

SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1. Purchase Authority: Public Law 92-218 as amended		
2. Request for Proposal (RFP) Number: RFP-NIAID-DAIT-NIHA12008034	3. Issue Date: October 10, 2008	4. Set Aside: ☒ No ☐ Yes See Part IV Section L
5. Title : Non-human Primate Reagent Resource		
6. ISSUED BY: Office of Acquisitions National Institute of Allergy and Infectious Diseases National Institutes of Health		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 3:00pm local time on February 10, 2009. 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 TO TWO DIFFERENT LOCATIONS. THE OFFICIAL POINT OF RECEIPT FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY IS THE ADDRESS PROVIDED FOR THE OFFICE OF ACQUISITIONS AS STATED IN ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." 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 HHSAR CLAUSE 352.215-70, ENTITLED, "LATE PROPOSALS, AND REVISIONS" 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. http://www.ccr.gov		
11. FOR INFORMATION CALL: Tom Bahrami PHONE: (301)451-2654 e-MAIL: bahramit@niaid.nih.gov COLLECT CALLS WILL NOT BE ACCEPTED.		
6700B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892		David T. Lisle Contracting Officer Office of Acquisitions National Institute of Allergy and Infectious Diseases

RFP TABLE OF CONTENTS

PART I - THE SCHEDULE	4
SECTION A - SOLICITATION/CONTRACT FORM	1
SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS	4
SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT	6
SECTION D - PACKAGING, MARKING AND SHIPPING	8
SECTION E - INSPECTION AND ACCEPTANCE	9
SECTION F - DELIVERIES OR PERFORMANCE	10
SECTION G - CONTRACT ADMINISTRATION DATA	11
SECTION H - SPECIAL CONTRACT REQUIREMENTS	14
PART II - CONTRACT CLAUSES	25
PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS	33
SECTION J - LIST OF ATTACHMENTS	33
SOLICITATION ATTACHMENTS	33
TECHNICAL PROPOSAL ATTACHMENTS	33
BUSINESS PROPOSAL ATTACHMENTS	33
INFORMATIONAL ATTACHMENTS	34
PART IV - REPRESENTATIONS AND INSTRUCTIONS	35
SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	35
SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS	36
1. GENERAL INFORMATION	36
a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION	36
b. NAICS CODE AND SIZE STANDARD	40
c. TYPE OF CONTRACT AND NUMBER OF AWARDS	40
d. ESTIMATE OF EFFORT	40
e. COMMITMENT OF PUBLIC FUNDS	40
f. COMMUNICATIONS PRIOR TO CONTRACT AWARD	41
g. RELEASE OF INFORMATION	41
h. PREPARATION COSTS	41
i. SERVICE OF PROTEST	41
j. LATE PROPOSALS AND REVISIONS	41
2. INSTRUCTIONS TO OFFERORS	41
a. GENERAL INSTRUCTIONS	41
1. Contract Type and General Clauses	42
2. Authorized Official and Submission of Proposal	42
3. Proposal Summary and Data Record (NIH-2043)	42
4. Separation of Technical and Business Proposals	42
5. Alternate Proposals	43
6. Evaluation of Proposals	43
7. Potential Award Without Discussions	43
8. Use of the Metric System of Measurement	43
9. Standards for Privacy of Individually Identifiable Health Information	43
10. Privacy Act - Treatment of Proposal Information	43

11. Selection of Offerors.....	44
12. Institutional Responsibility Regarding Conflicting Interests of Investigators.....	45
13. ROTC Access and Federal Military Recruiting on Campus.....	45
14. Past Performance Information.....	45
15. Electronic and Information Technology Accessibility	46
16. Prohibition on Contractor Involvement with Terrorist Activities.....	47
17. Solicitation Provisions Incorporated by Reference.....	47
b. TECHNICAL PROPOSAL INSTRUCTIONS.....	47
1. Technical Discussions.....	48
2. Other Considerations.....	49
3. Technical Evaluation.....	50
4. Care of Live Vertebrate Animals.....	50
5. Obtaining and Disseminating Biomedical Research Resources.....	51
6. Information Security.....	52
c. BUSINESS PROPOSAL INSTRUCTIONS.....	55
1. Basic Cost/Price Information.....	55
2. Proposal Cover Sheet.....	55
3. Information Other than Cost or Pricing Data.....	56
4. Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data.....	57
5. Salary Rate Limitation in Fiscal Year 2008.....	58
6. Small Business Subcontracting Plan.....	59
7. HUBZone Small Business Concerns.....	60
8. Extent of Small Disadvantaged Business Participation.....	61
9. Other Administrative Data.....	62
10. Qualifications of the Offeror.....	64
11. Subcontractors.....	65
12. Proposer's Annual Financial Report.....	65
13. Representations and Certifications - SECTION K.....	65
14. Travel Costs/Travel Policy.....	65
15. Certification of Visas for Non-U.S. Citizens.....	65
SECTION M - EVALUATION FACTORS FOR AWARD.....	67
1. GENERAL.....	67
2. EVALUATION OF OPTIONS.....	67
3. EVALUATION OF DATA SHARING PLAN.....	67
4. TECHNICAL EVALUATION CRITERIA.....	67
5. PAST PERFORMANCE FACTOR.....	68
6. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION.....	69

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 shall satisfy the NIAID, Division of Allergy, Immunology, and Transplantation (DAIT) requirement for a Reagent Resource by developing, obtaining, evaluating, producing, and distributing a wide variety of reagents to facilitate and advance Non-Human Primate (NHP) research in infectious and immune-mediated diseases.

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

- a. The estimated cost of the Base Period of this contract is \$TBD.
- b. The fixed fee for the Base Period of this contract is \$TBD. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer. Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract. Payment of fixed fee shall not be made in less than monthly increments.
- c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee for the Base Period is \$TBD.
- d. 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 represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

	Estimated Cost (\$)	Fixed Fee (\$)	Estimated Cost Plus Fixed Fee (\$)
Base Period	TBD	TBD	TBD
Option Period(s):	TBD	TBD	TBD
Total [Base Period and Option(s)]	TBD	TBD	TBD

- e. Total funds currently available for payment and allotted to this contract are \$TBD of which \$TBD represents the estimated costs, and of which \$TBD represents the fixed fee. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses.

- f. It is estimated that the amount currently allotted will cover performance of the contract through TBD.
- g. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

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

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. [DESCRIPTION-SPECIFICATION-WORKSTATEMENT-STATEMENT OF WORK]

- a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated August, 28, 2008, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one (1) hardcopy of each report shall be submitted to the Contracting Officer, unless otherwise specified.

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, it is estimated that in addition to the required electronic version(s) 1 hard copies of these 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. **Source Code and Object Code**

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

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 Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040-A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract

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
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Office of Acquisition
6700-B Rockledge Drive
MSC 7612, Room 3214
Bethesda, Maryland 20892- 7612

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

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

SECTION D - PACKAGING, MARKING AND SHIPPING

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

SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, Project Officer is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Division of Allergy, Immunology and Transplantation
6610 Rockledge Drive
Bethesda, MD 20892

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

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

FAR Clause 52.246-9, Inspection of Research and Development (Short Form) (April 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

- a. The period of performance of this contract shall be from September 1, 2009 through August 31, 2014.
- b. If the Government exercises its option(s) 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
1st One Year Extension Contract Year 6	09/01/2014-09/31/2015
2nd One Year Extension Contract Year 7	09/01/2015-08/31/2016

ARTICLE F.2. DELIVERIES

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

- a. The items specified and as described in Attachment 4 Reporting Requirements and Deliverables of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified in the delivery schedule and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract.

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

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

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

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

(To be specified prior to award)

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

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

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

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.270-5 (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 in contract	

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.

- 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

E-Mail: NIAIDOAInvoices@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 .
- b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NIAID OA Invoices .
- 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 the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H of this contract. For billing purposes, certified invoices are required for the billing period during which the

applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H of the above referenced contract."

ARTICLE G.4. INDIRECT COST RATES

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

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

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

ARTICLE G.5. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication, entitled, "Contractor's Guide for Control of Government Property," which can be found at:

http://www.hhs.gov/oamp/policies/contractors_guide_for_control_of_gov_property.pdf.

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

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

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

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

b. Electronic Access to Contractor Performance Evaluations

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

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

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

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

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

ARTICLE H.2. HUMAN MATERIALS

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

ARTICLE H.3. RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (Including Human Gene Transfer Research)

All research involving Recombinant DNA Molecules shall be conducted in accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>) and the September 24, 2007 Notice, "Reminder of NIH Policy for Enhancing the Science, Safety, and Ethics of Recombinant DNA Research" (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-096.html>) (and any subsequent revisions to the Guide Notice) which stipulates biosafety and containment measures for recombinant DNA research and delineates critical, ethical principles and key safety reporting requirements for human gene transfer research (See Appendix M of the Guidelines). These guidelines apply to both basic and clinical research studies.

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

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

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

ARTICLE H.4. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

Pursuant to the current HHS annual appropriations act, 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.5. NEEDLE EXCHANGE

Pursuant to the current HHS annual appropriations act, 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.6. PRESS RELEASES

Pursuant to the current HHS annual appropriations act, 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.7. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING SCIENTIFIC INFORMATION

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to disseminate scientific information that is deliberately false or misleading.

ARTICLE H.8. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to employ workers described in section 274A(h)(3) of the Immigration and Nationality Act, which reads as follows:

"(3) Definition of unauthorized alien. - As used in this section, the term 'unauthorized alien' means, with respect to the employment of an alien at a particular time, that the alien is not at that time either (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

ARTICLE H.9. SALARY RATE LIMITATION LEGISLATION PROVISIONS

- a. Pursuant to the current HHS annual appropriations act, the Contractor shall not use NIH Fiscal Year funds to pay the direct salary of an individual through this contract at a rate in excess of Executive Level I. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as "indirect costs" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor. The annual salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.
- b. Payment of direct salaries is limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred. 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 / cursor to bottom of page and select year / Executive Schedule / Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

ARTICLE H.10. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at:

<http://grants1.nih.gov/grants/olaw/references/phspol.htm>.

ARTICLE H.11. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

All Contractor personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL:

<http://www1.od.nih.gov/oma/manualchapters/intramural/3044-2/>

ARTICLE H.12. 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.13. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

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

b. Subcontracting Reports

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 Contract Specialist shall be included as a contact for notification purposes.

ARTICLE H.14. INFORMATION SECURITY

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

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

a. Information Type

☐ Administrative, Management and Support Information

☒ Mission Based Information

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. Position Sensitivity Designations

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

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

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

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

2. The Contractor shall submit a roster, by name, position, 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 Project Officer, with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. Any revisions to the roster as a result of staffing changes shall be submitted within 15 calendar days of the change. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for Contractor use at: <http://ais.nci.nih.gov/forms/Suitability-roster.xls>.

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: <http://ais.nci.nih.gov>.

