rockledge Drive, Suite 310, 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(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The first annual utilization report shall be due on or before January 5, 2014. Thereafter, reports shall be due on or before the 30th Calendar day following the reporting period. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
Office of Acquisitions, Division of Extramural Affairs
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Department of Health and Human Services
6700 B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892-7612

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

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

SECTION D - PACKAGING, MARKING AND SHIPPING

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

SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, the Contracting Officer's Representative is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:
Division of AIDS
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Department of Health and Human Services
6700B Rockledge Drive
Bethesda, Maryland 20892

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

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

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

SECTION F - DELIVERIES OR PERFORMANCE**ARTICLE F.1. PERIOD OF PERFORMANCE**

- a. The period of performance of this contract shall be from December 6, 2013 through December 5, 2014.
- b. If the Government exercises its options pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased as listed below:

Option	Option Period
Option 1 (Year 2)	December 6, 2014 through December 5, December 2015
Option 2 (Year 3)	December 6, 2015 through December 5, December 2016
Option 3 (Year 4)	December 6, 2016 through December 5, December 2017
Option 4 (Year 5)	December 6, 2017 through December 5, December 2018
Option 5 (Year 6)	December 6, 2018 through December 5, December 2019
Option 6 (Year 7)	December 6, 2019 through December 5, December 2020

ARTICLE F.2. LEVEL OF EFFORT

- a. During the period of performance of this contract, the Contractor shall provide hours/months/years direct labor hours/months/years. The labor hours/months/years Include vacation, holiday, and sick leave. These labor hours/months/years Include subcontractor labor hours/months/years . It is estimated that the labor hours/months/years are constituted as specified below and will be expended approximately as follows:

Labor [HOURS, MONTHS, YEARS]

Labor Category	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Professional							
Other Professional							
Support							
Totals							

- b. The Contractor shall have satisfied the requirement herein if not less than 90% nor more than 110% of the total direct labor effort specified herein are furnished.

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

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

52.247-35, F.o.b. Destination Within Consignees Premises (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) will represent the Government for the purpose of this contract:

To be specified prior to award

The COR 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 for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its COR designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.242-70 (January 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

(End of Clause)

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 Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

- a. The original invoice shall be submitted to the following **designated billing office**:

National Institutes of Health
Office of Financial Management
Commercial Accounts
2115 East Jefferson Street, Room 4B-432, MSC 8500
Bethesda, MD 20892-8500

- b. One copy of the invoice shall be submitted to the following **approving official**:

Contracting Officer
Office of Acquisitions, Division of Extramural Activities
National Institute of Allergy and Infectious Diseases, NIH, DHHS
6700B Rockledge Drive, Room 3214, MSC 7612 Room __
Bethesda, Maryland 20892 MSC 7612
If using overnight delivery, use 20817- __

E-Mail: NIAIDOAIInvoices@niaid.nih.gov

The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.

[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

- a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Institute of Allergy and Infectious Diseases (NIAID) .
- b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NIAIDInvoices@niaid.nih.gov .
- c. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
- d. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
- e. Invoice Matching Option. This contract requires a two-way match.

- f. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

- b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6452.

- c. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I 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 HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of the above referenced contract."

ARTICLE G.4. 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, "HHS Contracting Guide for Contract of Government Property," which can be found at:

http://www.hhs.gov/hhsmanuals/logisticsmanual/Appendix Q_HHS Contracting Guide.pdf.

ARTICLE G.5. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

- a. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) will be prepared on an annual basis..

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 may access evaluations through a secure Web site for review and comment at the following address:

<http://www.cpars.gov>

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. RESEARCH INVOLVING HUMAN FETAL TISSUE

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

The Contractor shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Contractor.

ARTICLE H.5. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

NIH-funded investigators shall 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-08-033.html>.

ARTICLE H.6. NEEDLE DISTRIBUTION

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

ARTICLE H.7. ACKNOWLEDGEMENT OF FEDERAL FUNDING

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.

ARTICLE H.8. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

The Contractor shall not use contract funds 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.

ARTICLE H.9. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

ARTICLE H.10. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (October 2009)

- a. Before undertaking performance of any contract involving animal-related activities where the species is regulated by USDA, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR sections 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.
- b. The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.
- c. The Contractor agrees that the care, use and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.

- d. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (E-mail: ace@aphis.usda.gov; Web site: (http://www.aphis.usda.gov/animal_welfare).

(End of Clause)

ARTICLE H.11. ANIMAL WELFARE

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

In addition, the research involving live vertebrate animals shall be conducted in accordance with the description set forth in the Vertebrate Animal Section (VAS) of the contractor's technical proposal, as modified in the Final Proposal Revision (FPR), dated _____, which is incorporated by reference.

ARTICLE H.12. INTRODUCTION OF RODENTS AND RODENT PRODUCTS

No rodent or rodent product shall be delivered into the NIH, NIAID environment (NIH) directly, or through collaborative research or holding facilities under contract to NIAID except by permit. Direct shipments to NIH from a Division of Veterinary Resources (DVR), Office of Research Services (ORS) approved source will be considered exempt. Non-exempt sources must be approved by permit issued through the DVR, ORS. The permit must be obtained by the Contractor prior to the shipment to NIH of the rodents and/or rodent products. The Contractor must be sure that this permit exists and is current before transferring rodents or rodent products into the NIH, NIAID environment. Refusal or negligence to do so will be considered a material breach of contract and may be treated as any other such material breach. Applications for permits should be submitted by facsimile not less than 30 days prior (60 days in situations where quarantine is likely) to shipping date to: NIH Division of Veterinary Resources (DVR), Office of Research Services (ORS), Building 14G, Service Rd. South, Room 102, BETHESDA MD 20892-5210, (301)496-2527, FAX: (301) 402-0352.

ARTICLE H.13. 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 FAR Clause 52.217-9, Option to Extend the Term of the Contract 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 of the contract will be increased as set forth in the ESTIMATED COST Article in SECTION B of this contract.

ARTICLE H.14. 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 due on the following dates for the entire life of this contract:

April 30th
October 30th
Expiration Date of Contract

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:

To be specified prior to award
Contracting Officer

ARTICLE H.15. INFORMATION AND PHYSICAL ACCESS SECURITY

A. HHS-Controlled Facilities and Information Systems Security

- a. To perform the work specified herein, Contractor personnel are expected to have routine (1) physical access to an HHS-controlled facility; (2) physical access to an HHS-controlled information system; (3) access to sensitive HHS data or information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).
- b. To gain routine physical access to an HHS-controlled information system, and/or access to sensitive data or information, the Contractor and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; Office of Management and Budget Memorandum (M-05-24); and Federal Information Processing Standards Publication (FIPS PUB) Number 201; and with the personal identity verification and investigations procedures contained in the following documents:
 1. HHS Information Security Program Policy (<http://www.hhs.gov/read/irmpolicy/121504.html>)
 2. HHS Office of Security and Drug Testing, Personnel Security/Suitability Handbook, dated February 1, 2005 (<http://www.hhs.gov/ohr/manual/pssh.pdf>)

3. HHS HSPD-12 Policy Document, v. 2.0 (<http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-24.pdf>)
4. Information regarding background checks/badges (<http://idbadge.nih.gov/background/index.asp>)

c. Position Sensitivity Levels:

This contract will entail the following position sensitivity levels:

Level 6: Public Trust - High Risk. Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).

Level 5: Public Trust - Moderate Risk. Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

Level 1: Non-Sensitive. Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

- d. The personnel investigation procedures for Contractor personnel require that the Contractor prepare and submit background check/investigation forms based on the type of investigation required. The minimum Government investigation for a non-sensitive position is a National Agency Check and Inquiries (NACI) with fingerprinting. More restricted positions - i.e., those above non-sensitive, require more extensive documentation and investigation.

The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access and/or maintain a Federal Information System(s). The roster shall be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, within 14 calendar days after the effective date of the contract. 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://ocio.nih.gov/docs/public/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.

The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.

All contractor and subcontractor employees shall comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract.

Contractors may begin work after the fingerprint check has been completed.

- e. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.
- f. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more than the cost of the additional investigation(s).

- g. The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).
- h. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.
- i. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

B. Standard for Security Configurations, HHSAR 352.239-70, (January 2010)

- a. The Contractor shall configure its computers that contain HHS data with the applicable Federal Desktop Core Configuration (FDCC) (see <http://nvd.nist.gov/fdcc/index.cfm>) and ensure that its computers have and maintain the latest operating system patch level and anti-virus software level.
Note: FDCC is applicable to all computing systems using Windows XPTM and Windows Vista™, including desktops and laptops - regardless of function - but not including servers.
- b. The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS. The following security configuration requirements apply: FDCC.
- c. The Contractor shall ensure IT applications operated on behalf of HHS are fully functional and operate correctly on systems configured in accordance with the above configuration requirements. The Contractor shall use Security Content Automation Protocol (SCAP)-validated tools with FDCC Scanner capability to ensure its products operate correctly with FDCC configurations and do not alter FDCC settings - see <http://nvd.nist.gov/validation.cfm>. The Contractor shall test applicable product versions with all relevant and current updates and patches installed. The Contractor shall ensure currently supported versions of information technology products met the latest FDCC major version and subsequent major versions.
- d. The Contractor shall ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.
- e. The Contractor shall ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.
- f. The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (<http://csrc.nist.gov/publications/fips/fips201-1/FIPS-201-1-chng1.pdf>), Homeland Security Presidential Directive 12 (HSPD-12) card readers with the purchase of servers, desktops, and laptops; and (2) comply with FAR Subpart 4.13, Personal Identity Verification.
- g. The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.

C. Standard for Encryption language, HHSAR 352.239-71, (January 2010)

- a. The Contractor shall use Federal Information processing Standard (FIPS) 140-2-compliant encryption (Security) Requirements for Cryptographic Module, as amended) to protect all instances of HHS sensitive information during storage and transmission. (Note: The Government has determined that HHS information under this contract is considered "sensitive" in accordance with FIPS 199, Standards for Security Categorization of Federal Information and Information Systems, dated February 2004).

- b. The Contractor shall verify that the selected encryption product has been validated under the Cryptographic Module Validation Program (see <http://csrc.nist.gov/cryptval/>) to confirm compliance with FIPS 140-2 (as amended). The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer's Technical Representative.
- c. The Contractor shall use the Key Management Key (see FIPS 201, Chapter 4, as amended) on the HHS personal identification verification (PIV) card; or alternatively, the Contractor shall establish and use a key recovery mechanism to ensure the ability for authorized personnel to decrypt and recover all encrypted information (see <http://csrc.nist.gov/drivers/documents/ombencryption-guidance.pdf>). The Contractor shall notify the Contracting Officer and the Contracting Officer's Technical Representative of personnel authorized to decrypt and recover all encrypted information.
- d. The Contractor shall securely generate and manage encryption keys to prevent unauthorized decryption of information in accordance with FIPS 140-2 (as amended).
- e. The Contractor shall ensure that this standard is incorporated into the Contractor's property management/control system or establish a separate procedure to account for all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive HHS information.
- f. The Contractor shall ensure that its subcontractors (all all tiers) which perform work under this contract comply with the requirements contained in this clause.

D. Security Requirements For Federal Information Technology Resources, HHSAR 352.239-72, (January 2010)

- a. **Applicability.** This clause applies whether the entire contract or order (hereafter "contract"), or portion thereof, includes information technology resources or services in which the Contractor has physical or logical (electronic) access to, or operates a Department of Health and Human Services (HHS) system containing, information that directly supports HHS' mission. The term "information technology (IT)", as used in this clause, includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services) and related resources. This clause does not apply to national security systems as defined in FISMA.
- b. **Contractor responsibilities.** The Contractor is responsible for the following:
 - 1. Protecting Federal information and Federal information systems in order to ensure their -
 - a. Integrity, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;
 - b. Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and
 - c. Availability, which means ensuring timely and reliable access to and use of information.
 - 2. Providing security of any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor, regardless of location, on behalf of HHS.
 - 3. Adopting, and implementing, at a minimum, the policies, procedures, controls and standards of the HHS Information Security Program to ensure the integrity, confidentiality, and availability of Federal information and Federal information systems for which the Contractor is responsible under this contract or to which it may otherwise have access under this contract. The HHS Information Security Program is outlined in the HHS Information Security Program Policy, which is available on the HHS Office of the Chief Information Officer's (OCIO) Web site.

- c. **Contractor security deliverables.** In accordance with the timeframes specified, the Contractor shall prepare and submit the following security documents to the Contracting Officer for review, comment, and acceptance:
1. **IT Security Plan (IT-SP)** - due within 30 days after contract award. The IT-SP shall be consistent with, and further detail the approach to, IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The IT-SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT-SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT-SP applies.
 - a. The Contractor's IT-SP shall comply with applicable Federal laws that include, but are not limited to, the Federal Information Security Management Act (FISMA) of 2002 (Title III of the E-Government Act of 2002, Public Law 107-347), and the following Federal and HHS policies and procedures:
 - i. Office of Management and Budget (OMB) Circular A-130, Management of Federal Information Resources, Appendix III, Security of Federal Automation Information Resources.
 - ii. National Institutes of Standards and Technology (NIST) Special Publication (SP) 800-18, Guide for Developing Security Plans for Information Systems, in form and content, and with any pertinent contract Statement of Work/Performance Work Statement (SOW/PWS) requirements. The IT-SP shall identify and document appropriate IT security controls consistent with the sensitivity of the information and the requirements of Federal Information Processing Standard (FIPS) 200, Recommend Security Controls for Federal Information Systems. The Contractor shall review and update the IT-SP in accordance with NIST SP 800-26, Security Self-Assessment Guide for Information Technology Systems and FIPS 200, on an annual basis.
 - iii. HHS-OCIO Information Systems Security and Privacy Policy.
 2. **IT Risk Assessment (IT-RA)** - due within 30 days after contract award. The IT-RA shall be consistent, in form and content, with NIST SP 800-30, Risk Management Guide for Information Technology Systems, and any additions or augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy. After resolution of any comments provided by the Government on the draft IT-RA, the Contracting Officer shall accept the IT-RA and incorporate the Contractor's final version into the contract for Contractor implementation and maintenance. The Contractor shall update the IT-RA on an annual basis.
 3. **FIPS 199 Standards for Security Categorization of Federal Information and Information Systems Assessment (FIPS 199 Assessment)** - due within 30 days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard. After resolution of any comments by the Government on the draft FIPS 199 Assessment, the Contracting Officer shall accept the FIPS 199 Assessment and incorporate the Contractor's final version into the contract.
 4. **IT Security Certification and Accreditation (IT-SC&A)** - due within 3 months after contract award. The Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed for applicable information systems - see paragraph (a) of this clause. The Contractor shall perform the IT-SC&A in accordance with the HHS Chief Information Security Officer's Certification and Accreditation Checklist; NIST SP 800-37, Guide for the Security, Certification and Accreditation of Federal Information Systems; and NIST 800-53, Recommended Security Controls for Federal Information Systems. An authorized senior management official shall sign the draft IT-SC&A and provided it to the Contracting Officer for review, comment, and acceptance.
 - a. After resolution of any comments provided by the Government on the draft IT SC&A, the Contracting Officer shall accept the IT-SC&A and incorporate the Contractor's final version into the contract as a compliance requirement.