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

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

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

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

d. Information Security Training

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

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

e. Rules of Behavior

The Contractor/Subcontractor employees shall comply with the NIH Information Technology General Rules of Behavior at: <http://irm.cit.nih.gov/security/nihitrob.html>.

f. Personnel Security Responsibilities

Contractor Notification of New and Departing Employees Requiring Background Investigations

1. The Contractor shall notify the Contracting Officer, the Project Officer, and the Security Investigation Reviewer **within five working days** before a new employee assumes a position that requires a suitability determination or when an employee with a security clearance stops working under the contract. The Government will initiate a background investigation on new employees requiring security clearances and will stop pending background investigations for employees that no longer work under the contract.
2. New employees: 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.
3. Departing employees:
 - Provide the name, position title, and security clearance level held by or pending for the individual.
 - 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 Project Officer and/or Contracting Officer upon request.

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

1. Contractor Agreement

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

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

2. Contractor-Employee Non-Disclosure Agreements

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

h. NIST SP 800-53 Self-Assessment

The contractor shall annually update and re-submit its Self-Assessment required by NIST SP 800-53, *Recommended Security Controls for Federal Information Systems*. (<http://csrc.nist.gov/publications> - under Special Publications).

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

The annual update shall be submitted to the Project Officer, with a copy to the Contracting Officer no later than the completion date of the period of performance.

i. Information System Security Plan

The Contractor's draft ISSP submitted with its proposal shall be finalized in coordination with the Project Officer no later than 90 calendar days after contract award.

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

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

j. Common Security Configurations

The contractor shall ensure that any information technology acquired under this contract incorporates the applicable common security configuration established by the National Institute of Standards and Technology (NIST) at <http://checklists.nist.gov>.

ARTICLE H.15. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY (January 2008)

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, and/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>.

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 order/contract exceeding \$100,000 when the order/contract 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 in the Product Assessment Template, remediation of the products and/or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor at its own expense.

In the event of a modification(s) to the contract/order, which adds new EIT products and services or revised the type of, or specifications for, products and 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 and services support Section 508 accessibility requirements. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at <http://508.hhs.gov>.

[(End of HHSAR 352.270-19(b))]

Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding increment 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 Contracting Officer's Technical Representative (also known as Project Officer or Contracting Officer's Representative). 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 at: <http://508.hhs.gov/> 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 incremental funding, as applicable.

Schedule for Contractor Submission of Section 508 Annual Report: Annually on contract anniversary date.

[End of HHSAR 352.270-19(c)]

ARTICLE H.16. CONFIDENTIALITY OF INFORMATION

The following information is covered by **HHSAR 352.224-70, Confidentiality of Information** (January 2006): TBD

ARTICLE H.17. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS

The Contractor 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 principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded under NIH contracts) will not be biased by any conflicting financial interest. 45 CFR Part 94 is available at the following Web site: <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=cc7504e541bc62939c52389e9afc27d5&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45>

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

- a. Maintain a written, enforceable policy on conflict of interest that complies with 45 CFR Part 94 and inform each investigator of the policy, the investigator's reporting responsibilities, and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.
- b. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in NIH-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a *Significant Financial Interest* could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 CFR Part 94, under Management of Conflicting Interests.
- c. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.
- d. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.
- e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

If a conflict of interest is identified, the Contractor shall report to the Contracting Officer, the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the NIH-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research.

The Contracting Officer may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in NIH-funded research, including a review of all records pertinent to compliance with 45 CFR Part 94. The Contracting Officer may require submission of the records or review them on site. On the basis of this review, the Contracting Officer may decide that a particular 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 Contractor has not managed, reduced, or eliminated the conflict of interest. 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 conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

ARTICLE H.18. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.270-6, 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. TBD"

ARTICLE H.19. 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.20. 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.21. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

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

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

ARTICLE H.22. SHARING RESEARCH DATA

The data sharing plan submitted by the Contractor is acceptable. 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.23. 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.24. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

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

ARTICLE H.25. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

Beginning April 7, 2008, 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.26. 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.27. GUIDELINES FOR INCLUSION OF WOMEN, MINORITIES, AND PERSONS WITH DISABILITIES IN NIH-SUPPORTED CONFERENCES

Pursuant to the NIH Revitalization Act (P.L. 103-43, Section 206), which adds Section 402(b) to the Public Health Service Act, it is required that NIH, "in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research." In addition, Section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act of 1990 require reasonable accommodations to be provided to individuals with disabilities.

It is NIH policy that organizers of scientific meetings should make a concerted effort to achieve appropriate representation of women, racial/ethnic minorities, and persons with disabilities, and other individuals who have been traditionally underrepresented in science, in all NIH sponsored and/or supported scientific meetings.

Therefore, it is the contractor's responsibility to ensure the inclusion of women, minorities, and persons with disabilities in all events when recruiting speakers and/or participants for meetings or conferences funded by this contract.

See the policy announcement for additional details and definitions at:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-066.html>

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

The complete listing of these clauses may be accessed at:

<http://rcb.cancer.gov/rcb-internet/appl/general-clauses/clausesDGS.jsp>

General Clauses for a Cost-Reimbursement Research and Development Contract

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 substitution(s) will be made part of the resultant contract:

- a. FAR Clauses **52.215-15, Pension Adjustments And Asset Reversions** (October 2004); **52.215-18, Reversion Or Adjustment Of Plans For Post Retirement Benefits (PRB) Other Than Pensions** (July 2005); and, 52.215-19, **Notification Of Ownership Changes** (October 1997), are deleted in their entirety.
- b. **Alternate IV** (October 1997) of FAR Clause **52.215-21, Requirements For Cost Or Pricing Data Or Information Other Than Cost Or Pricing Data--Modifications** (October 1997) is added.
- c. **Alternate II** (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (April 2008) is added.
- d. FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefor. **[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]**
- 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** (December 2007).
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://www.oig.hhs.gov/hotline/OIG_Hotline_Poster.pdf

3. FAR Clause **52.216-15, Predetermined Indirect Cost Rates** (April 1998).
4. 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 60 days 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."
5. FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (July 2005).

"(c) Waiver of evaluation preference.....
 [] Offeror elects to waive the evaluation preference."
6. FAR Clause **52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting** (April 2008).
7. FAR Clause **52.223-12, Refrigeration Equipment and Air Conditioners** (May 1995).
8. FAR Clause **52.226-1, Utilization of Indian organizations and Indian-owned Economic Enterprises** (June 2000).

9. FAR Clause **52.227-14, Rights in Data - General** (December 2007).
 10. **Alternate IV** (December 2007), FAR Clause **52.227-14, Rights in Data - General** (December 2007).
 11. **Alternate V** (December 2007), FAR Clause **52.227-14, Rights in Data--General** (December 2007).
 12. FAR Clause **52.227-16, Additional Data Requirements** (June 1987).
 13. FAR Clause **52.230-5, Cost Accounting Standards - Educational Institution** (April 1998).
 14. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (March 2008).
 15. FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).
 16. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).
 17. FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984).
 18. FAR Clause **52.247-63, Preference for U.S. Flag Air Carriers** (June 2003).
- b. *DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:*
1. *HHSAR Clause **352.224-70, Confidentiality of Information** (January 2006).*
 2. *HHSAR Clause **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).*
 3. *HHSAR Clause **352.270-9(b), Care of Live Vertebrate Animals** (January 2006).*
- c. *NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:*
- The following clauses are attached and made a part of this contract:*
1. ***NIH (RC)-7, Procurement of Certain Equipment** (April 1984).*

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

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

This contract incorporates the following clauses in full text.

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

a. FAR Clause **52.219-28, Post-Award Small Business Program Representation** (June 2007).

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

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend Services, or other appropriate authority.

Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause.

(b) If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall rerepresent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the exercise date specified in the contract for any option thereafter.

(c) The Contractor shall rerepresent its size status in accordance with the size standard in effect at the time of this rerepresentation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at <http://www.sba.gov/services/contractingopportunities/sizestandardstopics/>.

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the rerepresentation required by paragraph (b) of this clause by validating or updating all its representations in the Online Representations and Certifications Application and its data in the Central Contractor Registration, as necessary, to ensure they reflect current status. The Contractor shall notify the contracting office by e-mail, or otherwise in writing, that the data have been validated or updated, and provide the date of the validation or update.

(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in ORCA, or does not have a representation in ORCA for the NAICS code applicable to this contract, the Contractor is required to complete the following rerepresentation and submit it to the contracting office, along with the contract number and the date on which the rerepresentation was completed:

The Contractor represents that it [] is, [] is not a small business concern under NAICS Code assigned to contract number.

[Contractor to sign and date and insert authorized signer's name and title].

(End of clause)

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

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

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

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

Notice to Employees

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

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

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

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

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

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

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

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

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

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

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

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

(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and

(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or

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

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

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 2021, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

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

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

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c).

For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint

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

(End of Clause)

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 Attachment Section at the end of this RFP
Attachment 2:	Proposal Intent Response Sheet	See Attachment Section at the end of this RFP
Attachment 3:	Statement of Work	See Attachment Section at the end of this RFP
Attachment 4:	Reporting Requirements and Deliverables	See Attachment Section at the end of this RFP
Attachment 5:	Additional Technical Proposal Instructions and Format for Technical Proposal; and Table of Contents	See Attachment Section at the end of this RFP
Attachment 6:	Additional Business Proposal Instructions and Uniform Cost Assumptions	See Attachment Section at the end of this RFP

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 7:	Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Attachment 8:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 9:	Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Attachment 10:	Small Business Subcontracting Plan	http://www.hhs.gov/osdbu/read/SampleSubcontractingPlan.doc
Attachment 11:	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 12:	Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Attachment 13:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sfillin.pdf

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 14:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 15:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Attachment 16:	Government Property Schedule	To be determined during negotiations.
Attachment 17:	Commitment to Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Attachment 18:	Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Attachment 19:	Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

1. Go to the Online Representations and Certifications Application (ORCA) at: <https://orca.bpn.gov/> and complete the Representations and Certifications; and
2. Complete, and include as part of your BUSINESS PROPOSAL, SECTION K which can be accessed electronically from the INTERNET at the following address:
<http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf>

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

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, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following 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, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror 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 541711.
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

It is anticipated that one award will be made from this solicitation and that the award(s) will be made on/about September 1, 2009.

It is anticipated that the award(s) from this solicitation will be a multiple-year Cost-Reimbursement type Completion contract with a period of performance of 5 years with two 1 year options, and that incremental funding will be used (See Section L.2.c. Business Proposal Instructions).

d. ESTIMATE OF EFFORT

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 5.1 FTEs per year. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

e. COMMITMENT OF PUBLIC FUNDS

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

f. COMMUNICATIONS PRIOR TO CONTRACT AWARD

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

g. RELEASE OF INFORMATION

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

h. PREPARATION COSTS

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

i. 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:

Contracting Officer
Office of Acquisitions
National Institute of Allergy and Infectious Diseases
6700B Rockledge Drive, Room 3214 MSC 7612
BETHESDA MD 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)

j. LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70 (January 2006)

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

(End of provision)

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

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

1. Contract Type and General Clauses

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

2. Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the 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 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 technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

7. Potential Award Without Discussions

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

8. Use of the Metric System of Measurement

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all 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. Standards for Privacy of Individually Identifiable Health Information

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

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

10. Privacy Act - Treatment of Proposal Information

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the Government Accountability Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

11. Selection of Offerors

- a. The acceptability of the [scientific and] technical portion of each [research] contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b. The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d. If the Government intends to conduct discussions prior to awarding a contract -
 1. Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal,

but may be considered in rating proposals for the purpose of establishing the competitive range.

2. The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NIAID's policy to conduct discussions with all offerors in the competitive range, NIAID reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

- e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror.
- 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.

12. Institutional Responsibility Regarding Conflicting Interests of Investigators

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 conflicting financial interest of an Investigator. The Institution shall comply with all requirements of 45 CFR Part 94 at <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=cc7504e541bc62939c52389e9afc27d5&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45>.

13. 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.

14. 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 \$550,000.00.

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.

15. **Electronic and Information Technology Accessibility, HHSAR 352.270-19(a) (January 2008)**

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 Provisions (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:

1. 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
2. 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.

Accordingly, any vendor submitting a proposal/quotations/bid in response to this solicitation must demonstrate compliance with the established EIT accessibility provisions. 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>.

The Section 508 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 Assessment Template may be found at <http://508.hhs.gov>.

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 and/or services that are incidental to the project, which would constitute an exception to Section 508 requirements. If a vendor claims its products and/or services, including EIT deliverables such as electronic documents and reports, meet applicable Section 508 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 and/or services delivered do not conform to the described accessibility in the Product Assessment Template, remediation of the products and/or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor at its expenses.

(End of provision)

16. Prohibition on Contractor Involvement with Terrorist Activities

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

17. 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. Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).*
- c. Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).*
- d. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).*
- e. 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, as applicable, as well as for the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

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. Care of Live Vertebrate Animals

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

Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, HHSAR 352.270-9(a) (January 2006)

The PHS Policy on Human Care and Use of Laboratory Animals 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 which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No award involving the use of animals shall be made unless OLAW approves the Animal Welfare Assurance. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information contact OLAW, at NIH, Bethesda, Maryland 20892 (301-496-7163).

(End of Provision)

The following specific address for OLAW is provided for ease of contact:

Office of Laboratory Animal Welfare
National Institutes of Health
RKL 1 - Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982 (For Hand-delivered/express mail use Zip code 20817)

FAX copies of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at <http://www.grants.nih.gov/grants/olaw/olaw.htm>.

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

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

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

- The Animal Welfare Assurance number.
- The date last certified by OLAW. (i.e. assurance letter from OLAW)
- Evidence of recent AAALAC Accreditation, if required by the SOW contained in this solicitation.

5. Obtaining and Disseminating Biomedical Research Resources

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

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

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

<http://ott.od.nih.gov/NewPages/64FR72090.pdf>

a. Sharing Research Data

[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>

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

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

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

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

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

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

a. Information Type

[] Administrative, Management and Support Information:

[X] Mission Based Information:

b. Security Categories and Levels

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

c. Position Sensitivity Designations

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

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

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

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

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

<http://ais.nci.nih.gov/forms/Suitability-roster.xls>

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: <http://ais.nci.nih.gov>.

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

d. Information Security Training

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

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

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

e. Offeror's Official Responsible for Information Security

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

f. NIST SP 800 53 Self Assessment

The offeror must include in the "Information Security" part of its Technical Proposal, a completed Self-Assessment required by NIST Draft SP 800-53, Recommended Security Controls for Federal Information Systems. (<http://csrc.nist.gov/publications> - under Special Publications).

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

g. Draft Information System Security Plan

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

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

Note to Offeror: The resultant contract will require the draft ISSP to be finalized in coordination with the Project Officer no later than 90 calendar days after contract award. Also, a contractor is required to update and resubmit its ISSP to NIH every three years following award or when a major modification has been made to its internal system.

h. Common Security Configurations

The contractor shall ensure that any information technology acquired under this contract incorporates the applicable common security configuration established by the National Institute of Standards and Technology (NIST) at <http://checklists.nist.gov>.

i. References

1. Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); <http://csrc.nist.gov/drivers/documents/FISMA-final.pdf>
2. DHHS Personnel Security/Suitability Handbook: <http://www.hhs.gov/ohr/manual/pssh.pdf>
3. NIH Computer Security Awareness Training Course: <http://irtsectraining.nih.gov/>

The following NIST publications may be found at the following site: <http://csrc.nist.gov/publications/>

[Note: The search tool on the left side of this page provides easy access to the documents.]

4. NIST Special Publication 800-16, Information Technology Security Training Requirements; and Appendix A-D
5. NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems
6. NIST SP 800-26, Revision 1, Computer Security
7. NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems
8. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I; and Volume II, Appendices to Guide For Mapping Types of Information and Information Systems To Security Categories, Appendix C, and Appendix D
9. NIST SP 800-64, Security Considerations in the Information System Development Life Cycle
10. FIPS PUB 199, Standards for Security Categorization of Federal Information and Information Systems
11. FIPS PUB 200, Minimum Security Requirements for Federal Information and Information Systems

c. BUSINESS PROPOSAL INSTRUCTIONS

1. Basic Cost/Price Information

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

2. Proposal Cover Sheet

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

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

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

3. Information Other than Cost or Pricing Data

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

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

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

1. **Direct Labor**

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

2. **Materials**

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

3. **Subcontracted Items**

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

4. **Raw Materials**

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

5. **Purchased Parts**

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

6. **Fringe Benefits**

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

7. Indirect Costs

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

8. Special Equipment

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

9. Travel

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

10. Other Costs

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

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

(a) Exceptions from cost or pricing data.

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

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

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

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

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

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

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

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

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15.2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406.2.

(End of provision)

Alternate I (October 1997) of FAR Clause **52.215-20, Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data** (October 1997). As prescribed in 15.408(l), **substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:**

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

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

5. Salary Rate Limitation in Fiscal Year 2008

Offerors are advised that pursuant to P.L.110-161, no NIH Fiscal Year 2008 (October 1, 2007 - September 30, 2008) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 110-161 applies only to Fiscal Year 2008 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limitation also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 110-161 states in pertinent part:

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

LINK TO EXECUTIVE SCHEDULE SALARIES: <http://www.opm.gov/oca/08tables/pdf/ex.pdf>

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

6. Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of \$550,000 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 \$550,000 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:

23% for Small Business; 5% for Small Disadvantaged Business; 5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

7. 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>.

8. 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 \$550,000 (\$1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b)). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

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

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) 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.arnet.gov/References/sdbadjustments.htm>.

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

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS 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.

9. 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. The voluntary consensus standard or industry leading practices and standards to be used in the management of Government property, or existing property management plans, methods, practices, or procedures for accounting for property.

NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from the Contractor possessing Government property, and for evaluation purposes only, adjust the offers using a rental equivalent evaluation factor, as appropriate.

3. Government-Furnished Property

No Government Furnished Property is offered for this acquisition

4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, Contractors Guide for Control of Government Property, which can be found at: <http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm>

b. Royalties

The offeror shall furnish information concerning royalties which are anticipated to be paid in connection with performance of work under the proposed contract.

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

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

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

(End of Provision)

d. Financial Capacity

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

e. Incremental Funding

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

elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provision is applicable:

Incremental Funding, HHSAR 352.232-75 (January 2006)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds as specified in FAR 52.232-22. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. The Government intends to allot additional funds up to and including the full estimated cost of the contract for the remaining years of performance by contract modifications. However, the Government is not obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor is the Contractor obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract, as specified in FAR 52.232-22, shall supersede the Limitation of Cost clause found in the Section I, Contract Clauses.

(End of provision)

10. 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.

11. 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>

12. Proposer's Annual Financial Report

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

13. Representations and Certifications - SECTION K

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

14. Travel Costs/Travel Policy

a. 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.

15. Certification of Visas for Non-U.S. Citizens

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States

and its outlying areas, then the offeror must indicate in the proposal that these individuals have the required visas.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, 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 criteria listed below.

2. EVALUATION OF OPTIONS

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

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 option(s).

3. 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.

4. TECHNICAL EVALUATION CRITERIA

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

OFFERORS AND REVIEWERS ARE ADVISED TO REFER TO - Additional Technical Proposal Instructions
- OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATION RELATED TO THE
PREPARATION OF TECHNICAL PROPOSALS.

CRITERIA

WEIGHT

CRITERION 1: TECHNICAL PLAN/APPROACH

55

Documented technical understanding, adequacy and feasibility of the technical approach for the project as a whole, and in the following areas:

- a. Soundness and feasibility of the proposed technical approaches, and alternative methods, and quality control and assurance procedures for reagent identification, development, process development, production, purification, formulation, and validation/evaluation.
- b. Feasibility and adequacy of proposed plans/procedures for databases and data management, including the registration of requestors, generating and tracking requests, distribution, inventory tracking, reporting system, and database updating.
- c. Appropriateness of plan for the development and maintenance of a public NHP Reagent Resource website and for communications with the NHP research community.
- d. Feasibility and adequacy of proposed methods and procedures to identify and assess reagent development priorities.
- e. Feasibility and adequacy to continue services described for the base period of the contract for an additional one (1) year period to be exercised by the government up to two (2) times during the life of the contract.

CRITERION 2: SCIENTIFIC AND TECHNICAL PERSONNEL**20****A. Principal Investigator**

Documented adequacy and relevance of the education, training, experience, expertise, qualifications and effort of the PI for planning, managing, and directing projects of similar scope, complexity and size to accomplish the Statement of Work.

B. Scientific and Technical Personnel

Documented adequacy and relevance of expertise, experience, and availability of the proposed scientific and technical staff, including subcontractors, collaborators, and consultants, to perform their roles with respect to the requirements of the Statement of Work.

CRITERION 3: PROJECT MANAGEMENT**15**

- a. Feasibility and adequacy of proposed plans for organizing, staffing and managing the tasks identified in the Statement of Work.
- b. Feasibility and efficiency of proposed organization that delineates clear lines of authority and responsibility and plans for communication with the Contracting and Project Officers.
- c. Feasibility of the plan to manage and coordinate consultants, collaborators, and subcontractor efforts.
- d. Efficiency and effectiveness of proposed operating procedures, particularly with regard to timeliness, and decision making processes, including prioritization of important project elements.

CRITERION 4: FACILITIES, EQUIPMENT AND OTHER RESOURCES**10**

Documented availability and adequacy of the facilities, equipment and resources dedicated by the prime contractor and any proposed subcontractors for the duration of the contract required to fulfill the Statement of Work.

TOTAL POSSIBLE WEIGHT:**100**

Feasibility and adequacy of proposed plans for organizing, staffing and managing the tasks identified in the Statement of Work.

5. PAST PERFORMANCE FACTOR

An evaluation of offerors' past performance information will be conducted prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any

offeror whose proposal will not be admitted to the competitive range on the basis of the results of the evaluation of factors other than past performance.

6. 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. Extent of participation of SDB concerns in terms of the value of the total acquisition.