- b. The Contractor shall also perform an annual security control assessment and provide to the Contracting Officer verification that the IT-SC&A remains valid. Evidence of a valid system accreditation includes written results of:
 - i. Annual testing of the system contingency plan; and
 - ii. The performance of security control testing and evaluation.
- d. **Personal identity verification.** The Contractor shall identify its employees with access to systems operated by the Contractor for HHS or connected to HHS systems and networks. The Contracting Officer's Representative (COR) shall identify, for those identified employees, position sensitivity levels that are commensurate with the responsibilities and risks associated with their assigned positions. The Contractor shall comply with the HSPD-12 requirements contained in "HHS-Controlled Facilities and Information Systems Security" requirements specified in the SOW/PWS of this contract.
- e. **Contractor and subcontractor employee training.** The Contractor shall ensure that its employees, and those of its subcontractors, performing under this contract complete HHS-furnished initial and refresher security and privacy education and awareness training before being granted access to systems operated by the Contractor on behalf of HHS or access to HHS systems and networks. The Contractor shall provide documentation to the COR evidencing that Contractor employees have completed the required training.
- f. **Government access for IT inspection.** The Contractor shall afford the Government access to the Contractor's and subcontractors' facilities, installations, operations, documentation, databases, and personnel used in performance of this contract to the extent required to carry out a program of IT inspection (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the integrity, confidentiality, and availability, of HHS data or to the protection of information systems operated on behalf of HHS.
- g. **Subcontracts.** The Contractor shall incorporate the substance of this clause in all subcontracts that require protection of Federal information and Federal information systems as described in paragraph (a) of this clause, including those subcontracts that -
 - a. Have physical or electronic access to HHS' computer systems, networks, or IT infrastructure; or
 - b. Use information systems to generate, store, process, or exchange data with HHS or on behalf of HHS, regardless of whether the data resides on a HHS or the Contractor's information system.
- h. **Contractor employment notice.** The Contractor shall immediately notify the Contracting Officer when an employee either begins or terminates employment (or is no longer assigned to the HHS project under this contract), if that employee has, or had, access to HHS information systems or data.
- i. **Document information.** The Contractor shall contact the Contracting Officer for any documents, information, or forms necessary to comply with the requirements of this clause.
- j. **Contractor responsibilities upon physical completion of the contract.** The Contractor shall return all HHS information and IT resources provided to the Contractor during contract performance and certify that all HHS information has been purged from Contractor-owned systems used in contract performance.
- k. **Failure to comply.** Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause shall be grounds for the Contracting Officer to terminate this contract.

(End of Clause)

Note: The NIST Special Publication SP-800-26 cited in subparagraph c.1.a.(ii) of this clause has been superseded by NIST SP 800-53A, "Guide for Assessing the Security Controls in Federal Information Systems and Organizations" for use for the assessment of security control effectiveness. See <http://csrc.nist.gov/publications/PubsSPs.html> to access NIST Special Publications (800 Series).

E. Additional NIH Requirements

1. SECURITY CATEGORIZATION OF FEDERAL INFORMATION AND INFORMATION SYSTEMS (FIPS 199 Assessment)

a. Information Type:

Administrative, Management and Support Information:

Mission Based Information:

The Contractor will be required to conduct studies and report study data and results of animals studies to the COR by email and electronic submission of data files.

b. Security Categories and Levels:

Confidentiality Level:	<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
Integrity Level:	<input type="checkbox"/> Low	<input checked="" type="checkbox"/> Moderate	<input type="checkbox"/> High
Availability Level:	<input checked="" type="checkbox"/> Low	<input type="checkbox"/> Moderate	<input type="checkbox"/> High
Overall Level:	<input type="checkbox"/> Low	<input checked="" type="checkbox"/> Moderate	<input type="checkbox"/> High

- c. In accordance with HHSAR Clause 352.239-72, the contractor shall submit a FIPS 199 Assessment within 30 days after contract award. Any differences between the contractor's assessment and the information contained herein, will be resolved, and if required, the contract will be modified to incorporate the final FIPS 199 Assessment.

2. INFORMATION SECURITY TRAINING

In addition to any training covered under paragraph (e) of HHSAR 352.239-72, the contractor shall comply with the below training:

a. Mandatory Training

- i. All Contractor employees having access to (1) Federal information or a Federal information system or (2) sensitive data/information as defined at HHSAR 304.1300(a) (4), shall complete the NIH Computer Security Awareness Training course at <http://irtsectraining.nih.gov/> before performing any work under this contract. Thereafter, Contractor employees having access to the information identified above shall complete an annual NIH-specified refresher course during the life of this contract. The Contractor shall also ensure subcontractor compliance with this training requirement.
- ii. The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working on this contract and having access of the kind in paragraph 1.a(1) above, who has completed the NIH required training. Any additional security training completed by the Contractor/Subcontractor staff shall be included on this listing. The list shall be provided to the COR and/or Contracting Officer upon request.

b. Role-based Training

HHS requires role-based training when responsibilities associated with a given role or position, could, upon execution, have the potential to adversely impact the security posture of one or more HHS systems. Read further guidance at [Secure One HHS Memorandum on Role-Based Training Requirement](#).

For additional information see the following: <http://ocio.nih.gov/security/security-communicating.htm#RoleBased>.

The Contractor shall maintain a list of all information security training completed by each contractor/subcontractor employee working under this contract. The list shall be provided to the COR and/or Contracting Officer upon request.

c. Rules of Behavior

The Contractor shall ensure that all employees, including subcontractor employees, comply with the NIH Information Technology General Rules of Behavior (<http://ocio.nih.gov/security/nihitrob.html>), which are contained in the NIH Information Security Awareness Training Course <http://irtsectraining.nih.gov>.

3. **PERSONNEL SECURITY RESPONSIBILITIES**

In addition to any personnel security responsibilities covered under HHSAR 352.239-72, the contractor shall comply with the below personnel security responsibilities:

- a. In accordance with Paragraph (h) of HHSAR 352.239-72, the Contractor shall notify the Contracting officer and the COR **within five working days** before a new employee assumes a position that requires access to HHS information systems or data, or when an employee with such access stops working on this contract. The Government will initiate a background investigation on new employees assuming a position that requires access to HHS information systems or data, and will stop pending background investigations for employees that no longer work under the contract or no longer have such access.
- b. **New contractor employees who have or will have access to HHS information systems or data:** The Contractor shall provide the COR with the name, position title, e-mail address, and phone number of all new contract employees working under the contract and provide the name, position title and position sensitivity level held by the former incumbent. If an employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate position sensitivity level.
- c. **Departing contractor employees:** The Contractor shall provide the COR with the name, position title, and position sensitivity level held by or pending for departing employees. The Contractor shall perform and document the actions identified in the Contractor Employee Separation Checklist (<http://ocio.nih.gov/nihsecurity/Emp-sep-checklist.pdf>) when a Contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the COR upon request.
- d. **Commitment to Protect Non-Public Departmental Information and Data.**

The Contractor, and any subcontractors performing under this contract, 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)

Each employee, including subcontractors, having access to non-public Department information under this acquisition shall complete the "Commitment to Protect Non-Public Information - Contractor Employee Agreement" located at: <http://ocio.nih.gov/docs/public/Nondisclosure.pdf>.

A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer/COR prior to performing any work under this acquisition.

ARTICLE H.16. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-73(b) (January 2010)

- a. Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 provisions is available at <http://www.section508.gov/>. The complete text of Section 508 Final provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm>.
- b. The Section 508 standards applicable to this contract/order are identified in the Statement of Work. The contractor must provide a written Section 508 conformance certification due at the end of each contract/order exceeding \$100,000 when the contract/order duration is one year or less. If it is determined by the Government that EIT products and services provided by the Contractor do not conform to the described accessibility standards in the Product Assessment Template, remediation of the products or services to the level of conformance specified in the Contractor's Product Assessment Template will be the responsibility of the Contractor at its own expense.
- c. In the event of a modification(s) to this contract/order, which adds new EIT products or services or revises the type of, or specifications for, products or services the Contractor is to provide, including EIT deliverables such as electronic documents and reports, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products or services support Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS Office on Disability Web site (<http://www.hhs.gov/od/>).

[(End of HHSAR 352.239-73(b))]

- d. Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Annual Report to the Contracting Officer and Project Officer. Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available in the Section 508 policy on the HHS Office on Disability Web site under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding funding, as applicable.

Schedule for Contractor Submission of Section 508 Annual Report:

Section 508 Annual Report shall be submitted on December 6th each year of performance.

[(End of HHSAR 352.239-73(c))]

ARTICLE H.17. CONFIDENTIALITY OF INFORMATION

- a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.
- b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.
- c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth

in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

- d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.
- e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.
- f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.
- g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

The following information is covered by this article:

Materials, data, or other information from third party providers and laboratories; and any data of a personal nature that may accompany human materials/supplies.

ARTICLE H.18. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Institution (includes any contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under NIH contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&rgn=div5&view=text&node=45:1.0.1.1.52&idno=45>

As required by 45 CFR Part 94, the Institution shall, at a minimum:

- a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
 1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. Included are payments and equity interests;
 2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or
 3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

Significant financial interests do not include the following:

1. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and
 2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
- b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any NIH-funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.
 - c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the NIH-funded research.
 - d. Require that each Investigator who is planning to participate in the NIH-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for NIH-funded research. Require that each Investigator who is participating in the NIH-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.
 - e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to NIH-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to NIH-funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest: Could be affected by the NIH-funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.
 - f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).
 - g. Provide initial and ongoing FCIO reports to the Contracting Officer pursuant to Part 94.5(b).
 - h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.
 - i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
 - j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Offerors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the NIH-funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the NIH-funded research project.

The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests.. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the NIH-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that NIH-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was managed or reported by the Institution, the shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

ARTICLE H.19. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, 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. to be determined at the time of award."

ARTICLE H.20. 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.21. YEAR 2000 COMPLIANCE

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

- 1. Service Involving the Use of Information Technology**
YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY

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

(End of Clause)

ARTICLE H.22. 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, "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice," (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/pdfs/64FR72090.pdf> is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

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

a. Sharing of Model Organisms for Biomedical Research

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

ARTICLE H.23. SHARING RESEARCH DATA

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

The NIH endorses the sharing of final research data to serve health. this contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

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

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

ARTICLE H.24. 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.25. CONSTITUTION DAY

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

ARTICLE H.26. USE OF FUNDS FOR CONFERENCES, MEETINGS AND FOOD

The Contractor shall not use contract funds to conduct meetings or conferences without prior written Contracting Officer approval.

In addition, the use of contract funds to purchase food for meals, light refreshments, or beverages is expressly prohibited.

The following conferences and/or meetings have been approved by the Contracting Officer and are hereby authorized under this contract:

Conference or Meeting Title	Conference or Meeting Location	Federal/NonFederal Space	Date of Conference	Not to Exceed Estimate Cost
		<input type="checkbox"/> Federal <input type="checkbox"/> NonFederal		
		<input type="checkbox"/> Federal <input type="checkbox"/> NonFederal		
		<input type="checkbox"/> Federal <input type="checkbox"/> NonFederal		
		<input type="checkbox"/> Federal <input type="checkbox"/> NonFederal		

ARTICLE H.27. USE OF FUNDS FOR PROMOTIONAL ITEMS

The Contractor shall not use contract funds to purchase promotional items. Promotional items include, but are not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees. This includes items or tokens given to individuals as these are considered personal gifts for which contract funds may not be expended.

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:

The complete listing of these clauses may be accessed at: <http://oamp.od.nih.gov/DGS/generalClauses.aspx>

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS

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 substitutions will be made part of the resultant contract:

- a. FAR Clauses **52.215-15, Pension Adjustments and Asset Reversions** (October 2010); **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.
- b. **Alternate IV** (October 2010) of FAR Clause **52.215-21, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data--Modifications** (October 2010) is added.
- c. **Alternate II** (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (January 2011) is added.
- d. FAR Clause **52.232-17, Interest** (October 2010) is applicable to this contract.
- e. FAR Clauses **52.249-6, Termination (Cost-Reimbursement)** (May 2004) and **52.249-14, Excusable Delays** (April 1984), are deleted in their entirety and FAR Clause **52.249-5, Termination for Convenience of the Government (Educational and Other Nonprofit Institutions)** (September 1996), is substituted therefore.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (April 2010).
2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (December 2007).

".....(3) Any required posters may be obtained as follows:

Poster(s)	Obtain From"
HHS Contractor Code of Ethics and Business Conduct Poster	http://oig.hhs.gov/fraud/report-fraud/OIG_Hotline_Poster.pdf

3. FAR Clause **52.210-1, Market Research** (April 2011).
4. FAR Clause **52.216-15, Predetermined Indirect Cost Rates** (April 1998).
5. FAR Clause **52.217-9, Option to Extend the Term of the Contract** (March 2000).

"(a) The Government may extend the term of this contract by written notice to the Contractor within 30 days of contract expiration; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension."

"c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 7 years."

6. FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (January 2011).

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

[] Offeror elects to waive the evaluation preference."

7. FAR Clause **52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting** (December 2010).
8. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (April 2012).
9. **Alternate IV** (December 2007), FAR Clause **52.227-14, Rights in Data - General** (December 2007).

10. **Alternate V** (December 2007), FAR Clause **52.227-14, Rights in Data--General** (December 2007).

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

11. FAR Clause **52.227-16, Additional Data Requirements** (June 1987).
12. FAR Clause **52.230-5, Cost Accounting Standards - Educational Institution** (May 2012).
13. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (June 2010).
14. FAR Clause **52.237-3, Continuity of Services** (January 1991).
15. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).
16. FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984).
17. FAR Clause **52.246-23, Limitation of Liability** (February 1997).
18. FAR Clause **52.251-1, Government Supply Sources** (April 2012).

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

1. HHSAR Clause **352.223-70, Safety and Health** (January 2006).
2. HHSAR Clause **352.231-70, Salary Rate Limitation** (March 2012).

Note: P.L. 112-74 sets forth the Salary Rate Limitation at the Executive Level II Rate, effective December 23, 2011.

See the following Web site for Executive Schedule rates of pay: <http://www.opm.gov/oca/> .

(For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

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

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

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

There are no clauses applicable to this contract.

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.

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

1. FAR Clause 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (February 2012)

(a) The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIS) on a semi-annual basis, throughout the life of the contract, by posting the required information in the Central Contractor Registration database at <https://www.acquisition.gov>.

(b) As required by section 3010 of the Supplemental Appropriations Act, 2010 (Pub. L. 111-212), all information posted in FAPIS on or after April 15, 2011, except past performance reviews, will be publicly available. FAPIS consists of two segments--

(1) The non-public segment, into which Government officials and the Contractor post information, which can only be viewed by--

- (i) Government personnel and authorized users performing business on behalf of the Government; or
- (ii) The Contractor, when viewing data on itself; and

(2) The publicly-available segment, to which all data in the non-public segment of FAPIS is automatically transferred after a waiting period of 14 calendar days, except for--

- (i) Past performance reviews required by subpart 42.15;
- (ii) Information that was entered prior to April 15, 2011; or
- (iii) Information that is withdrawn during the 14-calendar-day waiting period by the Government official who posted it in accordance with paragraph (c)(1) of this clause.

(c) The Contractor will receive notification when the Government posts new information to the Contractor's record.

(1) If the Contractor asserts in writing within 7 calendar days, to the Government official who posted the information, that some of the information posted to the non-public segment of FAPIS is covered by a disclosure exemption under the Freedom of Information Act, the Government official who posted the information must within 7 calendar days remove the posting from FAPIS and resolve the issue in accordance with agency Freedom of Information procedures, prior to reposting the releasable information. The contractor must cite 52.209-9 and request removal within 7 calendar days of the posting to FAPIS.