ATTACHMENT 1: PACKAGING AND DELIVERY OF THE PROPOSAL

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

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

A. EXTERNAL PACKAGE MARKING:

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

**"RFP-NIAID-DAIT-NIHAI2008034
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"**

B. PAPER COPIES and CD-Rom to:

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

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

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

C. NUMBER OF COPIES:

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

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

FORMATTING AND LAYOUT:

Use your usual word processing and spreadsheet programs to prepare and format the technical and business proposals.

Documents submitted using Adobe .pdf shall be submitted using a .pdf searchable format.

- Type size must be 10 to 12 points.
- Type spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
- Print margins must be at least one inch on each edge of the paper.
- Print setup should be single-sided on standard letter size paper (8.5 x 11" in the U.S., A4 in Europe).
- Proposals shall NOT include links to Internet Web site addresses (URLs) or otherwise direct readers to alternate sources of information.

CREATING AND NAMING ELECTRONIC FILES:

1. A separate CD should be submitted for the Technical Proposal and Business Proposal information.
Offerors who submit both Technical and Business Proposals on the same CD will be required to resubmit them on separate CDs.

2. It is requested that the Technical Proposal be submitted as one document.

Note: if multiple files are submitted for the either proposal, please include the name of the section in the file name.

EXAMPLE: *XYX Company-08-04-Technical-Approach-3-6-06*

3. CDs should be named using the following format:

Technical Proposal: *Company name-RFP number-technical-date*

Business Proposal: *Company name-RFP number-business-date*

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

PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE PROVIDED TO THE REVIEWERS TO BE READ OR EVALUATED.

OFFERORS MUST CERTIFY THAT THE INFORMATION IN THE PAPER AND ELECTRONIC COPIES IS EXACTLY THE SAME.

Document	Number of Copies	Page Limits
Technical Proposal and all Appendices	<u>PAPER</u> One (1) unbound SIGNED ORIGINAL. Six (6) unbound COPIES <u>ELECTRONIC FILES ON CD</u> Three (3) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices)	<u>Not to Exceed 150 pages (inclusive of all Attachments and Appendices)</u>
Business Proposal	<u>PAPER</u> One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES <u>ELECTRONIC FILES ON CD</u> Three (3) Compact Disks containing an electronic copy of the Business Proposal	N/A
Breakdown of Proposed Estimated Cost using Electronic Cost Proposal EXCEL Workbook	This Attachment to the Business Proposal should be submitted as a separate EXCEL file on the Business Proposal Compact Disk. See Section J, Attachment entitled <u>Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet</u> to access the Excel Workbook.	N/A

ATTACHMENT 2: PROPOSAL INTENT RESPONSE SHEET

RFP No.: RFP-NIAID-DAIT-NIHAI2008034

RFP Title: Non-human Primate Reagent Resource

Please review the attached Request for Proposal. Furnish the information requested below and return this page by November 10, 2008. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

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

☐ 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, NIAID, NIH

Room 3214

6700-B Rockledge Drive, MSC 7612

Bethesda, MD 20892-7612

Attn: Tom Bahrami

RFP-NIH-NIAID-DAIT-NIHAI2008034

FAX# (301) 451-2654

Email : bahramit@NIAID.NIH.GOV

ATTACHMENT 3: STATEMENT OF WORK

Non-human Primate Reagent Resource RFP-NIAID-DAIT-NIHAI2008034

1. BACKGROUND and INTRODUCTION:

The Division of Allergy, Immunology, and Transplantation (DAIT) of the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Department of Health and Human Services (DHHS), supports basic, translational, and clinical research to understand immunological responses and to apply these research findings to the development of effective vaccine, preventive and therapeutic strategies for infectious and immune-mediated diseases. The use of non-human primates (NHPs) for translational research is a key component of the Institute's efforts to achieve these goals.

NHP species are the preferred model for many pre-clinical studies because they approximate the human in physiology and genetics more closely than other animal models. The most commonly used NHP species in immunological research are the Cynomolgus macaque (*Macaca fascicularis*), the Rhesus macaque (*Macaca mulatta*), the Baboon (*Papio hamadryas*), and the Pigtail macaque (*Macaca nemestrina*). These species are extremely powerful models to 1) evaluate the safety and efficacy of candidate vaccines against human pathogens, including NIAID Category A, B, and C Priority Pathogens (<http://www3.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/research/CatA.htm>); 2) develop and evaluate new strategies to prolong the survival of, and induce immune tolerance to, transplanted organs and cells; and 3) study the pathogenesis of, and evaluate novel immune-based therapies for, infectious and immune-mediated disease. However, many immune-monitoring, -depleting, and -modulating reagents developed for mouse or human research and clinical use either do not cross-react, react sub-optimally, or are not available for use in NHP research, as is the case for many immune-based therapeutics held or developed by pharmaceutical companies and slated for clinical trials. In addition, immune-monitoring reagents that have been optimized for NHP research are generally not commercially available.

In FY2004, the NIAID awarded a contract to Beth Israel Deaconess Medical Center (BIDMC) for the establishment of a NHP Reagent Resource to meet the specialized reagent needs of the NHP research community (Contract No. N01-AI-40101; Part I of RFP NIH-NIAID-DAIT-04-24 titled Development of Immune Monitoring Reagents and MHC Typing Technologies for Non-human Primates - <http://www.niaid.nih.gov/contract/archive/RFP0424.pdf>). This contract also supports the NHP Reagent Resource public website and a searchable database of information about commercial reagents that cross-react with NHP species. The reagents and activities supported by the NIAID contract can be found at (<http://nhpreagents.bidmc.harvard.edu/NHP/default.aspx>). The current NHP Reagent Resource contract has over 100 registered users and provides an invaluable service to the NHP research community. To date, over 35 reagents have been developed for production or obtained for distribution under this contract and approximately 200 shipments are made annually.

This contract will support the continued operation and management of the NHP Reagent Resource to facilitate and accelerate immunological research in this valuable animal model through the development, evaluation, production and distribution of key immunologic reagents to the NHP research community, including reagents to 1) monitor or determine the dynamics and parameters of immune responses *in vitro* and *in vivo*, 2) deplete select immune cells *in vivo*, and 3) therapeutically modulate the immune response *in vivo*.

2. SCOPE:

The Contractor shall operate and manage the NHP Reagent Resource to develop, obtain, evaluate, produce, and distribute a wide variety of reagents to facilitate and advance NHP research in infectious and immune-mediated diseases.

- Examples of reagent categories include monoclonal antibodies (mAbs), receptor/ligands, chimeric/recombinant proteins or mAbs, transformed cell lines, transforming virus stocks, and other novel state-of-the-art reagents required for *in vivo* or *in vitro* 1) evaluation or monitoring of immune responses; 2) depletion of select immune cells; and 3) modulation or alteration of immune responses. The development of new reagents and the modification of existing reagents for use in NHP research will be supported.
- The NHP species that are the primary focus of this RFP are the 1) Cynomolgus macaque (*Macaca fascicularis*); 2) Rhesus macaque (*Macaca mulatta*); 3) Pigtail macaque (*Macaca nemestrina*); and 4) Baboon (*Papio hamadryas*). Reagent development for additional species of non-human primates may be required to meet the needs of the Government or the research community.
- Under unusual circumstance, a reagent may be provided for limited use for other than NHP research, e.g. by an investigator who has provided a given mAb cell line to the Contractor and requires material for his/her own non-NHP research use.
- Costs for reagent production are recovered from investigators only for large quantities of reagents, typically gram quantities used for *in vivo* experiments. All other costs are covered under the contract.
- Initial distribution capacity shall be for approximately 300 shipments per year, with potential to increase to 400 shipments per year.
- The base period of performance for this contract is five (5) years. The Government reserves the right to exercise the option to extend the contract period of performance for up to an additional two (2) years to continue the services required for the base period.

The major scope of functions to be performed by the contractor are:

- A. Identification, Prioritization and Approval of Candidate Reagents**
- B. Reagent Development Proposals**
- C. Reagent Development**
- D. Reagent Production, Purification, and Quality Control**
- E. Distribution, Tracking and Inventory**
- F. NHP Reagent Resource Website and Communications with the NHP Research Community**

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 (SOW) below. Specifically, the Contractor shall:

A. IDENTIFICATION, PRIORITIZATION and APPROVAL OF CANDIDATE REAGENTS

1. Identify, Assess, and Prioritize Reagents needed by the NHP research community

- a. Within 30 calendar days of the contract effective date, submit, for Project Officer review, an Initial Prioritized List of Candidate Reagents for development or modification, or to obtain for distribution. Proposed reagents must have direct relevance to NHP models of transplantation, vaccine or adjuvant development and evaluation, or immune-mediated and infectious diseases, and may include monoclonal antibodies (mAb), receptors/ligands, chemokines/cytokines, chimeric/recombinant proteins and mAbs, transformed cell lines, transforming virus stocks, immunoglobulin (Ig) standards, and other novel, state-of-the-art reagents for application to:
 - i. *in vitro*, *in vivo*, and *ex vivo* detection or imaging of NHP cell surface, intracellular, or soluble molecules to monitor immune responses including, but not limited to, flow cytometry, immunohistochemistry, ELISpot, and ELISA methodologies;
 - ii. *in vivo* immune-modulation or immune-based therapeutic (e.g., immune agonist or antagonist); and
 - iii. *in vivo* depletion of select immune cells or subsets of cells.

For each candidate reagent recommended by the Contractor provide, at a minimum, the following:

- i. suitability, proposed use, and relevant background information
- ii. feasibility and special considerations for the development or acquisition, including any exceptional cost or Intellectual Property Rights considerations
- iii. a justification of need, including a list of any investigators who have expressed a need
- iv. proposed developmental approach and alternative approaches, and the degree of developmental difficulty
- v. additional information as requested by the Project Officer

In addition, for proposed candidate antibodies, discuss and justify whether: 1) the immunizing protein or DNA should be of NHP origin (NHP-specific), rather than human origin; and 2) the resulting mAb, if proposed for *in vivo* use, should be a mouse/human or mouse/NHP chimeric antibody, or a NHP antibody. Provide similar species-specific justifications for the development of soluble molecules, such as cytokines, chemokines, or other ligands or soluble receptors designed for *in vivo* use.

- b. Within 30 calendar days of the Contract effective date, submit for Project Officer approval a Draft Candidate Reagent Ongoing Identification Plan comprised, at a minimum, of the following components: (i) the sources to be used to identify candidate reagents, including organizations/institutions and individual investigators involved in NHP research, pharmaceutical and biotechnology companies; (ii) the methods to be used to solicit

recommendations for candidate reagents and the frequency of the solicitation process; and (iii) a description of the materials, data and other information to be submitted in order to assess the potential utility and feasibility of candidate reagents for further development.

- c. Revise the Draft NHP Candidate Reagent Ongoing Identification Plan in accordance with Project Officer comments and submit the final plan within 15 calendar days of receipt of Project Officer comments.
- d. On an ongoing basis, identify candidate reagents needed by the NHP research community, provide an updated Prioritized List of Candidate Reagents with each Quarterly Progress Report and Annual Progress Report, and as requested by the Project Officer. The identification process may require the purchase or acquisition of commercial and/or non-commercial source antibodies or proteins for evaluation of reactivity or suitability.