(2) The Contractor will also have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, i.e., for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.

(3) As required by section 3010 of Pub. L. 111-212, all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available.

(d) Public requests for system information posted prior to April 15, 2011, will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.

(End of clause)

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

There are no clauses applicable to this contract.

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 (R & D)	See Attachments at the end of the RFP
Attachment 2:	Proposal Intent Response Sheet	See Attachments at the end of the RFP
Attachment 3:	Statement of Work	See Attachments at the end of this RFP
Attachment 4:	Additional Technical Proposal Instructions	See Attachments at the end of this RFP
Attachment 5:	Additional Business Proposal Instructions	See Attachments at the end of the RFP
Attachment 6:	DAIDS Material Evaluation Agreement	See Attachments at the end of the RFP

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 7:	Technical Proposal Cost Summary	http://oamp.od.nih.gov/DGS/FORMS/Tech-Prop-Cost-Summ.pdf
Attachment 8:	Summary of Related Activities	http://oamp.od.nih.gov/DGS/FORMS/summary-related-activities.pdf
Attachment 9:	Contract Proposal Vertebrate Animal Section (VAS) Worksheet	http://grants.nih.gov/grants/olaw/VAScontracts.pdf
Attachment 10:	HHS Section 508 Product Assessment Template	http://www.hhs.gov/od/vendors/index.html

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 11:	Proposal Summary and Data Record, NIH-2043	http://oamp.od.nih.gov/DGS/FORMS/NIH2043.pdf
Attachment 12:	Small Business Subcontracting Plan	http://www.hhs.gov/about/smallbusiness/subcontractplan.html
Attachment 13:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	http://oamp.od.nih.gov/contracts/BUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls
Attachment 14:	Offeror's Points of Contact	http://oamp.od.nih.gov/DGS/FORMS/point-of-contact.pdf
Attachment 15:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://www.gsa.gov/portal/forms/download/116430

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 16:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://oamp.od.nih.gov/DGS/FORMS/rc4.pdf
Attachment 17:	Safety and Health, HHSAR Clause 352.223-70	http://oamp.od.nih.gov/DGS/FORMS/Safety-Health-hhsar-1-06.pdf
Attachment 18:	Government Property Schedule	See Attachments at the end of the RFP
Attachment 19:	Commitment to Protect Non-Public Information Contractor Agreement	http://ocio.nih.gov/docs/public/Nondisclosure.pdf
Attachment 20:	Roster of Employees Requiring Suitability Investigations	http://ocio.nih.gov/docs/public/Suitability-roster.xls
Attachment 21:	Employee Separation Checklist	http://ocio.nih.gov/nihsecurity/Emp-sep-checklist.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

1. Go to the **Online Representations and Certifications Application (ORCA)** and complete the Representations and Certifications. Offerors must access ORCA through The System for Award Management (SAM) at <http://www.sam.gov> ; and
2. Complete, and **INCLUDE as part of your BUSINESS PROPOSAL:**
SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS
which is included as an Attachment in Section J-LIST OF ATTACHMENTS, SOLICITATION ATTACHMENTS of this solicitation.

If you are unable to access this SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Provision 52.215-1 (January 2006)]

(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, 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 statements, specifying the particular portions of the proposal which are to be restricted:

"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 (HHS), data contained in the portions of this proposal which the offeror has specifically identified by page number, paragraph, etc. as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that HHS may not be able to withhold a record (e.g. data, document, etc.) nor deny access to a record requested pursuant to the Act and that the HHS's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if HHS 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 must 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 statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).

(f) *Contract award.*

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

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

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

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be

in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

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

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

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

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

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

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

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

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.

(ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.

(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;

(iv) A summary of the rationale for award.

(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

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.

b. NAICS CODE AND SIZE STANDARD

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

1. The North American Industry Classification System (NAICS) code for this acquisition is 541712.
2. The small business size standard is 500.

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

c. TYPE OF CONTRACT AND NUMBER OF AWARDS

1. It is anticipated that one award will be made from this solicitation and that the award will be made on/about December 6, 2013.
2. It is anticipated that the award from this solicitation will be a multiple-year Cost-Reimbursement type Level of Effort contract with a Term of 1Year, and will include annual options to extend the period of performance for a total performance period of 7 years..
3. FAR 16.301-3 limits use of any contract type, other than firm-fixed price, to a contractor whose accounting system is adequate for determining costs applicable to the contract. To be considered for an award under this solicitation, the Offeror is required to certify, in its Business Proposal, the adequacy of its accounting system. See the paragraph entitled, Adequate Accounting System in Section L.2. Business Proposal Instructions in this solicitation for additional information about this certification.

d. LEVEL OF EFFORT

The Government's requirement for the work set forth in the Statement of Work of this solicitation is 6.0 Full Time Equivalents (FTEs). It is estimated that the FTEs are constituted as specified below and will be expended approximately as follows:

Full Time Equivalents

Labor Category	Base Period	Option 1 Year 2	Option 2 Year 3	Option 3 Year 4	Option 4 Year 5	Option 5 Year 6	Option 6 Year 7
Professional	.75	.75	.75	.75	.75	.75	.75
Other Professional	2.75	2.75	2.75	2.75	2.75	2.75	2.75
Technical Support	2.50	2.50	2.50	2.50	2.50	2.50	2.50
Totals	6.00	6.00	6.00	6.00	6.00	6.00	6.00

NOTE: The labor mix provided above is not intended to be restrictive. The Contractor should propose the labor mix deemed most appropriate to carry out the Statement of Work. Please note, however, that the total number of FTEs is required and the Contractor should propose the total number of FTEs to meet this requirement.

e. COMMITMENT OF PUBLIC FUNDS

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

f. PROMOTING EFFICIENT SPENDING

On September 21, 2011, the Office of Management and Budget issued [Memorandum M-11-35](#), entitled, "Eliminating Conference Spending and Promoting Efficiency in Government," emphasizing the President's priority to ensure that the Government operates with the utmost efficiency and eliminates unnecessary or wasteful spending. This was followed by the Executive Order on Delivering an Efficient, Effective, and Accountable Government ([EO 13576](#)) and the Executive Order on Promoting Efficient Spending ([EO 13589](#)). On January 3, 2012, the Department of Health and Human Services (DHHS) issued the memorandum "HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items, and Printing, and Publications" (See http://www.hhs.gov/asfr/ogapa/acquisition/effspendpol_memo.html).

In support of these directives, the NIH issued a January 30, 2012, Memorandum, entitled, "NIH Guidance Related to the HHS Policies on Promoting Efficient Spending: Use of Appropriated Funds for Conferences, Conference Grants and Meetings, Food, Promotional Items, and Printing and Publications." (See <http://oamp.od.nih.gov/>)

Any contract awarded as a result of this solicitation will:

- Specifically prohibit the use of contract funds for the provision of food for meals, light refreshments and beverages for any NIH funded meeting or conference; and
- Limit the procurement of meeting space, promotional items, printing and publications.

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. PREPARATION COSTS

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

j. SERVICE OF PROTEST (SEPTEMBER 2006) - 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:

John Manouelian
Contracting Officer
Office of Acquisitions, Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
National Institutes of Health, DHHS
6700B Rockledge Drive, Room 3151, MSC 7612
Bethesda, Maryland 20892

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

(End of Provision)

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

2. Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, 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, printed/copied double-sided, on at least 30 percent post consumer fiber paper, as required by FAR 4.302(b), 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 SECTION J, 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 proposals in accordance with the factors 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 procurements, 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. Selection of Offerors

- a. The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation factors 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.
- 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.

10. Institutional Responsibility Regarding Investigator Conflicts of Interest

45 CFR Part 94 promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research to be performed under NIH contracts will be biased by any Investigator financial conflicts of interest. The Institution shall comply with all requirements of 45 CFR Part 94 at <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&rgn=div5&view=text&node=45:1.0.1.1.52&idno=45>

11. ROTC Access and Federal Military Recruiting on Campus

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

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

12. Past Performance Information

- a. Offerors shall submit the following information as part of their Business proposal.

A list of the last 5 contracts completed during the past Three years and all contracts currently being performed 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 may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as any subcontract exceeding \$650,000 in total cost.

Include the following information for each contract or subcontract listed:

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. North American Industry Classification System (NAICS) Code

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

- b. 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. 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.acquisition.gov/far/index.html>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a. Data Universal Numbering System (DUNS) Number, FAR Provision 52.204-6 (April 2008).
- b. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
- c. Limitations on Pass-Through Charges--Identification of Subcontract Effort, FAR Provision 52.215-22, (October 2009).
- 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.

Note to Offerors: Beginning May 25, 2008, the offeror shall include the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.

1. Technical Discussions

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

a. 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

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

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 of work, as applicable, by contract year as well as for the overall contract. 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.

b. 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. Single 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. 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.

3. Technical Evaluation

Proposals will be technically evaluated in accordance with SECTION M - Evaluation Factors for Award of this solicitation.

4. Human Subjects

IMPORTANT NOTE TO OFFERORS: The following subparagraph shall be addressed, as applicable, in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

- a. **Research Involving Human Fetal Tissue**

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

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

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

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

5. Care of Live Vertebrate Animals

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

Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, HHSAR 352.270-5(a) (January 2006)

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) establishes a number of requirements for research activities involving animals. Before award may be made to an applicant organization, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance (Assurance) which commits the organization to comply with the provisions of the PHS Policy, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC). In accordance with the PHS Policy, applicant organizations must establish an Institutional Animal Care & Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. Applicant organizations are required to provide verification of IACUC approval prior to release of an award involving live vertebrate animals. No award involving the use of animals shall be made unless OLAW approves the Assurance and verification of IACUC approval for the proposed animal activities has been provided to the Contracting Officer. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Assurance and verification of IACUC approval are required. The Contracting Officer will request that OLAW negotiate an acceptable Assurance with those Contractor(s) and request verification of IACUC approval. For further information contact OLAW, at NIH, 6705 Rockledge Drive, RKL1, Suite 360, MSC 7982 Bethesda, Maryland 20892-7982 (E-mail: olaw@od.nih.gov; Phone: 301-496-7163).

(End of Provision)

The PHS Policy is available on the internet at: <http://www.grants.nih.gov/grants/olaw/olaw.htm>.

6. Research Involving Live Vertebrate Animals

It is intended that live vertebrate animals will be used during performance of this contract. The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (authority derived from the Health Research Extension Act of 1985) specifies that certain information is required from offerors in contract proposals submitted to the NIH that will use live vertebrate animals.

The following five points must be addressed in a separate section of the Technical Proposal titled "Vertebrate Animal Section" (VAS):

- a. Detailed description of the proposed use of the animals, including species, strains, ages, sex and number to be used.
- b. Justification for the use of animals, choice of species, and numbers to be used.
- c. Information on the veterinary care of the animals.
- d. Description of procedures for minimizing discomfort, distress, pain and injury.
- e. Method of euthanasia and the reasons for the selection.

A concise (no more than 1-2 pages), complete description addressing these five points must be provided. The description must be cohesive and include sufficient information to allow evaluation by reviewers and NIH staff. For more discussion regarding the five points in the VAS, see NIH Guide Notice NOT-OD-10-049 at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-049.html>.

The Contract Proposal VAS Worksheet is provided as an Attachment in SECTION J of this solicitation to assist in the preparation of the VAS as part of the Technical Proposal. It can be accessed at: <http://grants.nih.gov/grants/olaw/VAScontracts.pdf>.

7. 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/pdfs/64FR72090.pdf>

a. Sharing Research Data

[Note: This policy applies to **all** NIH contracts, regardless of dollar value, that are expected to generate research data.]

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

technical proposal for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:

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

b. Sharing of Model Organisms for Biomedical Research

The NIH Research Tools Policy (http://www.ott.nih.gov/policy/research_tool.html) also referred to as NIH Principles and Guidelines for Sharing of Biomedical Resources: Final Notice, December 1999, supports the concept of timely sharing and distribution of research resources. In accordance with NIH Guide Notice NOT-OD-04-042 at:

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>), dated May 7, 2004, and the September 10, 2004 extension of this policy NOT-OD-04-066 at:

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-066.html>),

the NIH provides further sharing guidance with particular attention on model organisms for biomedical research. Such organisms include, but are not limited to: mammalian models such as the mouse and rat, and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

Offerors must include in their technical proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, OR provide appropriate reasons why such sharing is restricted or not possible. A reasonable time frame for periodic disposition of material and associated data must be specified in the proposal. In addition, the plan must address if, or how, offerors will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. At a minimum, the plan should address the following:

- Will material transfers be made with no more restrictive terms than in a Simple Letter Agreement (SLA) at:
http://ott.od.nih.gov/forms_model_agreements/forms_model_agreements.aspx (See "Material Transfer Agreement (MTA)" Section on this page.); for the transfer of materials or the Uniform Biological Material Transfer Agreement (UBMTA) (<http://www.autm.net/aboutTT/> , then search "Implementing Letter")
- How will inappropriate "reach-through" requirements (as discussed in the NIH Research Tools Policy) on materials transferred be discussed?
- How will technologies remain widely available and accessible to the research community, for example, if any intellectual property rights arise for which a patent application may be filed?

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

8. Information and Physical Access 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 BUSINESS PROPOSAL entitled "Information Security."

The Homeland Security Presidential Directive (HSPD)-12 and 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.

A. HHS-Controlled Facilities and Information Systems Security

- a. To perform the work specified herein, Contractor personnel are expected to have routine (1) physical access to an HHS-controlled facility; (2) physical access to an HHS-controlled information system; (3) access to sensitive HHS data or information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

- b. To gain routine physical access to an HHS-controlled information system, and/or access to sensitive data or information, the Contractor and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; Office of Management and Budget Memorandum (M-05-24); and Federal Information Processing Standards Publication (FIPS PUB) Number 201; and with the personal identity verification and investigations procedures contained in the following documents:
 1. HHS Information Security Program Policy (<http://www.hhs.gov/read/irmpolicy/121504.html>)
 2. HHS Office of Security and Drug Testing, Personnel Security/Suitability Handbook, dated February 1, 2005 (<http://www.hhs.gov/ohr/manual/pssh.pdf>)
 3. HHS HSPD-12 Policy Document, v. 2.0 (<http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-24.pdf>)
 4. Information regarding background checks/badges (<http://idbadge.nih.gov/background/index.asp>)

- c. Position Sensitivity Levels:

This contract will entail the following position sensitivity levels:

Level 6: Public Trust - High Risk. Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).

Level 5: Public Trust - Moderate Risk. Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

Level 1: Non-Sensitive. Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

- d. The personnel investigation procedures for Contractor personnel require that (upon award) the Contractor prepare and submit background check/investigation forms based on the type of investigation required. The minimum Government investigation for a non-sensitive position is a National Agency Check and Inquiries (NACI) with

fingerprinting. More restricted positions - i.e., those above non-sensitive, require more extensive documentation and investigation.

As part of its proposal, and if the anticipated position sensitivity levels are specified in paragraph (d) above, the Offeror shall notify the Contracting Officer of (1) its proposed personnel who will be subject to a background check/investigation and (2) whether any of its proposed personnel who will work under the contract have previously been the subject of national agency checks or background investigations.

Upon award, the Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access and/or maintain a Federal Information System(s). The roster shall be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, within 14 calendar days after the effective date of the contract. 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://ocio.nih.gov/docs/public/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.

The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.

All contractor and subcontractor employees shall comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract.

Contractors may begin work after the fingerprint check has been completed.