Sources for the ongoing identification of candidate reagents shall include the NHP research community (see SOW 3.F. below); the NIAID NHP Reagent Resource External Scientific Advisory Group (ESAG), comprised of NHP investigators; and the NIAID NHP Reagent Resource Committee (NRC), comprised of NIH program staff designated by the Project Officer (see SOW Section 3.A.2a. below).

2. Review and Approval of NHP Candidate Reagents Recommended for Development

- a. NIAID External Scientific Advisory Group (ESAG) and NIAID NHP Reagent Resource Committee (NRC): The Project Officer oversees the NHP Reagent Resource operations and approves all reagents for development. The Project Officer will appoint two groups post award to provide recommendations to the Project Officer regarding reagent priorities including reagent needs of the scientific community and resource activities.
 - i. The NRC will be comprised of NIH program staff selected by the Project Officer.
 - ii. The ESAG will be appointed by the Project Officer and will be comprised of NHP investigators from the research community. The Contractor shall have an opportunity to provide recommendations of investigators to serve on the ESAG to the Project Officer within 15 calendar days of the contract effective date and throughout the Contract period.
- b. NHP candidate reagents recommended for development by the Contractor will be reviewed by the Project Officer and the ESAG and the NRC, as determined by the Project Officer. The Contractor shall respond to questions and requests for clarification and additional information from these entities during the review process.
- c. The Project Officer, with advice from the ESAG and/or the NRC, will determine those candidate NHP reagents to be developed by the Contractor. Candidate NHP reagents shall proceed to the development stage only after receipt of electronic Project Officer approval.

- d. For reagents approved for development and provided by third parties, the Contractor shall enter into Material Transfer Agreements (MTAs), where applicable, to specify rights and responsibilities with respect to intellectual property, reagent use for research purposes, data rights and publication of data generated under the contract.
- e. The Government may or may not elect to proceed with development of the particular reagents proposed by the Contractor based on the advice of the ESAG, NRC, and/or needs of the Government. In addition, the Project Officer may direct the Contractor to develop reagents identified and recommended by the ESAG or NRC, based on the needs of the Government.

B. REAGENT DEVELOPMENT PROPOSAL

1. Within 30 calendar days of electronic Project Officer approval for development of a Contractor proposed reagent or Project Officer request for development of a specific reagent, submit a detailed Draft Reagent Development Proposal delineating the following:
 - a. proposed methods, technologies and processes to be used for development
 - b. alternative or additional approaches, when required to ensure timely and successful development
 - c. performance milestones, decision checkpoints, and approximate timelines for the conduct and completion of each step in the reagent development
 - d. estimated direct costs for development, including materials, supplies and other required resources

Reagent development activities include optimization of purification procedures, formulation, and storage conditions for optimum stability and activity, where applicable, and may also require obtaining and/or modifying antibodies or reagents, e.g., generation of a select fluorochrome conjugate when a commercial reagent is not available. The scope of developmental technologies to be utilized may include, but is not limited to:

- i. recombinant methodologies to create chimeric mAbs or proteins
- ii. cloning of antibody genes and development or modification of expression vectors to optimize protein expression
- iii. cloning and sequencing of NHP genes
- iv. strategies for immunization and isolation of clones of desirable immunoglobulin subclasses, high production capacity and optimal cross-reactivity among NHP species
- v. adduct technologies for tagging proteins/antibodies for *in vitro* and *in vivo* uses (e.g., fluorophores and biotin modification)
- vi. production of fully NHP antibodies or humanized/primatized antibodies through the use or development of Ig transgenic mice, complementarity determining region (CDR) grafting, screening of fully human or NHP antibody libraries, or other technologies
- vii. creation and/or screening of antibody libraries

2. Draft Reagent Development Proposals will be reviewed by the Project Officer and by the ESAG and the NRC, as determined by the Project Officer. The Contractor shall respond to questions and requests for clarification and additional information.
3. Revise the Draft Reagent Development Proposals, if required, in accordance with Project Officer comments, and submit the final plan within 15 calendar days of receipt of Project Officer comments.

C. REAGENT DEVELOPMENT

The Contractor shall carry out the reagent development activities specified in the approved Reagent Development Proposals, adhering to the performance milestones and timelines, decision checkpoints, and proposed procedures, informing the Project Officer of any significant problems impeding progress or significant changes to the proposed plans, as they occur. Development activities shall include the following:

1. **Develop, obtain partially or fully developed reagents, and / or modify existing reagents**
2. **Validation /Evaluation:** At a minimum, validation and/or evaluation shall include reagent specificity, stability, activity, unique characteristics, and potency of the developed reagent prior to full production scale-up. Validation and evaluation shall encompass:
 - a. assessment of reactivity across multiple NHP species, where applicable.
 - b. development of new assays, reagents and standards, as determined by the Contractor in consultation with the Project Officer.
 - c. prioritization of validation/evaluation by the Contractor, in consultation with the Project Officer, to the most promising reagents of a given specificity (e.g. individual clones), particularly those with cross-species reactivity.
 - d. distribution of reagents to NHP researchers for evaluation prior to production scale-up, when appropriate and with Project Officer approval.
 - e. in some instances, production and purification process development (as specified in Section 3.D.1. of the SOW) may be warranted before validation or evaluation is completed, as determined by the Contractor in consultation with the Project Officer.

Examples of appropriate validation/evaluation methods include:

- i. *in vitro* testing with NHP cells or tissues, including flow cytometry
- ii. Ig isotyping
- iii. DNA sequence confirmation of recombinant products
- iv. *in vitro* biological activity assessment, including receptor blockade/modulation
- v. gel electrophoresis and isoelectric focusing
- vi. spectrometric and chromatographic analyses
- vii. *in vivo* testing in consultation with, and approval by, the Project Officer (see SOW Section 3.C.4.)

3. ***In Vitro* Assays and/or Protocols:** For reagents developed or obtained for distribution, or as required by the Government, develop and/or optimize *in vitro* assays and/or protocols, including controls, standards, and/or antibody pairs, as necessary. The Contractor shall evaluate and optimize the potency, specificity, and reproducibility of the assays developed.
4. ***In Vivo* Use Reagent Evaluation:** It is anticipated that *in vivo* evaluations shall be performed by, or in collaboration with, appropriate NHP researchers and in consultation with the Project Officer. Selection of investigators to conduct the *in vivo* evaluations shall be made in consultation with the Project Officer. Detailed plans for *in vivo* evaluation shall be submitted to the Project Officer for review and approval at the milestone time point specified in the approved Reagent Development Proposal. These plans shall include at a minimum: identification of investigators to conduct the studies, numbers of animals required, protocol, outcomes to be measured, timelines, and anticipated results.
5. **Identification, Development and Incorporation of New Processes, Approaches and Technologies:** To ensure state-of-the-art reagent development, quality control, and production capabilities, the Contractor shall keep abreast of and provide recommendations to the Project Officer for incorporation of new processes, approaches and technologies relevant to reagent development, production, or purification as they become available. Written recommendations for any substantive changes to technologies or processes shall include (i) detailed descriptions of new processes, approaches and technologies identified, (ii) their applicability to reagent development for NHP research within the scope of the contract, (iii) advantages over currently used processes, approaches and technologies, and (iv) associated costs for incorporation into the contract. Incorporation of any new processes, approaches and technologies shall be incorporated as determined by the Contractor, in consultation with the Project Officer.
6. **Additional Reagent-Related Services:** Identify additional needs of the NHP research community related to reagents and reagent usage and provide services to meet those needs, e.g. the provision of quality assessment programs for flow cytometry. Project Officer electronic approval is required before implementation of any additional services.

D. REAGENT PROCESS DEVELOPMENT, PRODUCTION, PURIFICATION, AND QUALITY CONTROL

1. **Reagent Production Process Development:** Provide production process development. Process development for the purposes of this solicitation means the activity developing optimum methods and procedures for the final production, purification, formulation, storage and batch reproducibility.
2. **Reagent Production:** Provide optimized production capabilities for both small-scale and large-scale reagent production. For purposes of this contract, small-scale mAb/chimeric protein production and purification is

defined as production of under 1.5 grams/year/mAb; large-scale production is defined as 1.5 grams or more/year/mAb.

Although production levels may vary significantly between specificities and individual clones and smaller amounts of protein may be adequate for some uses, the Contractor shall provide for the production and purification of at least three (3) small-scale production runs at any given time, at an estimated rate of 500 mg each of purified protein per four (4) months. In addition, the Contractor shall provide for the large-scale production and purification of a minimum of three (3) mAb specificities per year, assuming that at least 400 liters production, or the equivalent, per year total will be required. Although production and/or purification methods of reagents other than mAb may vary significantly, it is anticipated that mAbs production will require the greatest volume production runs.

3. Purification, Formulation, Storage Requirements and Batch

Reproducibility: Provide for optimized purification, formulation, batch reproducibility and storage requirements of reagents.

Although GMP grade material is not required, low endotoxin levels, as to be specified by the Project Officer in consultation with the Contractor post-award, shall be required for *in vivo* use reagents. In addition, all products shall be provided sterile, where applicable.

4. Quality Control/Quality Assurance (QC/QA): Establish, implement and monitor adherence to QA and QC procedures for each product line and batch. QC/QA procedures shall include, where applicable, characterization as to purity, concentration, specificity, stability, biological activity, potency, endotoxin level, sterility, batch reproducibility and other parameters as determined by the Contractor in consultation with the Project Officer.

5. Maintenance of Reagent Development, Production, and Validation

Records: The contractor shall maintain detailed reagent development, production, and validation records for all assays, protocols, and reagents developed under the Contract. At a minimum, these records shall include: the laboratory notebooks; stock numbers and sources of materials, where applicable; methods and protocols; all assay results; and storage location and quantities of reference samples and materials produced. Reagent development and production process development records may be maintained in a non-electronic format. Production batch records, including final batch assay results shall be maintained electronically. Detailed procedure manuals of all production, assay and purification protocols and updates shall also be maintained electronically and made available to the Project Officer electronically upon request.

6. Assistance for Small-Batch Production: On a case-by-case basis and with Project Officer approval, provide assistance to NHP investigators in small-batch (approximately 1.5 grams or less) production of existing antibodies or fusion proteins for *in vivo* pilot studies. For any such assistance, individual investigators shall be responsible for costs involved in pilot production runs.

E. RECEIPT, STORAGE, DISTRIBUTION, TRACKING, AND INVENTORY OF BIOLOGICAL MATERIALS

- 1. Receipt, Storage and Inventory of Biological Materials:** Develop, implement and maintain adherence to protocols and systems to: (a) receive and store all biological materials, including cell lines, reagents, proteins, and vectors; (b) prepare and label aliquots of cell lines, vectors, and reagents developed; (c) provide for reliable, continuous, storage of all biological materials under appropriate conditions, including storage back-up systems; and (d) maintain an accurate inventory of all biological materials.

2. Electronic Reagent Distribution Tracking and Reporting Systems:

- a. Develop and/or establish and maintain, using commercially available software, one or more secure electronic databases and backup systems and associated protocols for tracking and reporting on multiple activities, including: inventory of all biological materials and reagents; Material Transfer Agreements (MTAs); quantities of reagents available for distribution to investigators; registered users; reagent requests received; shipments completed and pending; and timelines for processing and filling reagent requests.
- b. Within 30 calendar days of the contract effective date, submit, for Project Officer review, a Draft Tracking and Data Management Plan, including database requirements and format of the backup system. The Draft Tracking and Data Management Plan shall include all databases required under the Contract, if more than one database is utilized. Revise the Draft Plan in accordance with Project Officer comments. Submit the Final Plan within 20 calendar days of receipt of Project Officer comments, and ensure that electronic database systems and associated SOPs are implemented no later than 90 calendar days from the contract effective date.
- c. Update the database on at least a weekly basis and provide secure web-based access to the Project Officer or, in lieu of providing secure web-based access, provide electronic updates on a monthly basis that shall include the status of all reagents under production and development, reagent requests received, shipments completed, and pending shipments.

3. Reagent Distribution

- a. Standard Operating Procedures (SOPs) and Systems for Submission of Reagent Requests:
 - i. Obtain and maintain a completed User Registration Form from each investigator before any reagent request is approved for processing. The User Registration Form shall be signed by the investigator and the institutional business official and, at a minimum, state that all reagents provided by the NHP Reagent Resource will be used only for NHP research and not distributed to third parties, and agree to acknowledge the NHP Reagent Resource contract in all publications

resulting from the use of the reagents provided. User Registration Forms shall remain valid unless the investigator changes institutions, in which case a new User Registration Form must be submitted. Provision of some reagents may require a Material Transfer Agreement (MTA), as determined by the Contractor, in consultation with the Project Officer.

- ii. Develop and/or maintain and ensure implementation of and compliance with a system for individual reagent requests from registered investigators. Investigators must complete an electronic Reagent Request Form for each request. The Reagent Request Form shall, at a minimum, provide a brief description of the research project and intended use of the reagent requested, amount of material required and, if applicable, the grant/contract number for the research project and the sponsoring organization. In addition, the shipping address, express delivery billing account number and investigator contact information must be included.
- iii. Under unusual circumstance, a reagent may be provided for limited use for other than NHP research, e.g. by an investigator who has provided a given mAb cell line to the Contractor and requires material for his/her own non-NHP research use. All requests for materials that are not explicitly for NHP research use must be electronically approved in advance by the Project Officer. In addition, under no circumstances shall materials be provided for human diagnostic or clinical use, or for use in making clinical treatment decisions.
- iv. Costs for reagent production are recovered from investigators only for large quantities of reagents, typically gram quantities used for *in vivo* experiments. Reagents and quantity of reagents requiring cost recovery will be determined in consultation with and approval by the Project Officer.
- v. Initial distribution capacity shall be for approximately 300 shipments per year, with potential to increase to 400 shipments per year.

b. Reagent Packaging and Shipping:

- i. Maintain sufficient inventory so that most reagents are shipped within 7 calendar days of processing of Reagent Request Forms. In general, "backorders" shall be rare events and shipments shall be completed in 14 to 30 calendar days after processing of Reagent Request Forms.
- ii. The Contractor shall provide a package insert detailing reagent specifications and guidelines for use.
- iii. Obtain appropriate licenses and permits required by local, State and Federal authorities for the safe transport of biological materials, as well as appropriate interstate, intrastate and foreign import/export shipping licenses and permits.
- iv. Supply shipping cartons, cushioning and insulation materials, necessary labels (e.g. fragile), and all other supplies necessary to ensure safe and intact arrival of reagents in accordance with all domestic and international requirements.

- v. Request investigators to pay for delivery costs to their institution, except when the Contractor requests that an investigator evaluate a reagent. Under the latter circumstances, the Contractor shall provide cost of shipping.
- vi. Provide investigators with shipping information on the day of shipment. Request notification that reagents have been received; in instances where reagents are not delivered or are damaged, ship and confirm receipt of replacement reagents.

F. NHP REAGENT RESOURCE WEBSITE AND COMMUNICATIONS with the NHP RESEARCH COMMUNITY

1. Establish, maintain and update the NHP Reagent Resource public website

At a minimum, this website shall contain:

- a. information on the background, purpose and scope of activities of the NHP Reagent Resource
- b. reagents available, technical specifications and use protocols
- c. registration information and procedures
- d. procedures for online reagent requests
- e. online user feedback capability
- f. an updated searchable database of cross-reactive antibodies that are available commercially or non-commercially

With respect to item f. above, it is not the intent of the Government to duplicate public databases and, therefore, the Contractor may be directed by the Project Officer to contribute to and/or link to existing publicly accessible websites for cross-reactive antibody information.

- 2. Within 30 calendar days of the contract effective date, submit, for Project Officer review, a detailed draft of the website contents and plans to inform the scientific community of the existence of the website and resource, in the event the contract transitions to a new Contractor. Revise the draft contents to accommodate Project Officer comments. Submit the final contents within 15 calendar days of receipt of Project Officer comments, and ensure website posting no later than 90 days from the contract effective date.
- 3. Maintain ongoing communications with and outreach to the NHP research community to promote awareness of the resources and services available under this contract, identify reagent needs (See Statement of Work A.1.d. above), and solicit feedback on the reagents and services provided. This shall include at least one presentation, poster session or other similar activity per year at a relevant scientific society meeting/workshop. Other activities related to increasing awareness of the resource or to solicit input about the reagent needs of the research community, such as advertising, may be implemented by the Contractor following approval by the Project Officer.

G. SCIENTIFIC AND TECHNICAL PERSONNEL

Provide and maintain qualified and appropriately trained scientific and technical personnel necessary to carry out the functions specified in the Statement of Work. This shall include:

- 1.** Principal Investigator: The Contract Principal Investigator will have overall responsibility for the scientific and technical leadership of the NHP Reagent Resource and the management, coordination and integration of all contract activities, including directing development and production and recommending modifications to the project requirements and timelines. The Principal Investigator shall have demonstrated expertise in leading state-of-the-art immunologic reagent development and production projects of similar scientific scope and complexity.
- 2.** Other scientific and technical personnel with experience and expertise necessary to perform all functions specified in the SOW, including at a minimum expertise in protein expression, production, and purification; molecular biology and gene cloning; immunology; and IT database and website administration;
- 3.** Provide appropriate personnel with responsibility for overall business and financial management, integration and coordination of the contract and activities carried out under subcontracts.

H. PROJECT MANAGEMENT

1. Overall Project Management

The Contractor shall provide for the following:

- a. The overall management, integration and coordination of all contract activities, including the management and coordination of activities carried out under subcontract, collaborative, and fee-for-service arrangements and overall business and financial management, integration and coordination of the contract and activities carried out under subcontracts.
- b. A technical and administrative infrastructure to ensure the efficient planning, initiation, implementation and timely completion of all projects carried out under this contract and effective communications with the Project Officer and the Contracting Officer.
- c. A Principal Investigator with responsibility for overall project management and communications; making a wide range of decisions about staffing, priorities, and intellectual property issues; tracking, monitoring and reporting on project status and progress; and recommending modifications to project requirements and timelines, including projects undertaken by subcontractors, collaborators, and fee-for-service providers.
- d. A Project Manager may be included with responsibility for assisting in managing and coordinating the day-to-day operations of contract activities, including participating in the development and implementation of actions to improve progress and timeliness of the

performance of contract activities and answering technical questions from the scientific community.

2. Contract Meetings and Teleconferences

a. Monthly Meetings/Teleconferences with the Project Officer

Plan and conduct monthly meetings or teleconferences with the Project Officer to review overall progress, identify scientific and technical problems and develop approaches for their resolution, discuss any issues relevant to the scientific or financial management of contract activities, and future plans. The monthly meetings/teleconferences shall be attended by the Principal Investigator and the Project Officer. The Contracting Officer may also participate in the monthly meetings/teleconferences as needed, depending on topics to be discussed. The schedule for monthly meetings/teleconferences will be established by the Project Officer, in consultation with the Contractor, post-award.

The Contractor shall be responsible for:

- i. preparing and distributing to all meeting/teleconference participants agendas and relevant background information/data no less than 2 calendar days in advance of each meeting/teleconference.
- ii. preparing and distributing to all meeting/teleconference participants written summaries of major decisions and action items resulting from meetings/teleconferences within 2 calendar days of meeting/teleconference completion.

b. ESAG and NRC Meetings/Teleconferences

Plan and conduct one or more meetings or teleconferences per year with the ESAG and the NRC to: provide updates on progress and the status of projects; obtain input on reagent needs of the NHP research community; and review future plans. These meetings/teleconferences shall include the Principal Investigator, key scientific and technical personnel of the Contractor and any subcontractors, as determined by the Contractor in consultation with the Project Officer. The schedule and frequency for ESAG and NRC meetings/teleconferences, and whether the meetings/teleconferences with the two groups will be held jointly or separately, will be established by the Project Officer, in consultation with the Contractor, post-award.

The Contractor shall be responsible for:

- i. preparing and distributing to all meeting/teleconference participants agendas and relevant background information/data no less than 2 calendar days in advance of each meeting/teleconference.
- ii. preparing and distributing to all meeting/teleconference participants written summaries of major decisions and action items

resulting from meetings/teleconferences within 7 calendar days of meeting/teleconference completion.

c. Annual Meetings

Plan and conduct annual one-day meetings with the Project Officer, other NIAID staff designated by the Project Officer, and the Contracting Officer, to be held in the Bethesda, Maryland area or at the Contractor's site as determined by the Project Officer in consultation with the Contractor. Annual meetings shall be attended by the Principal Investigator and key scientific personnel of the Contractor and any subcontractors, as determined by the Contractor, in consultation with the Project Officer.

The Contractor shall be responsible for:

- i. preparing and distributing to all meeting participants agendas and relevant background information/data no less than 2 calendar days in advance of each meeting.
- ii. preparing and distributing to all meeting participants written summaries of major decisions and action items resulting from each meeting within 7 calendar days of meeting completion.

I. Intellectual Property

- a. The Contractor shall be solely responsible for the timely acquisition of all appropriate proprietary rights, including intellectual property rights, and all materials needed to perform the project. Before, during, and subsequent to the award, the U.S. Government is not required to obtain for the Contractor any proprietary rights, including intellectual property rights, or any materials needed by the Contractor to perform the project. The Contractor is required to report to the U.S. Government all inventions made in the performance of the project, as specified in FAR 52.227-11 (Bayh-Dole Act).
- b. Contractors are expected to exercise their Bayh-Dole rights in a manner that does not conflict with the goals of this award or the intent of the Bayh-Dole Act to promote the utilization, commercialization and availability of U.S. Government-funded inventions for public benefit. Since the goal of this contract is to support the development of reagents for the NHP research community, the Contractor is strongly encouraged to ensure that the reagents developed under this contract are and remain accessible to the NHP research community.
- c. Individual and institutional intellectual property rights and rights to inventorship under U.S. patent law will not be affected by participation in this contract. The involvement of the NIH in the performance of this contract will not affect ownership rights of the participating parties beyond U.S. Government rights under any funding agreement as specified under 35 U.S.C. #202. All licensing agreements entered into by the Contractor for completion of any and all tasks listed in the STATEMENT OF WORK shall be transferable to the Government.
- d. Negotiate MTAs for efficient and advantageous utilization and distribution of reagents under the Contract.