- e. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.
- f. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more than the cost of the additional investigation(s). Accordingly, if position sensitivity levels are specified in paragraph (d) above, the Offeror shall ensure that the employees it proposes for work under this contract/order have a reasonable chance for approval.
- g. The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

- h. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer.
- i. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

B. Standard for Security Configurations, HHSAR 352.239-70, (January 2010)

- a. The Contractor shall configure its computers that contain HHS data with the applicable Federal Desktop Core Configuration (FDCC) (see <http://nvd.nist.gov/fdcc/index.cfm>) and ensure that its computers have and maintain the latest operating system patch level and anti-virus software level.

Note: FDCC is applicable to all computing systems using Windows XPTM and Windows VistaTM, including desktops and laptops - regardless of function - but not including servers.
- b. The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS. The following security configuration requirements apply:
FDCC.
- c. The Contractor shall ensure IT applications operated on behalf of HHS are fully functional and operate correctly on systems configured in accordance with the above configuration requirements. The Contractor shall use Security Content Automation Protocol (SCAP)-validated tools with FDCC Scanner capability to ensure its products operate correctly with FDCC configurations and do not alter FDCC settings - see <http://nvd.nist.gov/validation.cfm>. The Contractor shall test applicable product versions with all relevant and current updates and patches installed. The Contractor shall ensure currently supported versions of information technology products met the latest FDCC major version and subsequent major versions.
- d. The Contractor shall ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.
- e. The Contractor shall ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.
- f. The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (<http://csrc.nist.gov/publications/fips/fips201-1/FIPS-201-1-chng1.pdf>), Homeland Security Presidential Directive 12 (HSPD-12) card readers with the purchase of servers, desktops, and laptops; and (2) comply with FAR Subpart 4.13, Personal Identity Verification.
- g. The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.

C. Standard for Encryption language, HHSAR 352.239-71, (January 2010)

- a. The Contractor shall use Federal Information processing Standard (FIPS) 140-2-compliant encryption (Security) Requirements for Cryptographic Module, as amended) to protect all instances of HHS sensitive information during storage and transmission. (Note: The Government has determined that HHS information under this contract is considered "sensitive" in accordance with FIPS 199, Standards for

Security Categorization of Federal Information and Information Systems, dated February 2004).

- b. The Contractor shall verify that the selected encryption product has been validated under the Cryptographic Module Validation Program (see <http://csrc.nist.gov/cryptval/>) to confirm compliance with FIPS 140-2 (as amended). The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer's Technical Representative.
- c. The Contractor shall use the Key Management Key (see FIPS 201, Chapter 4, as amended) on the HHS personal identification verification (PIV) card; or alternatively, the Contractor shall establish and use a key recovery mechanism to ensure the ability for authorized personnel to decrypt and recover all encrypted information (see <http://csrc.nist.gov/drivers/documents/ombencryption-guidance.pdf>). The Contractor shall notify the Contracting Officer and the Contracting Officer's Technical Representative of personnel authorized to decrypt and recover all encrypted information.
- d. The Contractor shall securely generate and manage encryption keys to prevent unauthorized decryption of information in accordance with FIPS 140-2 (as amended).
- e. The Contractor shall ensure that this standard is incorporated into the Contractor's property management/control system or establish a separate procedure to account for all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive HHS information.
- f. The Contractor shall ensure that its subcontractors (all all tiers) which perform work under this contract comply with the requirements contained in this clause.

D. Security Requirements For Federal Information Technology Resources, HHSAR 352.239-72, (January 2010)

- a. **Applicability.** This clause applies whether the entire contract or order (hereafter "contract"), or portion thereof, includes information technology resources or services in which the Contractor has physical or logical (electronic) access to, or operates a Department of Health and Human Services (HHS) system containing, information that directly supports HHS' mission. The term "information technology (IT)", as used in this clause, includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services) and related resources. This clause does not apply to national security systems as defined in FISMA.
- b. **Contractor responsibilities.** The Contractor is responsible for the following:
 - 1. Protecting Federal information and Federal information systems in order to ensure their -
 - a. Integrity, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;
 - b. Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and
 - c. Availability, which means ensuring timely and reliable access to and use of information.

2. Providing security of any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor, regardless of location, on behalf of HHS.
 3. Adopting, and implementing, at a minimum, the policies, procedures, controls and standards of the HHS Information Security Program to ensure the integrity, confidentiality, and availability of Federal information and Federal information systems for which the Contractor is responsible under this contract or to which it may otherwise have access under this contract. The HHS Information Security Program is outlined in the HHS Information Security Program Policy, which is available on the HHS Office of the Chief Information Officer's (OCIO) Web site.
- c. **Contractor security deliverables.** In accordance with the timeframes specified, the Contractor shall prepare and submit the following security documents to the Contracting Officer for review, comment, and acceptance:
1. **IT Security Plan (IT-SP)** - due within 30 days after contract award. The IT-SP shall be consistent with, and further detail the approach to, IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The IT-SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT-SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT-SP applies.
 - a. The Contractor's IT-SP shall comply with applicable Federal laws that include, but are not limited to, the Federal Information Security Management Act (FISMA) of 2002 (Title III of the E-Government Act of 2002, Public Law 107-347), and the following Federal and HHS policies and procedures:
 - i. Office of Management and Budget (OMB) Circular A-130, Management of Federal Information Resources, Appendix III, Security of Federal Automation Information Resources.
 - ii. National Institutes of Standards and Technology (NIST) Special Publication (SP) 800-18, Guide for Developing Security Plans for Information Systems, in form and content, and with any pertinent contract Statement of Work/Performance Work Statement (SOW/PWS) requirements. The IT-SP shall identify and document appropriate IT security controls consistent with the sensitivity of the information and the requirements of Federal Information Processing Standard (FIPS) 200, Recommend Security Controls for Federal Information Systems. The Contractor shall review and update the IT-SP in accordance with NIST SP 800-26, Security Self-Assessment Guide for Information Technology Systems and FIPS 200, on an annual basis.
 - iii. HHS-OCIO Information Systems Security and Privacy Policy.
 2. **IT Risk Assessment (IT-RA)** - due within 30 days after contract award. The IT-RA shall be consistent, in form and content, with NIST SP 800-30, Risk Management Guide for Information Technology Systems, and any additions or augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy. After resolution of any comments provided by the Government on the draft IT-RA, the Contracting Officer shall accept the IT-RA and incorporate the Contractor's final version into the contract for Contractor

implementation and maintenance. The Contractor shall update the IT-RA on an annual basis.

3. **FIPS 199 Standards for Security Categorization of Federal Information and Information Systems Assessment (FIPS 199 Assessment)** - due within 30 days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard. After resolution of any comments by the Government on the draft FIPS 199 Assessment, the Contracting Officer shall accept the FIPS 199 Assessment and incorporate the Contractor's final version into the contract.
4. **IT Security Certification and Accreditation (IT-SC&A)** - due within 3 months after contract award. The Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed for applicable information systems - see paragraph (a) of this clause. The Contractor shall perform the IT-SC&A in accordance with the HHS Chief Information Security Officer's Certification and Accreditation Checklist; NIST SP 800-37, Guide for the Security, Certification and Accreditation of Federal Information Systems; and NIST 800-53, Recommended Security Controls for Federal Information Systems. An authorized senior management official shall sign the draft IT-SC&A and provided it to the Contracting Officer for review, comment, and acceptance.
 - a. After resolution of any comments provided by the Government on the draft IT SC&A, the Contracting Officer shall accept the IT-SC&A and incorporate the Contractor's final version into the contract as a compliance requirement.
 - b. The Contractor shall also perform an annual security control assessment and provide to the Contracting Officer verification that the IT-SC&A remains valid. Evidence of a valid system accreditation includes written results of:
 - i. Annual testing of the system contingency plan; and
 - ii. The performance of security control testing and evaluation.
- d. **Personal identity verification.** The Contractor shall identify its employees with access to systems operated by the Contractor for HHS or connected to HHS systems and networks. The Contracting Officer's Representative (COR) shall identify, for those identified employees, position sensitivity levels that are commensurate with the responsibilities and risks associated with their assigned positions. The Contractor shall comply with the HSPD-12 requirements contained in "HHS-Controlled Facilities and Information Systems Security" requirements specified in the SOW/PWS of this contract.
- e. **Contractor and subcontractor employee training.** The Contractor shall ensure that its employees, and those of its subcontractors, performing under this contract complete HHS-furnished initial and refresher security and privacy education and awareness training before being granted access to systems operated by the Contractor on behalf of HHS or access to HHS systems and networks. The Contractor shall provide documentation to the COR evidencing that Contractor employees have completed the required training.
- f. **Government access for IT inspection.** The Contractor shall afford the Government access to the Contractor's and subcontractors' facilities, installations, operations, documentation, databases, and personnel used in performance of this contract to the extent required to carry out a program of IT inspection (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to

the integrity, confidentiality, and availability, of HHS data or to the protection of information systems operated on behalf of HHS.

- g. **Subcontracts.** The Contractor shall incorporate the substance of this clause in all subcontracts that require protection of Federal information and Federal information systems as described in paragraph (a) of this clause, including those subcontracts that -
 - a. Have physical or electronic access to HHS' computer systems, networks, or IT infrastructure; or
 - b. Use information systems to generate, store, process, or exchange data with HHS or on behalf of HHS, regardless of whether the data resides on a HHS or the Contractor's information system.
- h. **Contractor employment notice.** The Contractor shall immediately notify the Contracting Officer when an employee either begins or terminates employment (or is no longer assigned to the HHS project under this contract), if that employee has, or had, access to HHS information systems or data.
- i. **Document information.** The Contractor shall contact the Contracting Officer for any documents, information, or forms necessary to comply with the requirements of this clause.
- j. **Contractor responsibilities upon physical completion of the contract.** The Contractor shall return all HHS information and IT resources provided to the Contractor during contract performance and certify that all HHS information has been purged from Contractor-owned systems used in contract performance.
- k. **Failure to comply.** Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause shall be grounds for the Contracting Officer to terminate this contract.

(End of Clause)

Note: The NIST Special Publication SP-800-26 cited in subparagraph c.1.a.(ii) of this clause has been superseded by NIST SP 800-53A, "Guide for Assessing the Security Controls in Federal Information Systems and Organizations" for use for the assessment of security control effectiveness. See <http://csrc.nist.gov/publications/PubsSPs.html> to access NIST Special Publications (800 Series).

E. Additional NIH Requirements

1. SECURITY CATEGORIZATION OF FEDERAL INFORMATION AND INFORMATION SYSTEMS (FIPS 199 Assessment)

a. Information Type:

Administrative, Management and Support Information:

Mission Based Information:

The Contractor will be required to report study data and results of animals studies to the COR by email and electronic submission of data files.

b. Security Categories and Levels:

Confidentiality Level: Low Moderate High
 Integrity Level: Low Moderate High
 Availability Level: Low Moderate High
Overall Level: **Low** **Moderate** **High**

- c. In accordance with HHSAR Clause 352.239-72, the contractor shall submit a FIPS 199 Assessment within 30 days after contract award. Any differences between the contractor's assessment and the information contained herein, will be resolved, and if required, the contract will be modified to incorporate the final FIPS 199 Assessment.

2. INFORMATION SECURITY TRAINING

In addition to any training covered under paragraph (e) of HHSAR 352.239-72, the contractor shall comply with the below training:

a. Mandatory Training

- i. All Contractor employees having access to (1) Federal information or a Federal information system or (2) sensitive data/information as defined at HHSAR 304.1300(a)(4), shall complete the NIH Computer Security Awareness Training course at <http://irtsectraining.nih.gov/> before performing any work under this contract. Thereafter, Contractor employees having access to the information identified above shall complete an annual NIH-specified refresher course during the life of this contract. The Contractor shall also ensure subcontractor compliance with this training requirement.
- ii. The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working on this contract and having access of the kind in paragraph 1.a(1) above, who has completed the NIH required training. Any additional security training completed by the Contractor/Subcontractor staff shall be included on this listing. The list shall be provided to the COR and/or Contracting Officer upon request.

b. Role-based Training

HHS requires role-based training when responsibilities associated with a given role or position, could, upon execution, have the potential to adversely impact the security posture of one or more HHS systems. Read further guidance at [Secure One HHS Memorandum on Role-Based Training Requirement](#).

For additional information see the following: <http://ocio.nih.gov/security/security-communicating.htm#RoleBased>.

The Contractor shall maintain a list of all information security training completed by each contractor/subcontractor employee working under this contract. The list shall be provided to the COR and/or Contracting Officer upon request.

c. Rules of Behavior

The Contractor shall ensure that all employees, including subcontractor employees, comply with the NIH Information Technology General Rules of Behavior (<http://ocio.nih.gov/security/nihitrob.html>), which are contained in the NIH Information Security Awareness Training Course <http://irtsectraining.nih.gov>.

3. PERSONNEL SECURITY RESPONSIBILITIES

In addition to any personnel security responsibilities covered under HHSAR 352.239-72, the contractor shall comply with the below personnel security responsibilities:

- a. In accordance with Paragraph (h) of HHSAR 352.239-72, the Contractor shall notify the Contracting officer and the COR **within five working days** before a new employee assumes a position that requires access to HHS information systems or data, or when an employee with such access stops working on this contract. The Government will initiate a background investigation on new employees assuming a position that requires access to HHS information systems or data, and will stop pending background investigations for employees that no longer work under the contract or no longer have such access.
- b. **New contractor employees who have or will have access to HHS information systems or data:** The Contractor shall provide the COR with the name, position title, e-mail address, and phone number of all new contract employees working under the contract and provide the name, position title and position sensitivity level held by the former incumbent. If an employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate position sensitivity level.
- c. **Departing contractor employees:** The Contractor shall provide the COR with the name, position title, and position sensitivity level held by or pending for departing employees. The Contractor shall perform and document the actions identified in the Contractor Employee Separation Checklist (<http://ocio.nih.gov/nihsecurity/Emp-sep-checklist.pdf>) when a Contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the COR upon request.
- d. **Commitment to Protect Non-Public Departmental Information and Data.**

The Contractor, and any subcontractors performing under this contract, 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)

Each employee, including subcontractors, having access to non-public Department information under this acquisition shall complete the

"Commitment to Protect Non-Public Information - Contractor Employee Agreement" located at: <http://ocio.nih.gov/docs/public/Nondisclosure.pdf>. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer/COR prior to performing any work under this acquisition.

9. **Electronic and Information Technology Accessibility, Section 508 Compliance** 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, "Section 508 Compliance."