J. FACILITIES, EQUIPMENT AND OTHER RESOURCES

Provide all the facilities, state-of-the-art laboratory equipment, standard operating procedures, training and other resources necessary to carry out all the functions specified in the Statement of Work.

K. INITIAL AND FINAL TRANSITIONS

1. Initial Transition:

- a. In the event of a new contractor, plan, coordinate and implement an orderly, secure and efficient initial transition of contract-generated materials, data and other documents from the incumbent contractor. A copy of the transition plan of the incumbent contractor will be provided within 5 calendar days of the contract effective date and will include detailed information regarding the status of reagent development and distribution activities, electronic database systems, and arrangements/agreements with third party suppliers. Contract-generated materials, data and other resources to be transitioned include the following:

- i. all Standard Operating Procedures for production, purification, formulation, storage, distribution, tracking and reporting of reagents;
- ii. all genetic, biochemical, and biological materials acquired, developed, or inventoried;
- iii. databases, related software and source codes of all reagent requests, registered users, tracking and inventory.

- b. Draft Initial Transition Plan

Within 14 calendar days of the contract effective date, submit the Draft Initial Transition Plan for Project Officer review and approval. This draft plan shall detail the specific transition activities to be undertaken, including the development of new Material Transfer Agreements or other written agreements with third party suppliers, provide a timeline for implementation of each transition activity, and describe the capabilities and responsibilities of Contractor staff who will be assigned to implement the plan. The Project Officer will review and provide comments on the Draft Initial Transition Plan within 7 calendar days of receipt.

- c. Final Initial Transition Plan

Revise the Draft Initial Transition Plan in accordance with Project Officer comments, submit the Final Initial Transition Plan within 28 calendar days of the contract effective date, and implement the approved plan to ensure full operation of the NHP Reagent Resource within two (2) months of the contract effective date.

2. Final Transition:

a. Draft Final Transition Plan

No later than six (6) months prior to the completion date of the contract, unless otherwise directed by the Contracting Officer, submit, for Project Officer review and approval, a Draft Final Transition Plan to provide for the orderly, safe and efficient transfer of contract-generated materials, data and other resources to a successor contractor or to the Government. This shall include: all data, materials and other resources specified in Statement of Work Section 3.1.1.a. above; a detailed description of transition activities to be carried out, a timeline for the implementation of each transition activity, and a description of the capabilities and responsibilities of Contractor staff who will be assigned to implement the plan.

b. Final Transition Plan

Revise the Draft Final Transition Plan in accordance with Project Officer comments and submit the Final Transition Plan no later than two (2) months prior to the contract completion date, unless otherwise directed by the Contracting Officer. Implement the approved plan to ensure transfer of all contract-generated materials, data and other resources by the contract completion date, and maintain full operational capacity until the completion date of the contract.

L. OPTIONS

Option to Extend Term of the Contract

The Government reserves the right to exercise the option to extend the contract period of performance for one (1) year to continue the services required during the 5 year base period. This option may be exercised twice during the life of the contract.

ATTACHMENT 4: REPORTING REQUIREMENTS AND DELIVERABLES

Non-human Primate Reagent Resource RFP-NIAID-DAIT-NIHAI2008034

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one (1) hardcopy of each report shall be submitted to the Contracting Officer, unless otherwise specified.

A. Technical Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the DELIVERIES ARTICLE in SECTION F.

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

Format of Cover page: All reports shall include a cover page prepared in accordance with the following format:

- Contract Number and Project Title
- Period of Performance Being Reported
- Contractor's Name and Address
- Author(s)
- Date of Submission
- Delivery Address

1. Quarterly Progress Report

This report shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full three months of performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full calendar months. Each Quarterly Progress Report shall include the following:

- a) An executive summary, to include, but not necessarily limited to:
 - 1) A brief overview of the status of the project, including personnel, number of requests and shipments, new reagents available for shipment, and research and development activities.
 - 2) A brief overview of work that was completed during the current reporting period, justification for failure to complete intended work, obstacles encountered and/or resolved, any financial or technical problems, IP issues, and Key Personnel changes since the previous reporting period, including a

biosketchn of any new Key Personnel and documentation of prior approval by the Contracting and Project Officers (as required by Section G. Article G.2.).

- b) A full description to include, but not limited to:
- 1) The work performed during the reporting period, including status of all reagents under development.
 - 2) Relation between the accomplishments and the goals and/or milestones of the contract.
 - 3) A full disclosure of the results obtained during the performance period, explanations of any differences between planned and actual progress, and, if necessary, what corrective steps are planned or have been implemented.
 - 4) Inquiries/suggestions for development of new reagents from the NHP scientific community.
 - 5) An updated, Prioritized List of Candidate Reagents for development with the status including new reagents, with justifications, identified and recommended for development/production.
 - 6) Website updates since the last reporting period.
 - 7) Numbers of newly registered users.
 - 8) Feedback or follow-up from users.
 - 9) Shipment records summarized in table form for reagents, including:
 - i) Identification of the item shipped
 - ii) Quantity of item shipped
 - iii) Date of shipment
 - iv) Name and Institution of recipient
- c) Copies of manuscripts (published or unpublished) and abstracts derived from the research performed under the contract during the performance period.
- d) A full disclosure of intent to file patent applications or copyrights within or outside the U.S. on procedures or discoveries utilized, derived or established by the work supported under this contract; full disclosure of patent applications or copyrights filed, as well as copies of patent or copyright applications. All disclosures shall follow the guidelines established by the NIAID, NIH and outlined at the NIAID invention reporting website <http://www.niaid.nih.gov/ncn/sop/contracts/invention.htm> .

2. Annual Progress Report

This report includes a summation of the results of the entire contract work for the period covered. An Annual Progress Report will not be required for the period when the Final Report is due. A Quarterly Progress Report shall not be submitted when an Annual Progress Report is due.

The format and content shall be the same as the Quarterly Progress Report, but covering the entire year. In addition, include in summary format an additional listing of numbers of reagent shipments over the life of the contract and a listing reagents developed, obtained for modification or production, or

obtained for distribution for this annual reporting period and for the life of the contract. For any newly available reagents, provide a brief summary of specifications, methodologies used for development/production/purification, and anticipated annual volume requirements, projected production plans and inventory.

3. Final Report

This report is to include a summation of the work performed and the results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. An Annual Progress Report shall not be required for the period when the Final Report is due.

4. Summary of Salient Results

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

B. Other Reports and Deliverables

In addition to the above reports, the following are considered other reports and deliverables under this contract and are identified in the Statement of Work. A listing is included in the DELIVERIES Article in SECTION F.

(Check all that apply)

- ☐ **Human Subjects IRB Annual Report** (Form OMB No. 0990-0263- formerly Optional Form 310)
- ☒ **Invention Report Requirement** - *Use when Patent Rights (FAR 52.227-11 or 52.227-13) may be included in the contract.*
- ☒ **Source Code and Object Code** - *Use when software is used, produced, modified or enhanced*

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

SECTION D – PACKAGING, MARKING, AND SHIPPING

- ☐ Cannot be determined at this time
- ☒ Temperature controlled environment is required
- ☒ Shipments will be time sensitive/time critical
- ☐ International shipping will apply
- ☐ Shipping insurance is required
- ☐ Hazardous Materials shipping is applicable
- ☐ Other (list as necessary) _____
- ☐ N/A to this solicitation

ARTICLE F - DELIVERIES

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

The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract. will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below [and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract]:

a. Technical Progress Reports

Item	Reports	Recipients	Delivery Schedule
1.	Quarterly Progress Report	1 original to CO 1 elec. copy to PO and CO	Each report is due on/before the 15 th of each month following each reporting period.
2.	Annual Progress Report	1 original to CO 1 elec. copy to PO and CO	Due on or before the 30 th of the month following each anniversary date of the contract. Quarterly Progress Reports shall not be submitted when the the Annual Progress Report is due.
3.	Final Report and Summary of Salient Results	1 hard copy to PO 1 original to CO 1 elec. copy to PO and CO	Due on/before the completion date of the contract. Annual Progress Reports shall not be required when the Final Report is due.

b. Other Reports and Deliverables (Delivery Schedule)

Item	Deliverables	SOW Reference	Recipient	Delivery Schedule
1.	Draft Initial Transition Plan (if new contractor)	SOW 3. J.1.b.	1 elec. Copy to PO and to CO	14 calendar days of the contract effective date
2.	Final Initial Transition Plan (if new Contractor)	SOW 3.J.1.c.	1 elec. Copy to PO and to CO	28 calendar days of the contract effective date
3.	Recommendations for Investigators to serve on the NIAID ESAG	SOW 3.A.2a	1 electronic copy to PO	15 calendar days after contract effective date
4.	Prioritized List of Candidate Reagents	SOW 3.A.1a-1b	1 electronic copy to PO	30 calendar days after contract effective date
5.	Draft Candidate Reagent Ongoing Identification Plan	SOW 3.A.1c	1 electronic copy to PO	30 calendar days after contract effective date
6.	Final Candidate Reagent Ongoing Identification Plan	SOW 3.A.1d	1 electronic copy to PO	15 calendar days after receipt of Project Officer comments
7.	Draft Reagent Development Proposal	SOW 3.B.1	1 electronic copy to PO	30 calendar days after Program Officer approval of a reagent for development
8.	Final Reagent Development Proposal	SOW 3.B.3	1 electronic copy to PO	15 calendar days after receipt of Project Officer comments
9.	Updated Prioritized List of Candidate Reagents	SOW 3.A.1e	1 hard copy to CO 1 elec. copy to CO and PO	With each Quarterly and Annual Report and as requested by the Project Officer
10.	Draft Website Contents and Plan, with plans to inform the NHP community of new website, if new contractor	SOW 3.F.2	1 elec. copy to PO	30 calendar days after contract effective date, if new contractor
11.	Final Website Contents	SOW 3.F.2	1 elec. Copy to PO	15 calendar days after receipt of Project Officer comments
12.	Draft Data Electronic Management Plan	SOW 3.E.2.ii	1 elect copy to PO	30 calendar days after contract effective date;
13.	Final Data Electronic Management Plan	SOW 3.E.2.ii	1 elect. copy to PO	20 calendar days after receipt of Project Officer comments
14.	Monthly database update/status or provide real-time web-based secure access	SOW 3.E.2.iii.	1 elec. copy to PO	Monthly, by the 7 th calendar day each month, if not web-based access
15.	Agenda and Summary Monthly Meetings or Teleconferences with Project Officer	SOW 3.I.2.a.i-ii	1 elec. copy to PO and other participants	Agenda: 2 calendar days before meetings Summary: 2 calendar days following meetings
16.	Agenda and Summary for ESAG/NRC and Annual Meetings	SOW 3.I.2.b.i-ii 3.I.2.c.i-ii	1 elec. copy to all participants	Agenda: 2 calendar days before meetings Summary: 7 calendar days following meetings
17.	Draft Transition Plan	SOW 3.E.6iia	1 hard copy to CO 1 elec. copy to CO and PO	6 calendar months before the contract completion date