Electronic and Information Technology Accessibility, HHSAR 352.239-73(a) (January 2010)

- a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that, unless an exception applies, all EIT products and services developed, acquired, maintained, or used by any Federal department or agency permit--
 - i. Federal employees with disabilities to have access to and use information and data that is comparable to the access and use of information and data by Federal employees who are not individuals with disabilities; and
 - ii. Members of the public with disabilities seeking information or services from a Federal agency to have access to and use of information and data that is comparable to the access and use of information and data by members of the public who are not individuals with disabilities.
- b. Accordingly, any vendor submitting a proposal/quotations/bid in response to this solicitation must demonstrate compliance with the established EIT accessibility standards. Information about Section 508 visions is available at <http://www.section508.gov/>. The complete text of Section 508 Final Provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm>.
- c. The Section 508 accessibility standards applicable to this solicitation are identified in the Statement of Work/Specification/Performance Work Statement. In order to facilitate the Government's evaluation to determine whether EIT products and services proposed meet applicable Section 508 accessibility standards, offerors must prepare an HHS Section 508 Product Assessment Template, in accordance with its completion instructions, and provide a binding statement of conformance. The purpose of the template is to assist HHS acquisition and program officials in determining that EIT products and services proposed support applicable Section 508 accessibility standards. The template allows vendors or developers to self-evaluate their products or services and document in detail how they do or do not conform to a specific Section 508 standard. Instructions for preparing the HHS Section 508 Product Evaluation Template may be found under Section 508 policy on the HHS Office on Disability Web site (<http://www.hhs.gov/od/>).
- d. Respondents to this solicitation must also provide any additional detailed information necessary for determining applicable Section 508 standards conformance, as well as for documenting EIT products or services that are incidental to the project, which would constitute an exception to Section 508 requirements. If a vendor claims its products or services, including EIT deliverables such as electronic documents and reports, meet applicable Section 508 accessibility standards

in its completed HHS Section 508 Product Assessment Template, and it is later determined by the Government -- i.e., after award of a contract/order, that products or services delivered do not conform to the described accessibility standards in the Product Assessment Template, remediation of the products or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor and at its expense.

(End of provision)

The "HHS Section 508 Product Assessment Template" is included in SECTION J - List of Attachments, of this solicitation.

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 certified cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not required to be certified in accordance with FAR 15.406-2.

3. **Data Other than Certified Cost or Pricing Data**

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

Data submitted must support the price proposed. The offeror shall include sufficient detail or cross references to clearly establish the relationship of the data provided to the price proposed. The offeror shall support any data provided with explanations or supporting rationale, as needed, to permit the Contracting Officer and authorized representative to evaluate the documentation.

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

a. **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.

b. **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.).

c. **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 \$650,000, 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.

d. **Raw Materials**

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

e. **Purchased Parts**

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

f. **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.

g. **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.

h. **Special Equipment**

If direct charge, list any equipment in accordance with Item (13) Other Administrative Data, subparagraph (2) Government Property of this Section L.2.c of this solicitation.

i. **Travel**

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

j. Other Costs

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

4. Requirements for Certified Cost or Pricing Data and Data Other than Certified Cost or Pricing Data, FAR Clause 52.215-20 (October 2010)

(a) Exceptions from certified cost or pricing data.

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

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

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

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

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

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

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

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

(1) The offeror shall prepare and submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in accordance with the instructions contained in Table 15-2 of FAR 15.408, which is incorporated by reference with the same force and effect as though it were inserted here in full text. The instructions in Table 15-2 are incorporated as a mandatory format to be used in this contract, unless

the Contracting Officer and the Contractor agree to a different format and change this clause to use Alternate I.

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

(End of provision)

5. Salary Rate Limitation in Fiscal Year 2012

Offerors are advised that pursuant to P.L. 112-74, no NIH Fiscal Year 2012 (October 1, 2011 - September 30, 2012) 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 II* (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 II*. The salary rate limitation set by P.L 112-74 applies only to Fiscal Year 2012 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 II* annual salary rate limitation also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L.112-74 states:

"None of the funds appropriated in this title 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 II."

LINK TO EXECUTIVE SCHEDULE RATES OF PAY: <http://www.opm.gov/oca/>

(For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

***Note to Offerors:** The current Fiscal Year Executive Level II Salary Rate shall 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 Executive Level II Salary rates.

6. Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of \$650,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

- a. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
- b. The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This

includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c. The offeror understands that:

1. No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
2. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
3. If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.
4. Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.
5. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.
6. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d. Each plan must contain the following:

1. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
2. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
3. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.
4. A description of the method used to develop the subcontracting goals.
5. A description of the method used to identify potential sources for solicitation purposes.
6. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged,

Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

7. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
8. A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
9. Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of \$650,000 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 (Individual Subcontract Reports (ISRs) and Summary Subcontract Reports (SSRs) 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 in the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

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

28% for Small Business; 5% for Small Disadvantaged Business; 5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

7. Mentor-Protégé Program, HHSAR 352.219-70 (January 2010)

- a. Large business prime contractors serving as mentors in the HHS Mentor-Protégé program are eligible for HHS subcontracting plan credit, and shall submit a copy of their HHS Office of Small and Disadvantaged Business Utilization (OSDBU)-approved mentor protégé agreements as part of their offers. The amount of credit provided by the Contracting Officer to a mentor firm for protégé firm developmental assistance costs shall be calculated on a dollar for dollar basis and reported by the mentor firm in the Summary Subcontract Report via the Electronic Subcontracting Reporting System (eSRS) at <http://www.esrs.gov>. The mentor firm and protégé firm shall submit to the Contracting Officer a signed joint statement agreeing on the dollar value of the developmental assistance the mentor firm provided. (For example, a mentor firm would report a \$10,000 subcontract awarded to a protégé firm and provision of \$5,000 of developmental assistance as \$15,000 of developmental assistance.) The mentor firm may use this additional credit towards attaining its subcontracting plan participation goal under this contract.
- b. The program consists of--
 - i. Mentor firms--large businesses that: (i) demonstrate the interest, commitment, and capability to provide developmental assistance to small business protégé firms; and (ii) have a Mentor-Protégé agreement approved by HHS' OSDBU;
 - ii. Protégé firms--firms that: (i) seek developmental assistance; (ii) qualify as small businesses, veteran-owned small businesses, service-disabled veteran-owned small

businesses, HUBZone small businesses, small disadvantaged businesses, or woman-owned businesses; and (iii) have a Mentor-Protégé agreement approved by HHS' OSDDBU; and

- iii. Mentor-Protégé agreements--joint agreements, approved by HHS' OSDDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.

(End of provision)

8. 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>.

9. 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 Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed \$650,000 (\$1.5 million 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 in Section M - Evaluation Factors for Award 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) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: <http://www.sba.gov/size>

The Department of Commerce website for the annual determination for NAICS codes* is: <http://www.acquisition.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 Industry Subsector(s). The applicable authorized NAICS Industry 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 Industry 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.

10. Total Compensation Plan

a. Instructions

1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors as a part of their Business Proposal will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.
2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

b. Evaluation

1. Total Compensation Plan (Professional Employees)

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for

the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

2. Cost (Professional Compensation)

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

3. Other (Labor Relations)

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

4. Federal Acquisition Regulation Clauses incorporated by Reference

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees.

11. Other Administrative Data

a. Property

1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the Contracting Officer. If the offeror requests that Government property be provided, other than that specified under "Government Furnished Property," below, the proposal must include a comprehensive justification addressing the following items:

- a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.
- b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

2. Government Property

The offeror shall identify Government property in its possession which it proposes to use in the performance of the prospective contract as follows:

- a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);

- b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;
- c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and
- d. A description of the offeror's property management system, plan, and any customary commercial practices, voluntary consensus standards, or industry-leading practices and standards to be used in the offeror in managing Government property.

NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from an offeror or contractor possessing Government property. This will be done by adjusting the offers by applying, for evaluation purposes only, a rental equivalent evaluation factor, as specified in FAR 52.245-9.

3. Government-Furnished Property

A Listing of Government Furnished Property is provided in Section J - Solicitation Attachments of this solicitation

- 4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, "HHS Contracting Guide for Contract of Government Property," which can be found at: http://www.hhs.gov/hhsmanuals/logisticsmanual/Appendix Q_HHS Contracting Guide.pdf

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

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

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

(End of Provision)

c. Financial Capacity

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

d. Adequate Accounting System

FAR Part 16 sets forth the requirements and limitations for consideration of contract type. As stated in Section L.1., General Instructions of this solicitation, the resultant contract will not be Firm-Fixed Price. Therefore, the offeror's/contractor's accounting system and practices must be adequate and suitable for accumulating costs under government contracts.

To be considered for an award under this solicitation, the offeror shall include, in the Business Proposal, the following Certification:

"By submission of its signed offer, the Offeror certifies that its accounting system:

- Complies with generally accepted accounting principles (GAAP).
- Provides for:
 - Proper segregation of direct costs from indirect costs.
 - Identification and accumulation of direct costs by contract.
 - A logical and consistent method for the allocation of indirect costs to intermediate and final cost objectives.
 - Accumulation of costs under general ledger control.
 - A timekeeping system that identifies employees' labor by intermediate or final cost objectives.
 - A labor distribution system that charges direct and indirect labor to the appropriate cost objectives.
 - Interim (at least monthly) determination of costs charged to a contract through routine posting of books of account.
 - Exclusion from costs charged to government contracts of amounts that are not allowable in terms of FAR 31, "Contract Cost Principles and Procedures," or other contract provisions.
 - Identification of costs by contract line item and by units (as if each unit or line item were a separate contract) if required by the proposed contract.
 - Segregation of preproduction costs from production costs, if applicable.
- Accounting system provides financial information:
 - Required by contract clauses concerning limitation of cost (FAR 52.232-20 and 21) or limitation on payments (FAR 52.216-16).
 - Required to support requests for progress payments.
- Accounting system was designed, and records are maintained in such a manner that adequate, reliable data are developed for use in pricing follow-on acquisitions.

- Accounting system is currently in full operation.

The Contracting Officer reserves the right to request, with the Final Proposal Revision (FPR), a current (within 18 months) CPA opinion confirming that the Offeror's accounting system is compliant as certified above.

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

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

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

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

(End of Provision)

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

Fac Cap Cost of Money (Has) 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).

Fac Cap Cost of Money (Has Not) **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.

12. **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.

13. 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>

14. Proposer's Annual Financial Report

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

15. Travel Costs/Travel Policy

a. Travel Costs - Commercial

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

b. Travel Policy

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

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against 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. The Government intends 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 factors listed below.

2. COST/PRICE EVALUATION

Offeror(s) cost/price proposal will be evaluated for reasonableness. For a price to be reasonable, it must represent a price to the government that a prudent person would pay when consideration is given to prices in the market. Normally, price reasonableness is established through adequate price competition, but may also be determined through cost and price analysis techniques as described in FAR 15.404.

Cost Realism: The specific elements of each offeror(s) proposed costs are realistic when the proposed cost elements are evaluated and found to: 1) be realistic for the work to be performed; 2) reflect a clear understanding of the requirements; and 3) be consistent with the unique methods of performance and materials described in the offeror(s) technical proposal.

Cost Realism will be evaluated only on the offeror(s) inputs which the Government will use to determine the most probable cost to perform the contract in a manner consistent with the offeror's proposal. Cost realism analysis will be conducted in accordance with FAR 15.404-1(d). The result of the cost realism analysis will be considered in the making the best value tradeoff decision.]

3. LIVE VERTEBRATE ANIMALS EVALUATION

The offerors proposal must include, as a separate section of the Technical Proposal titled "Vertebrate Animal Section," (VAS) a complete, concise (no more than 1-2 pages) description addressing the following five points. (See NIH Guide Notice NOT-OD-10-049 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-049.html>):

- a. Detailed description of the proposed use of the animals, including species, strains, ages, sex and number to be used.
- b. Justification for the use of animals, choice of species, and numbers to be used.
- c. Information on the veterinary care of the animals.
- d. Description of procedures for minimizing discomfort, distress, pain and injury.
- e. Method of euthanasia and the reasons for the selection.

As part of the overall technical evaluation of proposals, the reviewers will consider the acceptability of the offeror's description in the VAS of the technical proposal. The discussion of all five points will be addressed and evaluated. Based on the evaluation of this Section, the VAS may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the description addressing each of the five points, or no discussion can be

found regarding the VAS), or "acceptable." If the reviewers find that this Section of the technical proposal is "unacceptable" they will provide a narrative supporting their findings.

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

4. 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.

5. 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.

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

The offeror's proposal must address the plans for sharing model organisms, OR state appropriate reasons why such sharing is restricted or not possible. Offerors must also address as part of the sharing plan if, or how, they will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. The discussion areas regarding intellectual property outlined in Section L should be addressed.

If your proposal does not include a plan, appropriate reasons for restricting sharing, or, if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your plan for sharing model organisms during discussions and in your Final Proposal Revision (FPR). If your plan for sharing model organisms is still considered "unacceptable," or your justification for restricting sharing is still considered inappropriate by the Government after discussions, your proposal may not be considered further for award.

7. TECHNICAL EVALUATION FACTORS

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

CRITERIA	WEIGHT
CRITERION 1: TECHNICAL APPROACH/UNDERSTANDING THE PROBLEM	50 points
Offerors will be evaluated on the basis of a demonstrated understanding of the objectives and needs of the proposed project in the following areas:	

CRITERIA	WEIGHT
<p>a. <i>In vivo</i> models: Availability, appropriateness, and adequacy of the components of the test systems proposed. The following elements will be considered: virus strains; engrafted immunodeficient mice (SCID-hu Thy/Liv and other), including capability to provide the required numbers (specified in Statement of Work) in groups engrafted with tissue from a single donor; plan for quality assurance/quality control of virus stocks, donor tissues, and engrafted immunodeficient mice; spectrum of agents and strategies that can be tested in the model; potential of the model to identify therapies useful for humans infected with HIV-1. (15 points)</p> <p>b. Experimental design: <i>in vivo</i> models. Scientific and technical adequacy and feasibility of the proposed experimental design and methodologies for quantifying efficacy and toxicity of candidate therapies. (15 points)</p> <p>c. <i>In vitro</i> test system: Scientific and technical adequacy and appropriateness of components of the test system and the methodologies proposed for quantifying efficacy and cytotoxicity. (10 points)</p> <p>d. Model development: Scientific and technical potential of the humanized mouse models to be modified to enhance their usefulness in the evaluation of therapies. Scoring will be based on the requested discussion of how the Offeror could further extend or adapt the proposed models or adapt other humanized mouse models for testing potential therapeutics. (10 points)</p>	
CRITERION 2: SCIENTIFIC AND TECHNICAL PERSONNEL	45 points
<p>a. Principal Investigator: Quality of recent work and relevance to the proposed contract; demonstrated scientific leadership in the area of animal models of HIV-1 infection; experience using the SCID-hu Thy/Liv and other humanized mouse models for evaluating HIV-1 therapies; his/her time availability for the proposed work; documented participation in similar projects; and demonstrated ability to coordinate a team effort. (20 points)</p> <p>b. Other professional, technical, and support staff: Spectrum of expertise offered, qualifications, and experience performing the manipulations required in the requested mouse models and in evaluating HIV-1 therapies <i>in vitro</i> and in the models, and availability; documented capability to conduct proposed studies. (20 points)</p> <p>c. Administrative support: Qualifications and experience managing federal contracts (5 points)</p>	
CRITERION 3: ORGANIZATIONAL STRUCTURE, FACILITIES, AND RESOURCES	10 points
<p>a. Adequacy and appropriateness of lines of authority and responsibility</p> <p>b. Adequacy, suitability, and availability of all necessary facilities, equipment, and resources to conduct all the tasks in the Work Statement; adequacy of the organization's Safety and Health Plan</p>	
TOTAL WEIGHT	105 points

8. EVALUATION OF ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY - SECTION 508

The offeror's proposal must demonstrate compliance with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194 for all electronic and information technology (EIT)

products and services developed, acquired, maintained, or used under this contract/order, including EIT deliverables such as electronic documents and reports.

If your proposal does not include a completed HHS "Section 508 Product Assessment Template" (hereafter referred to as the "Template") which demonstrates that EIT products and services proposed support applicable Section 508 accessibility standards, or, if the completed "Template" included in your proposal is considered "noncompliant," 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 the "Template" during discussions and in your Final Proposal Revision (FPR). If your "Template" is still considered "noncompliant" by the Government after discussions, your proposal may not be considered further for award.

9. PAST PERFORMANCE FACTOR

Offeror's past performance information will be evaluated subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

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.

10. 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.

**ATTACHMENT 1: PACKAGING AND DELIVERY OF THE PROPOSAL
HUMANIZED MOUSE MODELS FOR HIV THERAPEUTICS DEVELOPMENT
RFP-NIAID-DAIDS-NIHAI2012153**

I. PROPOSAL SUBMISSION

A. The National Institute of Allergy and Infectious Diseases (NIAID) currently requires proposals to be submitted in three methods:

1. Paper
2. Disc (CD or DVD)
3. Online

Notes:

- *The paper copy is the official copy for recording timely receipt of proposals. Submission of proposals by facsimile or e-mail is not acceptable.*
- *Paper, disc, and online proposals must be exactly the same.*

II. PAPER COPIES and DISCS (i.e., CD or DVD)

A. Delivery Instructions:

If Hand Delivery or Express Service	If using U.S. Postal Service
Dena Nannetti Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20817	Dena Nannetti Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612

1. Mark each package with the following items:

The solicitation number: NIAID-DAIDS-NIHAI2012153
**“TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL
 ONLY”**

2. All material sent to this office by courier should be sent to the Hand Delivery or Express Service address.
3. The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. The Government is not responsible for picking up any mail at a local post office.

4. Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated above by the date and time specified in the solicitation. If your proposal is not received by the date and time specified in the solicitation, it will be considered a “late proposal”, in accordance with **FAR Clause 52.215-1 Instructions to Offerors – Competitive Acquisition**.

B. Discs – Creating and Naming Files:

1. Create one PDF file of your Technical Proposal, including all attachments. The Technical Proposal should be created in a PDF format that enables word searches to the maximum extent practicable. Forms and/or documents requiring signature(s) may be scanned, but must be merged into the Technical Proposal PDF file.
2. The Business Proposal must be comprised of the following two files:
 - a. The first file must be a PDF of your Business Proposal, with all attachments, including the Solicitation Section J, Attachment entitled “[Breakdown of Proposed Estimated Costs \(plus Fee\) with Excel Spreadsheet](#).” The Business Proposal should be created in a PDF format that enables word searches to the maximum extent practicable. Forms and/or documents requiring signature(s) may be scanned and merged into the Business Proposal PDF file.
 - b. The second file must be the “Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet” in its original Excel format, not PDF.
3. A separate Disc must be submitted for the Technical Proposal and Business Proposal. *Offerors who submit both Technical and Business Proposals on the same Disc will be required to resubmit the proposals on separate Discs.*
4. Each of the proposals, Technical and Business, must be separate and complete in itself, so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other.
5. **File naming convention:** It is required that the filenames for both your Technical Proposal, Business Proposal, and Excel Workbook include the name of the offeror, the solicitation number, and the type of proposal (i.e., Technical, Business, or Excel Workbook).

Examples:

Technical Proposal: *XYZ Company_NIHAI2012001_Technical.pdf*

Business Proposal: *XYZ Company_NIHAI2012001_Business.pdf*

Excel Workbook: *XYZ Company_NIHAI2012001_Business.xlsx*

III. ONLINE SUBMISSION OF ELECTRONIC PROPOSALS

Note: *In addition to paper copies and discs, offerors are required to submit an electronic copy of proposals online through the NIAID electronic Contract Proposal Submission (eCPS) website at: <https://ecps.niaid.nih.gov>*

A. eCPS PROPOSAL SUBMISSION PROCESS

1. Internet access and an email-address are required.
2. An NIH eRA Commons account is required.
3. If you do not already have an eRA Commons account, your Business Official, or authorized representative designated by your Business Official, must register for an eRA Commons account at least four weeks prior to the proposal due date. The eRA Commons Online Registration is available at <https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp>
4. Log into eCPS with your eRA Commons password and username to upload your proposal at: <https://ecps.niaid.nih.gov>
5. Follow the “*How to Submit an Electronic Proposal*” instructions provided on the eCPS website at <https://ecps.niaid.nih.gov/Home/HowTo>

IV. FORMATTING, NUMBER OF COPIES, AND PAGE LIMITATIONS:

A. Formatting for paper copies, discs, and proposals submitted online through eCPS

1. Proposals shall not include links to internet web site addresses (URLs) or otherwise direct readers to alternate sources of information.
2. Font size must be 10 to 12 points.
3. Spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
4. Print margins must be at least one-inch on each edge of the paper.
5. Print setup shall be double-sided on standard letter size paper (8.5 x 11" in the U.S., A4 in Europe). If the offeror cannot print or copy double-sided, it shall print or copy single-sided on standard letter size paper.
6. **Failure to adhere to the formatting requirements above may impact whether your proposal is reviewed in entirety.**

B. Number of copies and applicable page limitations for paper copies, discs, and proposals submitted online through eCPS

1. Total page count does not include: Title and Back Page; Table of Contents; Section Dividers that do not contain information other than title of Section.
2. Pages that are 2-sided will count as two pages.

3. Pages in excess of this limitation will be removed from the proposal and will not be considered.

NUMBER OF COPIES AND APPLICABLE PAGE LIMITATIONS

Document	Number of Copies	Page Limits
Technical Proposal	<p><u>PAPER</u> One (1) unbound SIGNED ORIGINAL. Two (2) unbound COPIES</p> <p><u>DISC (i.e., CD or DVD)</u> One (1) Disc containing one electronic copy of the Technical Proposal (including all Attachments)</p> <p><u>ONLINE (using the eCPS website)</u> One (1) electronic copy of the Technical Proposal (including all Attachments)</p>	Not to Exceed 150 pages (inclusive of all Attachments)
Business Proposal	<p><u>PAPER</u> One (1) unbound SIGNED ORIGINAL. Two (2) unbound COPIES</p> <p><u>DISC (i.e., CD or DVD)</u> One (1) Disc containing two files, as instructed in section II.B above.</p> <p><u>ONLINE (using the eCPS website)</u> One (1) submission containing two files, as instructed below.</p> <ol style="list-style-type: none"> 1. One (1) electronic PDF copy of the Business Proposal (with all Attachments including the PDF rendering of the <u>Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet</u>). 2. One (1) Electronic Cost Proposal Excel Workbook See Solicitation Section J, Attachment entitled Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet to access the Excel Workbook. Microsoft Excel 2007 version or later is required. 	N/A

ATTACHMENT 2: PROPOSAL INTENT RESPONSE SHEET

**HUMANIZED MOUSE MODELS FOR HIV THERAPEUTICS DEVELOPMENT
RFP-NIAID-DAIDS-NIHAI2012153**

Please review the attached Request for Proposal. Furnish the information requested below and return this page by **February 28, 2013**. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

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

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

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

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

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

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):

(Continue list on a separate page if necessary)

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

Attn: Dena Nannetti, Contract Specialist
RFP No. NIAID- DAIDS-NIHAI2012153
FAX# (301) 480-4675
Email: dena.nannetti@nih.gov

ATTACHMENT 3: STATEMENT OF WORK

HUMANIZED MOUSE MODELS FOR HIV THERAPEUTICS DEVELOPMENT RFP NIAID-DAIDS-NIH-AI2012153

1. INTRODUCTION AND BACKGROUND

The mission of the Division of AIDS (DAIDS) of 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 transmission, pathogenesis, prevention and treatment of the Human Immunodeficiency Virus-1 (HIV-1); supporting the development of therapies for HIV-1 infection and its complications; and supporting the development of vaccines and other prevention strategies.

DAIDS supports a comprehensive portfolio of contract resources to discover and develop novel therapeutic agents for the prevention and treatment of infections caused by HIV-1, AIDS-associated opportunistic pathogens, and other infectious agents. Animal model resources constitute one element of this drug discovery and development program. NIAID initiates the preclinical evaluations of the efficacy and tolerability of novel HIV-1 therapeutics and selects the agents to be tested. The purpose of this solicitation is to re-compete an existing contract for small animal models that can be used to evaluate potential therapeutics for HIV-1 infection.

The current contract was awarded in 2006 to the University of California, San Francisco (contract number HHSN266200700002C) and will expire in December, 2013. The animal model being used is an immunodeficient mouse engrafted with human fetal thymus and liver (severe combined immunodeficiency (SCID)-hu Thy/Liv) and infected with well-characterized isolates of HIV-1. The types of therapeutics tested over the last six years include synthetic and natural agents as well as biologics. Experience with the SCID-hu Thy/Liv model has demonstrated its suitability for the evaluation of potential HIV-1 therapeutics. It is tissue-based, as is HIV-1 infection, and uses HIV-1 as the viral target. This solicitation is seeking proposals for the SCID-hu Thy/Liv model and for a second humanized mouse model. The second mouse model will consist of immunodeficient mice engrafted with human fetal thymus and liver tissue and other cells and/or tissues, such that the model (or mice) has the following characteristics: can be infected by the systemic or mucosal routes, reconstitutes gut-associated and other lymphoid tissues, and develops viremia and disseminated infection in engrafted human tissue. Such engrafted, infected mice should be capable of supporting longitudinal studies of infection. In summary, the present solicitation is for the SCID-hu Thy/Liv model and for an additional humanized mouse model.

Candidate therapeutic agents to be evaluated through this contract include low molecular weight organic molecules, natural products, and biologics. These agents will be provided by or through the NIAID.

2. SCOPE

The scope of the contract for Humanized Mouse Models for HIV Therapeutics Development is to conduct studies *in vitro* and in humanized mouse models, to improve the SCID-hu Thy/Liv and the second model, and to adapt other existing or newly discovered models, all for the purpose of developing novel therapies for HIV-1 disease.

The models shall employ state-of-the-art techniques and technologies for evaluating promising therapies and other interventions for HIV/AIDS.

The major functions of the contract are as follows:

- A. Evaluate potential HIV-1 therapeutics in an *in vitro* model
- B. Evaluate potential HIV-1 therapeutics *in vivo* in humanized mouse models
- C. Maintain quality control/assurance of viral stocks, donor tissue, and reconstituted immunodeficient mice
- D. Improve the SCID-hu Thy/Liv and the second model, and adapt other existing or newly discovered models for use by the contract
- E. Collect, package appropriately, and arrange shipment of samples of animal tissues and/or fluids to another site for analysis
- F. Maintain a safe worksite in accordance with applicable laws and regulations
- G. Manage and report study data and results
- H. Attend meetings and teleconferences
- I. Obtain human fetal tissue
- J. Prepare for transition to a new contractor
- K. Respond to options for extension of term, if exercised

3. TECHNICAL REQUIREMENTS

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

Specifically, the Contractor shall:

A. Evaluate potential HIV-1 therapeutics in an *in vitro* model

Evaluate potential HIV-1 therapeutics, alone and in combination, for efficacy in blocking or reducing HIV-1 replication and for cytotoxicity in an *in vitro* model system of infection.

- 1) Provide an *in vitro* model system that consists of:
 - a. human peripheral blood lymphocytes; and
 - b. a diverse panel of well characterized isolates and molecular clones of HIV-1 that replicate both *in vitro* and in the animal models.
- 2) Perform *in vitro* efficacy and toxicity evaluations. An *in vitro* evaluation shall consist of:
 - a. a dose response, with positive and negative controls;
 - b. a concurrent test for cytotoxicity; and
 - c. statistical analysis of the results.

The Contractor shall perform up to 10 *in vitro* evaluations of single therapies per year and up to 3 evaluations of combination therapies per year. The *in vitro* system shall be available for efficacy and cytotoxicity testing at the time of award.

B. Evaluate potential HIV-1 therapeutics *in vivo* in humanized mouse models

Evaluate potential HIV-1 therapeutics, alone and in combination, for efficacy and cytotoxicity *in vivo* in humanized mouse models.

1) Provide *in vivo* model systems that consist of:

a. humanized mice (The Contractor shall provide both kinds of humanized mice.)

i. SCID mice engrafted with human fetal thymus and liver tissue (SCID-hu Thy/Liv model).

The Contractor shall provide up to 600 SCID-hu Thy/Liv mice and 60 unengrafted SCID mice per year for evaluations of single and combination therapies. One cohort of up to 50 SCID-hu Thy/Liv mice per month, engrafted with tissue from a single donor, shall be available for evaluations. The *in vivo* system shall be available for efficacy and toxicity testing at the time of award.

ii. immunodeficient mice engrafted with human fetal thymus and liver tissue and other cells and/or tissues, such that the model (or mice) has the following characteristics: reconstitutes gut-associated lymphoid tissue, can be infected by the systemic or mucosal routes, and develops viremia and disseminated infection in engrafted human tissue. Such engrafted, infected mice should be capable of supporting longitudinal studies of infection.

The Contractor shall provide up to 480 engrafted immunodeficient mice and 50 unengrafted mice per year for evaluations of single and combination therapies. One cohort of up to 40 mice per month, engrafted with tissue from a single donor, shall be available for evaluations. The *in vivo* system shall be available for efficacy and toxicity testing at the time of award.

b. a diverse panel of well characterized isolates and molecular clones of HIV-1 that replicate both *in vitro* and in the animal models. The viruses that comprise the panel shall represent a spectrum with regard to replication kinetics and ability to cause pathogenic effects in the humanized mouse system.

2) Perform evaluations in the mouse models. An *in vivo* evaluation shall consist of:

a. preparation of a draft protocol, including the study design [route and timing of drug administration, number of dosages and of animals per group, measures of toxicity and/or efficacy to be studied, and other elements as specified by the Contracting Officer's Representative (COR)], for written approval by the COR, at least one week before initiation of the evaluation;

b. administration of therapeutic agents supplied by the COR;

- c. quantitative determinations of effects of the therapy on virus replication in the thymus organoid;
- d. quantitative determinations of effects of the therapy on thymocyte depletion and subset distribution;
- e. measurements of toxicity (for example, changes in blood chemistries, hematologic measurements such as differential cell counts, body weight, and other indicators of general health). The Contractor shall supply necropsy/pathology support as needed;
- f. pharmacokinetic determinations as warranted by study design. Contractors shall be required only to collect and prepare blood, cell, and tissue samples for shipment to another site for analysis; and
- g. data analysis and preparation of study report.

C. Maintain quality control/quality assurance of viral stocks, donor tissue, and reconstituted immunodeficient mice

Ensure the quality of all components of the model, regardless of the source of the component, including viral stocks, donor tissue, engrafted mice, and reference standards.

D. Improve the SCID-hu Thy/Liv and the second model, and adapt other existing or newly discovered models for use by the contract

Modify the *in vivo* models to enhance their usefulness in the evaluation of therapies or interventions to prevent infection or eliminate latent HIV-1; adapt other humanized mouse models and *in vitro* models as specified by the COR.

E. Obtain human fetal tissue

Obtain the necessary human fetal tissues for use under the contract, consistently and reliably, and in accordance with all applicable Federal, State, and Local guidelines and regulations regarding the use of human fetal tissues.

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

"Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Optional Form OMB No. 0990-0263 (or a self-designated form) certifying IRB review and approval of the protocol from which the human materials were obtained must be submitted to the COR and Contracting Officer by the contractor/subcontractor before research or collection involving human materials may be conducted under the contract.

F. Collect, package appropriately, and arrange shipment of samples of animal tissues and/or fluids to another site for analysis

G. Maintain a safe worksite in accordance with applicable laws and regulations

Maintain a safe worksite in accordance with the Safety and Health Clause of this contract, the Contractor's Safety and Health Plan and all applicable Federal, State, and Local health and safety regulations. The Contractor shall possess and follow a Safety and Health Plan for compliance with all relevant Federal, State, and Local guidelines and regulations regarding exposure to hazardous chemicals, drugs and potentially harmful and/or infectious biological materials. The plan shall include procedures and processes for such issues as training and monitoring of personnel, the use of protective garments and equipment by personnel and protocols for dealing with chemical and biological spills and accidents.

H. Manage and report study data and results

- 1) Use an efficient, reliable and secure data management system.
- 2) Report data and results as directed by the COR, including:
 - a. data, SOP's, and other information from animal studies, including clinical data and information about animals, by e-mail and electronic submission of data files, as requested by COR;
 - b. individual reports detailing the results of each completed study. Each report shall be in a format and quality that can be sent to the supplier of the tested material without modification by the COR. These reports shall contain:
 - i. cover page listing:
 - a) contract title and number,
 - b) project title and number,
 - c) contractor's name and address,
 - d) date of submission;
 - ii. summary table of data and graphical representations;
 - iii. introduction describing the study;
 - iv. discussion of materials and methods;
 - v. discussion and interpretation of the results;
 - vi. individual data (body weight, implant weight, p24 values, viral load values etc. for each mouse); and
 - vii. detailed statistics.
- 3) Maintain a cumulative list of drugs or therapies evaluated, with report number and date of study, and provide to COR as requested.
- 4) Maintain a cumulative list of oral presentations and published materials attributable to the contract, and provide to COR as requested.

I. Attend meetings and teleconferences

- 1) Participate in weekly teleconferences with the COR.
- 2) Establish a means of electronic communication with the COR sufficient to support daily exchange of e-mail and the submission of data files and reports to the COR

when requested;

- 3) Provide updates of project status via telephone, fax, or e-mail, as requested by COR;
- 4) Meet with the COR on-site once a year to discuss data and progress.
- 5) Contract Initiation Meeting - Within 60 calendar days after the effective date of the contract, the Contractor shall participate in a Contract Initiation Meeting with the COR, the Contracting Officer (CO) and other NIAID personnel designated by the COR, to be held at the Contractor's site, or by teleconference. The purpose of the Contract Initiation Meeting shall be to orient the Contractor to NIAID contract procedures.

J. Prepare for transition to a new contractor

Ensure an orderly transition of contract-related materials to a successor Contractor or to the Government:

- 1) Submit a draft Final Transition Plan to the COR and the CO six months prior to the expiration date of this contract for approval by the COR. The plan shall provide for the efficient and orderly transition of contract activities and resources to a successor Contractor or to the Government. The plan shall include a brief description of any unfinished projects and a status report on transition or shut down activities. The Contractor shall submit the Final Transition Plan three months prior to the expiration date of the contract to the COR and the CO for approval.
- 2) Deliver all original data and selected contract-purchased Government-titled equipment by the expiration date of this contract to a location(s) specified by the COR. Any unused test materials provided to the Contractor by outside suppliers shall be destroyed or returned to the supplier or NIAID as directed by the COR.
- 3) At the direction of the CO, complete the NIAID approved Final Transition or Close-out Plan by the expiration date of the contract.

K. Respond to options to extend term, if exercised

In addition to the above functions and services to be provided for the Base period, the Government may unilaterally exercise, at its discretion, Options to extend the term of the contract annually, for a total contract period of up to 7 years.

[END OF STATEMENT OF WORK]

ATTACHMENT 4: TECHNICAL PROPOSAL INSTRUCTIONS, FORMAT FOR TECHNICAL PROPOSAL, AND TABLE OF CONTENTS

Humanized Mouse Models for HIV Therapeutics Development RFP NIAID-DAIDS-NIH-AI2012153

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

These additional Technical Proposal instructions reflect the requirements of the RFP and provide specific instructions and formatting for the Technical Proposal. While Section L.2.b. of the RFP provides a generic set of Technical Proposal instructions applicable to all NIH R&D solicitations, these instructions are tailored to the specific requirements of the RFP. The information requested in these instructions should be used to format and prepare the Technical Proposal, and should be used as a Table of Contents for your Technical Proposal. Offerors should follow the instructions in Section L of the solicitation, and include the information requested here.

Offerors are advised to give careful consideration to the Statement of Work (SOW), all reference materials, and attachments, the Technical Evaluation Criteria in Section M, and the RFP as a whole in the development of their Technical Proposals.

Offerors proposing subcontracts to perform portions of the Statement of Work should clearly identify the specific tasks for which they plan to utilize subcontractors, as well as the method and level of integration/coordination between the prime Contractor and all proposed subcontractors, and the expected advantages of such an approach.

Offerors must refer to the RFP Attachment entitled “Packaging and Delivery of the Proposal”, which details strict guidelines, including page limitations, formatting and layout of proposals, and prohibits the offerors use of links to internet web site addresses (URLs) to direct readers to alternate sources of information.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1

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

SECTION 2: TECHNICAL PROPOSAL OVERVIEW (suggested 3-page maximum)

Provide a brief description of the humanized mouse models and proposed project, including:

- 1) A description of the activities to be performed by the Offeror and those that shall be provided by any proposed subcontractors, including the identification of the proposed subcontractors.
- 2) A list of key personnel of the Offeror and of the proposed subcontractors, with degrees and titles.
- 3) A brief description of the facilities, equipment, and other resources to be made available by the Offeror and any proposed subcontractors.

SECTION 3: SCIENTIFIC AND TECHNICAL PERSONNEL

The Technical Proposal should include all information relevant to document individual personnel training, education, experience, qualifications and expertise necessary for the successful completion of all contract requirements.

Proposals should include a Staffing Plan for the conduct of the Statement of Work with role descriptions and level of effort of scientific and technical personnel, including scientific and technical personnel of all proposed subcontractors. Clearly identify who is to be assigned as Key Personnel.

Provide CVs for the PI and scientific staff. Limit CVs to 2-3 pages and provide selected references for publications relevant to the scope of the RFP. Include experience with projects of similar scope, size and complexity carried out by the Offeror and any proposed subcontractors within the past 5 years.

In the Personnel categories below, identify specific expertise, as well as qualifications, experience, and accomplishments related to performing scientific and administrative activities needed for performing or managing contract work.

1) Principal Investigator (PI):

- a) Identify the proposed PI who will be responsible for overall planning, implementation and management of the contract and who will be the key contact for technical aspects of the project. Define the proposed duties of the PI. Indicate the level of effort the PI will commit to the project.
- b) Describe the experience and qualifications of the proposed PI for providing leadership in the planning, managing, directing, and coordinating projects of similar size, scope and complexity.
- c) Describe the experience and technical understanding of the proposed PI regarding the use of SCID-hu Thy/Liv model, especially performing the manipulations necessary for the reconstitution of SCID mice with human tissues and maintaining the essential quality control in the model, as well as performing evaluations of antiviral compounds, immune-based or other therapies; conducting pharmacologic and toxicologic studies; modifying or adapting models; and conducting basic research on the immunopathogenesis of HIV-1; and experience with other immunodeficient mouse models engrafted with human cells and/or tissues.

2) Other Scientific and Technical Personnel:

- a) Identify the proposed scientific personnel (e.g., Project Manager, laboratory technician, collaborator(s), or subcontractor(s)) who will be responsible for conducting the technical aspects of the Statement of Work to accomplish the goals of

the contract. Define the proposed duties of each, and describe the formal education, training, experience, accomplishments, and qualifications of each as related to the conduct of the requirements of the Statement of Work. Indicate the total time each person will commit to the project.

- b) Describe the experience of the proposed personnel in coordinating and conducting the services and work of similar size and scope as defined in the Statement of Work. Include any prior personal experience using the SCID-hu Thy/Liv model, especially performing the manipulations necessary for the reconstitution of SCID mice with human tissues and maintaining the essential quality control in the model, as well as performing evaluations of antiviral compounds, immune-based or other therapies; conducting pharmacologic and toxicologic studies; modifying models or developing new models; and conducting basic research on the immunopathogenesis of HIV-1; and experience with other immunodeficient mouse models engrafted with human cells and/or tissues.

3) Other Personnel:

- a) Identify any administrative personnel who will be responsible for the oversight or tracking of aspects of the project on a day-to-day basis. Describe the qualifications and experience of the personnel. State the estimated time each will spend on the project, and describe the proposed duties of each.
- b) List the names, titles, and proposed duties of additional personnel, if any, who will be required on a consultant or sub-contractor basis. Indicate the technical areas, nature and extent of consultant or subcontractor activity, and specify and justify the anticipated sources of consultant or subcontractor personnel. For all proposed personnel who are not currently members of the Offeror's staff, a letter of commitment is required. The letter is to include the area of expertise provided, the availability and time commitment, and resolution of publication and patent rights among consultants and subcontractors. Inclusion of a CV alone does not meet this requirement.

SECTION 4: TECHNICAL PLAN/APPROACH

The Technical Proposal should include a thorough description of how each aspect of the Statement of Work is to be accomplished, using as much detail as necessary to fully explain the proposed technical approaches and methods to be used and to demonstrate experience in performing the required services and assays and other tasks.

1) Evaluate potential HIV-1 therapeutics in an *in vitro* model

- a) Describe in detail the technical approach for evaluating potential therapies in an *in vitro* model. Provide a sample study design for an *in vitro* test of the efficacy of an experimental agent, including a sufficient range of concentrations to generate dose-response relationships and positive and negative controls. Types of therapeutic agents to be tested include but are not limited to: low molecular weight organic molecules, natural products, and biologics.
- b) Provide a sample study design for the concurrent assay of cytotoxicity.

2) Evaluate potential HIV-1 therapeutics, alone and in combination, for efficacy and toxicity *in vivo*, in the SCID-hu Thy/Liv model

- a) Describe in detail the technical approach for evaluating therapies. Provide a sample study design for assay of therapeutic efficacy of each test candidate, in which multiple dose levels of the test candidate are employed and positive and negative controls are included. Types of agents to be tested include but are not limited to: low molecular weight organic molecules, natural products, and biologics. Include a description of the experimental design (number of arms per study, number of animals per group, number of doses to be explored, potential routes of administration, variables to be measured, etc.) and a description of the methods to be used to carry out evaluations; to assure/control quality of viral stocks, tissue donors, and engrafted mice; and to analyze the data. Provide a rationale for the design, based on statistical considerations, as well as a discussion of potential logistical problems and possible solutions.
- b) Provide a sample study design for concurrent assessment of toxicity in the same animals, or in the absence of preliminary information on toxicity, in uninfected, engrafted mice.
- c) Discuss the types of therapies appropriately evaluated in the model and demonstrate the suitability and feasibility of using the model for those types of studies.
- d) Discuss the process to validate the animal model, by establishing its ability to predict the antiviral activity of agents approved for treatment of HIV-1 disease in humans.

3) Evaluate potential HIV-1 therapeutics, alone and in combination, for efficacy and toxicity *in vivo* in a second, humanized mouse model

Describe the second animal model in detail, including type of mice, engraftment with human tissues, degree of reconstitution of the immune system by human cells, and infection with HIV-1. Describe in detail the technical approach for evaluating therapies, as detailed in 2a above. Describe any experience of the laboratory in using such a model to evaluate antiretroviral therapeutic approaches, and discuss the process to validate the second model, as described in the previous paragraph (2d).

4) Quality assurance/quality control

- a) Describe quality systems for assuring viral stocks, donor tissue, engrafted mice, and reference standards.
- b) Identify the source for fetal human tissues to be used in the model, and document compliance with all applicable NIH policy and federal regulations (Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and <http://grants1.nih.gov/grants/guide/notice-files/not93-235.html> and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice), as well as state and local guidelines and regulations for use of fetal tissue. Provide documentation of successful acquisition of tissue over the past year.

c) Document ability to produce engrafted mice in quantities required for this project.

5) Modify the proposed *in vivo* models to enhance their usefulness in the evaluation of therapies or interventions to prevent infection or eliminate latent HIV-1; adapt other humanized mouse models and *in vitro* models as specified by the COR.

Briefly describe how the proposed *in vivo* models could be modified or further developed to provide additional information about potential effects (positive or negative) of therapies or to extend the spectrum of potential therapies or interventions that could be evaluated in the model.

SECTION 5: FACILITIES, EQUIPMENT AND OTHER RESOURCES

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

- 1) Location and features of facilities, including a floor plan and a list of instrumentation, equipment and resources dedicated to the project for the Offeror and any proposed subcontractors (lease or ownership information should be provided). Indicate what equipment and resources are under the control of the Principal Investigator and which are to be shared; if shared, indicate who is responsible for controlling access and how determination of priority usage is made.
- 2) Identification and description of ALL support resources (including IT systems) which will be required to effectively carry out the required research.

SECTION 6: PROJECT MANAGEMENT

- 1) Describe in detail the responsibilities for all proposed scientific personnel who will be assigned to the contract, including proposed subcontractors and consultants. Describe other personnel responsible for administrative and financial management.
- 2) Provide the proposed administrative structure in a flow chart format, indicating how members will interact according to lines of authority.
- 3) Describe the decision-making authority of the Principal Investigator in relation to the rest of the organization.
- 4) Describe procedures for initiation and performance of this contract's projects in a timely manner (describe how priorities for projects in general are set within the organization and the level of priority this contract will receive).
- 5) Describe plans to communicate effectively with the COR.

SECTION 7: OTHER CONSIDERATIONS

Section L of the RFP provides minimum documentation requirements for the following items. The required information described in Section L should be assembled together, in the following clearly marked sections of the Technical Proposal. Refer to Section L of the RFP for specific requirements. Read the section below carefully. In some cases, Offerors may be

asked to provide documentation which is in addition to the minimum requirements identified in Section L.

1) Care of Live Vertebrate Animals

Section L of the RFP specifies the minimum documentation requirements for Animal Welfare compliance. All related documentation should be included in the proposal in a clearly marked section. The Technical Proposal should document all information necessary to evaluate Animal Welfare issues.

2) Biohazard Safety and Security

The Technical Proposal should include a Health and Safety plan, detailing policies and procedures to ensure a safe and secure workplace.

3) Obtaining and Disseminating Biomedical Research Resources

Section L of the RFP specifies the minimum documentation requirements for this element. The Technical Proposal should document all information necessary to evaluate this issue.

4) Fetal Tissue Research

Section L of the RFP specifies the minimum documentation requirements for Fetal Tissue research. All related documentation should be included in the proposal in a clearly marked section.

5) Sharing Research Data

The RFP specifies the minimum requirements for the Data Sharing Plan. All related documentation should be included in the proposal in this clearly marked section. The technical proposal should include a plan for Data Sharing as required by this RFP.

**ATTACHMENT 5: ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS
AND UNIFORM COST ASSUMPTIONS**

**HUMANIZED MOUSE MODELS FOR HIV THERAPEUTICS DEVELOPMENT
RFP NIAID-DAIDS-NIHAI2012153**

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

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

BUSINESS PROPOSAL – TABLE OF CONTENTS

SECTION 1 – PROPOSAL COVER SHEET (use form NIH 2043 identified in Section J)

SECTION 2 – COST OR PRICE SUPPORT

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

SECTION 3 – UNIFORM COST ASSUMPTIONS

1) Technical Cost Assumptions

- a. 10 *in vitro* evaluations of single therapies per year and 3 evaluations of combination therapies per year.
- b. 600 SCID-hu Thy/Liv mice (50 mice per experiment) and 60 unengrafted SCID mice per year for evaluations of single and combination therapies.
- c. one cohort of up to 50 SCID-hu Thy/Liv mice per month, engrafted with tissue from a single donor.
- d. 480 engrafted immunodeficient mice per year (40 mice per experiment) and 50 unengrafted mice per year used for evaluations of single and combination therapies.
- e. one cohort of 40 mice per month, engrafted with tissue from a single donor.
- f. 15 draft protocols, 15 reports of completed studies, and 1 annual report each year.

The offeror should propose animal per diem costs and should include a complete breakdown of what is included in the animal per diem costs.

2) Travel

Contract Initiation Meeting: For purposes of preparing a cost proposal, Offerors should assume costs to host a one day face-to-face meeting at the Contractor's facility, within 60 days of contract award. Attendees from NIAID will include the Contracting Officer, the COR and up to 3 NIAID personnel designated by the COR. The purpose of the Contract Initiation Meeting shall be to orient the Contractor to NIAID contract procedures, so key Contractor personnel, including any administrative staff, should be present at the meeting.

General Scientific Meetings: For purposes of preparing a cost proposal, Offerors should assume that the Principal Investigator or designee will attend one domestic scientific meeting per year to present results obtained under this contract, with the approval of the COR.

3) Shipping of Samples

With prior COR and CO approval only, the Contractor may ship samples to a third party laboratory for additional testing and analyses. Assume standard shipping conditions and costs for domestic shipping of such samples (e.g., for frozen RNA). Assume 4-5 shipments per year of small volumes of tissues or bodily fluids, liquid or frozen as directed.

4) Storage

Offerors should include costs for providing appropriate facilities for the storage of up to 10,000 RNA samples per year for the assays to be conducted under this contract. Estimates should include costs for appropriate monitoring, safety, and security.

5) Government Furnished Equipment (GFE)

- Government Furnished Equipment available to be transferred from incumbent Contractor.
- The purchase of Government Furnished Equipment will not be authorized as a direct charge under this contract.

SECTION 4 – LEVEL OF EFFORT

The Government's requirement for the work set forth in the Statement of Work is 6.5 full time equivalents (FTEs). The direct labor includes vacation, holiday, and sick leave. It is estimated that the labor mix is to be constituted as specified below and will be expended approximately as follows:

FULL-TIME EQUIVALENTS

Labor Category	Base Period	Option 1 Year 2	Option 2 Year 3	Option 3 Year 4	Option 4 Year 5	Option 5 Year 6	Option 6 Year 7
Professional	0.75	0.75	0.75	0.75	0.75	0.75	0.75
Other Professional	2.75	2.75	2.75	2.75	2.75	2.75	2.75
Technical Support	2.50	2.50	2.50	2.50	2.50	2.50	2.50
Totals	6.00	6.00	6.00	6.00	6.00	6.00	6.00

SECTION 5 – OPTIONS

Offerors are requested to submit separate cost estimates for each of the Options to extend the term of the contract (Options 1 – 6).

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

1) Small Business Subcontracting Plan

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

2) Extent of Small Disadvantaged Business Participation

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

3) Past Performance Data, including references

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

4) IT Systems Security

The Business Proposal should include a plan for IT Systems security.

The contract is subject to Federal Information Security Management Act (FISMA) compliance.

The NIAID Cyber Security Program will collect FISMA deliverables from the contractor, perform FISMA security audits of contractor IT environment(s) where contractual data exists, and validate the systems/data security controls.

Validation criteria are based on NIST-recommended security controls for the Health Care Research and Practitioner Education Information type.

Validation recommendations are found in NIST Special Publication 800-60, Volume II, Revision 1, § D.14.5. Failure to comply with FISMA can void the contract.

ATTACHMENT 6: ADDITIONAL RFP-SPECIFIC MATERIALS

HUMANIZED MOUSE MODELS FOR HIV THERAPEUTICS DEVELOPMENT RFP NIAID-DAIDS-NIH-AI 2012153

The below RFP-Specific Materials are applicable to this solicitation.

DIVISION OF ACQUIRED IMMUNODEFICIENCY SYNDROME NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES MATERIAL EVALUATION AGREEMENT

This Material Evaluation Agreement is made and entered into between the Division of Acquired Immunodeficiency Syndrome (“DAIDS”) of the National Institute of Allergy and Infectious Diseases (“NIAID”), located at 6700B Rockledge Drive, Bethesda, Maryland 20892, and <insert company>, having its principal place of business located at <insert company’s address> (“Supplier”). DAIDS funds a comprehensive portfolio of contracts to discover and develop novel agents for the prevention and treatment of infections caused by human immunodeficiency virus (“HIV”), opportunistic infections associated with AIDS, hepatitis C, and tuberculosis. Supplier requests to voluntarily participate in one or more of the evaluation programs (e.g., in vitro, animal model, drug development) funded by DAIDS and submits for evaluation patented or unpatented drugs, compounds, or other products (“Material”) to DAIDS. Without cost to the Supplier, DAIDS may evaluate the submitted Material through its Contractors.

DAIDS shall determine which protocols shall be utilized to evaluate Supplier’s Material and the extent of the evaluation. Supplier shall have the right to request limitations on the scope and extent of evaluation of the Material by DAIDS.

DAIDS and Supplier therefore agree as follows:

1. Definitions.

- 1.1 “Confidential Information” is scientific, business, or financial information the Supplier or DAIDS deem to be proprietary or confidential and which information is identified as “Confidential” in writing. Confidential written information shall be marked “Confidential.” Oral disclosures must be reduced to writing, marked “Confidential,” and sent to the other Party’s Point of Contact listed in Section 11 within 10 business days after disclosure to be considered Confidential Information.
- 1.2 “Contractors” are DAIDS approved non-profit and for-profit testing laboratories with contractual obligations to DAIDS.
- 1.3 “DAIDS” is a division within NIAID, an institute of the National Institutes of Health (“NIH”), which is a component of the Department of Health and Human Services (“HHS”), an agency of the U.S. Government.
- 1.4 “Evaluations” will include the testing of the Materials in the manner described below.
 - a. <DAIDS to provide description of evaluations – use terms from “MEA examples list”>

- 1.5 “Invention” means any invention or discovery which is or may be patentable or otherwise protected under Title 35, United States Code (“U.S.C.”), or any novel variety or plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. §§ 2321 et seq.).
- 1.6 “Material” means:
- a. <DAIDS & Supplier to negotiate Description of Material - use terms from “MEA examples list” >
- 1.7 “Results” means all recorded data, results, and technical information produced from the Evaluations of the Material under this Agreement and not previously disclosed by the Supplier.

2. Submission and Evaluations of Material.

- 2.1 DAIDS represents that the contracts between DAIDS and the Contractors are consistent with the terms of this Agreement.
- 2.2 DAIDS has the right to decline to conduct Evaluations of any Material or to limit the scope of such Evaluations. Supplier understands that not all Evaluations offered by DAIDS are available at all times. Evaluations must be mutually agreed to by DAIDS and Supplier prior to commencement of Evaluations and are delineated in Section 1.4 above. After initiation of Evaluations listed in Section 1.4, Supplier and/or DAIDS may request additional Evaluations. Additional Evaluations are contingent upon meeting DAIDS criteria for such Evaluations and shall be mutually agreed upon in writing and attached hereto as an Amendment.
- 2.3 While Supplier may not select the Contractors, Supplier has the right to decline the use of particular Contractors conducting Evaluations prior to the communication of any Material to such Contractors.
- 2.4 Under the direction of DAIDS, Supplier shall forward to Contractors the Material to be tested together with a Material Safety Data sheet for each Material which contains pertinent available data as to chemical composition, purity, solubility, toxicity, and any precautions that need to be followed in handling, storing, and shipping the Material.
- 2.5 Material is to be used by Contractors for Evaluations under this Agreement only and for no other purpose. In addition, Material will not be chemically modified, replicated, derived, or reverse engineered unless specifically necessary for the performance of the Evaluations. Such modification would require Supplier’s written approval. Upon completion of Evaluations, DAIDS shall elect to either return to Supplier or destroy all unused Material.
- 2.6 DAIDS will use reasonable efforts to ensure rapid ongoing communication of Results to Supplier, and Supplier will in turn use reasonable efforts to keep DAIDS informed of Supplier’s own concurrent studies with the Material that may affect Evaluations or Results.

3. Confidentiality.

- 3.1 Supplier may provide Confidential Information relevant to the Evaluation of the Material to DAIDS and the Contractors. DAIDS represents that the Contractors are required by their DAIDS contracts to protect such Confidential Information with reasonable efforts as specified in Section 3.3 below.
- 3.2 DAIDS will not disclose the Confidential Information of the Supplier to any person except its employees, consultants, or contractors to whom it is necessary to disclose the Confidential Information for the purpose described above, and any such disclosures shall be under terms at least as restrictive as those specified herein.
- 3.3 To the extent permitted by law, Confidential Information disclosed to DAIDS or the Contractors will remain confidential for seven (7) years after the effective date of this Agreement unless the information:
 - a. Is known by the public or becomes known by the public through no fault of DAIDS or the Contractors;
 - b. Was obtained by DAIDS or the Contractors, without restriction, from a third party having no confidentiality obligation to the Supplier;
 - c. Has been independently developed by DAIDS or the Contractors without reference to the Supplier's Confidential information; or
 - d. Is required to be disclosed by law, regulation, or court order provided that Supplier has been notified and DAIDS or the Contractors have taken reasonable efforts to minimize the extent of the required disclosure.
- 3.4 No data about the Material, Evaluations, or Results will be kept in files open to the public either by DAIDS or the Contractors. Only personnel directly involved in the Evaluations will have access to the files containing Confidential Information.
- 3.5 Supplier acknowledges that Results are not Confidential Information as defined in Section 1.1, and may be disclosed by DAIDS and the Contractors only in accordance with Article 4 below.

4. Disclosure of Results.

- 4.1 DAIDS and the Contractors may publish or otherwise publicly disclose Results after a period of six (6) months from the date of transfer of Results to Supplier. The six-month delay in disclosure is intended to allow Supplier time to file patent applications if desired.
- 4.2 Publication of Results earlier than the six (6) month period by DAIDS or Contractors will require Supplier's prior written consent, which will not be unreasonably withheld.
- 4.3 Supplier is encouraged to pursue publication of Results in conjunction with or separately from DAIDS and the Contractors. Before Supplier or DAIDS submit a paper or abstract for publication or otherwise intend to publicly disclose information about Evaluations or Results related to Supplier's Material, such as a press release, DAIDS and Supplier will provide the other Party fourteen (14) days to review and comment on the proposed disclosure. DAIDS will require the Contractors to consult

with Supplier, whenever the Contractor intends to include Results in any publication or other public disclosure such as a press release.

- 4.4 Supplier will not be identified in DAIDS or Contractor publications as the source of Material without Supplier's prior written approval.
- 4.5 Supplier will not construe the involvement of DAIDS in Evaluations as an endorsement of Material by the U.S. Government or any of its agencies, employees, or Contractors.
- 4.6 Supplier will include acknowledgement of DAIDS/NIAID/NIH and the contract number(s) providing support in any public disclosure (e.g., publication, press release, poster at a meeting).

5. Intellectual Property.

- 5.1 Subject to applicable law, Supplier shall retain all of Supplier's existing intellectual property rights to Material. DAIDS acknowledges that this Agreement may not be construed as a grant by the Supplier of a license or any other right or interest to the Material beyond those expressly set forth herein.
- 5.2 Supplier acknowledges that the Contractors have the right to elect to retain title to any new Invention(s) made under DAIDS sponsored contracts [37 CFR 401.14(b)]. However, Contractors have agreed to an "Intellectual Property Option" as part of their contracts with DAIDS. Under the Intellectual Property Option the Contractors are required to:
 - a. Promptly notify DAIDS and the Supplier of any new Invention(s) made by the Contractors in the performance of the Evaluations under this Agreement;
 - b. Grant Supplier a paid-up, nonexclusive, nontransferable, royalty-free, world-wide license to all such new Invention(s) for research purposes only; and
 - c. Grant Supplier a time-limited first option to negotiate an exclusive, worldwide royalty-bearing license to Contractor's interest in all such new Invention(s) for all commercial purposes, including the right to grant sub-licenses, on terms to be negotiated in good faith by Supplier and the Contractor.

6. Warranty and Limitation of Liability.

- 6.1 DAIDS acknowledges and agrees that the Material is experimental in nature. **Supplier makes no representations and extends no warranty of any kind, either expressed or implied, including any warranty of merchantability or fitness for a particular purpose, or warranty that the use of Material will not infringe any patent, copyright, trademark, or other proprietary right.**
- 6.2 Supplier disclaims all liability for any claims, damages, or liability resulting from its activities under this agreement, unless caused by Supplier's gross negligence or willful misconduct. DAIDS shall be liable for any loss, claim, damage, or liability that DAIDS incurs as a result of its activities under this Agreement, except that DAIDS, as part of an agency of the United States, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. §§ 2671 et seq.

6.3 No indemnification for any loss, claim, damage, or liability is intended or provided by DAIDS under this Agreement. DAIDS is prohibited under statute, the Anti-Deficiency Act 31 U.S.C. §1341, from indemnifying any party, absent other specific statutory authorization.

7. Term and Termination.

7.1 This Agreement will be in effect for seven (7) years from the date of the last signature below.

7.2 DAIDS may terminate evaluations of Material based on demonstrated lack of efficacy, unanticipated toxicity, new information reported or published on drugs, compounds, or other products similar to Material, technical difficulties in performing Evaluations, lack of contract funds, or unavailability of resources. DAIDS shall notify Supplier in writing within five (5) business days of such a decision.

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

8. Amendments.

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

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

9. Governing Law.

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

10. Survivability.

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

11. Points of Contact.

For DAIDS

Name:
Title:
Organization:
Street/Bldg:
City: State: Zip:

Phone:
Fax:
Email:

For Supplier

Name:
Title:
Organization:
Street/Bldg:
City: State: Zip:

Phone:
Fax:
Email:

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

**The Division of AIDS (DAIDS), National
Institute of Allergy and Infectious Diseases
(NIAID), National Institutes of Health
(NIH)**
6700B Rockledge Drive
Bethesda, MD 20892

Insert Supplier Name
Insert Address

Authorized Signature:

Authorized Signature:

Carl W. Dieffenbach, PhD
Director, DAIDS, NIAID

<Insert Name: >
<Insert Title: >

Date
(Month/Day/Year): _____

Date
(Month/Day/Year): _____

ATTACHMENT 18
GOVERNMENT FURNISHED PROPERTY
FROM PREDECESSOR CONTRACT
RFP NIAID-DAIDS-NIHAI2012153

Item #	Description	MFR	Model	QTY	Value
1	Color Printer	Hewlett Packard	2605dn	1	\$370
2	Liquid Nitrogen Cryofreezer and 12 racks		MVE 815P	1	\$12,620
3	Class II Type A2 Biological Safety Cabinet	Nuaire, Inc.	NU-425-600	1	\$10,600
4	Precision Balance (820 g)	Mettler Toledo	MS802S	1	\$2,134
5	-80 Degree C Freezer	Revco	UXF 600BX 115V	1	\$11,729
6	-80 Upright Freezer			1	\$9,756
7	Centrifuge			1	\$7,514
8	3.8 Horizontal Rotor			1	\$2,449
9	Conical Adaptor			1	\$575
10	TB Adaptor			1	\$309
11	Bucket Covers			2	\$186
12	Microplate Carriers			1	\$630
	Microplate Covers			1	\$156
13	Personal Computers			3	\$4,958
14	Refrigerator/Freezer			1	\$3,939