Item	Deliverables	SOW Reference	Recipient	Delivery Schedule
18.	Final Transition Plan	SOW 3.E.6iib	1 hard copy to PO 1 elec. Copy to PO	2 calendar months before the contract completion date
19.	Specifications for, and all inventory of, biological and genetic material developed, produced, or procured under the contract.	SOW 3. A, C, D, E	To be specified 30 days prior to contract completion	At contract completion
20.	All Standard Operation Procedures for reagent development and production and protocols for novel technologies developed under the contract	SOW 3. A,C,D,E	To be specified 30 days prior to contract completion	At contract completion
21.	Complete database and source codes for all data generated, including requester registrations, all request for reagents and all shipment records.	SOW 3. E, F	To be specified 30 days prior to contract completion	At contract completion
22.	All hardware, software and equipment purchased and used solely for tasks required by the contract.	SOW 3. A, C, D, E, F	To be specified 30 days prior to contract completion	At contract completion
23.	All licensing agreements entered into by the Contractor for completion of any or all of the research listed in this contract and proposed by the Contractor in its Statement of Work shall be transferable to the government upon completion of the contract.	SOW 3. A, C, D, E, F, H, I	To be specified 30 days prior to contract completion	At contract completion

**ATTACHMENT 5: ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS,
FORMAT FOR TECHNICAL PROPOSAL, and TABLE OF CONTENTS**

**Non-human Primate Reagent Resource
RFP-NIAID-DAIT-NIHAI2008034**

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, 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 are reminded that the total page limitation for the entire Technical Proposal is 150 pages including all appendices and attachments. Any pages in excess of this limit will be expunged from the proposal and will not be considered in the technical review.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1:

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

SECTION 2: TECHNICAL PROPOSAL OVERVIEW (2-3 pages)

Provide a brief overview of the proposed program, including:

- 1) A summary describing the scope of product development, production, distribution, and activities providing information to the NHP community.
- 2) A description of the activities to be performed by the Offeror and those that shall be provided by any proposed subcontractors, collaborators, or consultants, including the identification of the proposed subcontractors, collaborators, or consultants and a list of Key Personnel of the Offeror and the proposed subcontractors, collaborators, or consultants with degrees and titles.
- 3) A brief description of the facilities and other resources to be made available by the Offeror and any proposed subcontractors, collaborators, or consultants.

SECTION 3: TECHNICAL PLAN / APPROACH

Offerors shall provide the information outlined below, as part of their technical proposal. For each proposed subcontract or collaboration, the technical proposal must provide a detailed description of the subcontract or collaboration research plan and contribution to the overall proposal. The technical proposal should provide information on how the project is to be organized, staffed and managed and a complete description of the facilities, and the professional backgrounds of the proposed personnel, within the appropriate sections of the technical proposal.

A. Identify, Assess, and Prioritize Candidate Reagents needed by the NHP research community (SOW item 3.A).

Provide:

- 1) A prioritized list of candidate reagents with a detailed justification of need and special considerations for development of each candidate molecule. See Statement of Work Section 3.A.1.b. for required justifications. This list of candidate reagents must include at least six (6) unique specificities, with a minimum of one (1) specific example for each of the categories of reagents Section 3.A.1a.i.-iii. of the SOW. Reagents from additional categories of appropriate reagents identified by the Offeror may be included within the prioritized list. In addition, discuss strategies to identify the reagent needs of the NHP research community (SOW items 3.A.1.b. and d.).

B. REAGENT DEVELOPMENT PROPOSAL, REAGENT DEVELOPMENT and REAGENT PROCESS DEVELOPMENT, PRODUCTION, PURIFICATION, and QUALITY CONTROL (SOW items 3.B, 3.C, and 3.D)

Provide:

- 1) Separate sample development and production protocols for an *in vitro* and an *in vivo* candidate reagent. Include:
 - A. Scientific basis, detailed approaches, methods, and assays for validation/evaluation, optimization for small or large scale production, purification, formulation and quality control and storage
 - B. Performance milestones, decision checkpoints and timelines
 - C. Strategies for conducting *in vivo* evaluation
 - D. Alternative approaches or methods for problem solving including the advantages and disadvantages of the proposed approach
 - E. Specific examples of experience or expertise including a discussion of problems encountered and how they were overcome, when appropriate.

The proposed reagents should be from the Offeror's prioritized list of candidate reagents, but not necessarily ones of the highest priorities. They should be selected on the basis of the breadth or potential complexity of the developmental strategies required to demonstrate the Offeror's capabilities to fulfill the SOW.

Assume production runs of approximately 100 mg for the *in vitro* use reagent and 10g for the *in vivo* use reagent.

The Offeror shall not name or contact investigators for support of the *in vivo* evaluation, unless the investigator(s) is a subcontractor or collaborator otherwise named in the proposal.

- 2) The detailed approaches, scientific basis, advantages, disadvantages, and relevant experience for all development techniques the Offeror proposes to use under the contract that were not detailed in the two sample development and production protocols described above. These additional approaches include but are not limited to one or more of the examples under Section 3.B.1.i.-vii. of the Statement of Work.
- 3) Describe expertise for validation/evaluation methods and assays proposed for use under the contract that were not detailed in the two sample development and production protocols described above. The validation/evaluation methods include, but are not limited to, the examples under Section 3.C.2.i.-vii. of the Statement of Work.

E. Receipt, Storage, Distribution, Tracking, and Inventory of Biological Materials (SOW item 3.E)

Provide a detailed description of:

- 1) Proposed protocols for receipt, storage and inventory of biological materials
- 2) Proposed procedures for all data management, including handling reagent requests, registration of users, and distribution.
- 3) The proposed electronic database system(s) for tracking and reporting. Include proposed procedures for backup and updating the database.

F. NHP Reagent Resource Website and Communications with the NHP Research Community (SOW item 3.F)

Provide a detailed description of:

- 1) The types of information to be included on the public NHP Reagent Website, design/layout and key features that enhance usability.
- 2) Procedures for updating website information and backup.
- 3) Plans to maintain ongoing communications with and outreach to the NHP research community and to obtain feedback on resource reagents and services.

SECTION 4: SCIENTIFIC AND TECHNICAL PERSONNEL

The Technical Proposal should include all information relevant to document individual training, education, experience, qualifications and expertise necessary for the

successful completion of all contract requirements. Clearly identify who is to be assigned as Key Personnel.

A. Principal Investigator (PI): include experience and qualifications of the PI to plan, manage, and direct the activities to be carried out under this contract:

- CV, limited to 2-3 pages
- Qualifications and relevant training
- Previous experience with management of projects of similar size and complexity (limited to the past 5 years)
- Percentage of the total time the PI will be committed to the project.
- References to relevant publications
- Summary of related activities, including a summary of achievements based on project goals; ability to assess progress, in accordance with established tasks and timelines; ability to recommend modifications to reagent development or production and the overall research program, based on new information and/or new and improved approaches and technologies; ability to keep projects on time and on budget; and ability to successfully manage IP issues; and ability to secure and manage productive collaborations and/or subcontracts.

B. Key Scientific and Technical Personnel:

Describe the training, education, experience and qualifications of the senior scientific and technical personnel proposed, as well as the percentage of the total time each will be committed to the project. This includes staff of the Offeror and all proposed subcontractors. Please provide documentation to describe:

- Key Scientific and Technical Personnel (limit CVs to 2-3 pages)
- Qualifications and relevant training
- Previous experience with projects of similar size and complexity (limited to the past 5 years)
- References to relevant publications
- Summary of related activities

C. Other Personnel

Offeror(s) should demonstrate the related experience and the role of other personnel as needed to address the requirements of the SOW.

SECTION 5: PROJECT MANAGEMENT

- 1) Provide a plan for project organization, staffing, and management in relation to the planning, initiation, implementation, conduct, monitoring and completion of tasks identified in the SOW. Describe in detail the responsibilities and level of effort for all proposed personnel who will be assigned to the contract, including proposed subcontractors and consultants. Provide an administrative and technical framework indicating clear lines of authority and responsibility for all proposed personnel. If consultants and/or subcontractors are proposed, include a plan to manage, coordinate, and oversee the work performed by consultants and/or subcontractor(s) and any methods and/or documented ability to identify and add new subcontractors or collaborators as needed. Include a chart of the proposed organizational and management structure for the project.

- 2) Outline how the contract PI will communicate with the Project Officer and Contracting Officer and how the PI will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities), including methods for prioritization.

SECTION 6: 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 SOW, including:

- 1) Location and features of facilities including a floor plan and a list of equipment and resources dedicated to the project for the prime contractor and any proposed subcontractors (lease or ownership information should be provided).
- 2) Identification and description of all support resources (including Information Technology systems) which will be required to effectively complete the Statement of Work.

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 each 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, if applicable.
- 2) **Biological Agents or Toxins**
The Technical Proposal should include a plan for biohazard safety and security requirements, if applicable.
- 3) **Sharing Research Data (Plan)**
Section L of the RFP specifies the minimum documentation requirements for Data Sharing. 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 6: ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS

Non-human Primate Reagent Resource RFP-NIAID-DAIT-NIHAI2008034

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

A) Technical Cost Assumptions

The Government does not have exact numbers of products to develop nor the specific quantities and related costs of production. The Offerors should assume that:

- 1) Approximately 40 previously developed and produced unique reagents will be inventoried and distributed in the first year of the contract. Storage of biological materials inventoried in the first year of the contract will require approximately 10 cubic feet of -80° centigrade storage space; 8,000 vial liquid nitrogen freezer storage space; and 20 cubic feet of 4°C storage space.
- 2) Approximately nine (9), small-scale production runs a year for either mAb or chimeric proteins will be required.
- 3) Approximately three (3) *in vivo* use reagents requiring multiple, large-scale production will be required in year one (1). However, assume all production and purification costs for large-scale production will be recovered from investigators who receive these reagents.
- 4) Individual shipments will be approximately 300 the first year. Investigator requesting reagents will pay all shipping costs to their institution.

- 5) A minimum of five (5) reagents will be under various stages of development at any one time.
- 6) Assume that any *in vivo* evaluations will require all costs, except the purchase of the animals. Shipping costs will be incurred. Assume six (6) non-human primates a year will be used for evaluation.
- 7) Community Outreach: Advertising costs to promote use of the Resource by the research community for up to (2) advertisements per year in appropriate journals.

B) Travel

- 1) Annual Meeting with Project Officer and NIAID Staff: Offerors shall include travel costs for the PI and 1-2 scientific staff and/or subcontractors or collaborators to attend a one-day meeting in Bethesda, Maryland.
- 2) Scientific Meetings: Offerors shall include travel costs for the PI and 1-2 scientific staff to attend one (1) domestic scientific meeting per year, on a topic related to the contract Statement of Work.
- 3) Community Outreach: Offerors shall include travel costs for the PI and/or 1-2 scientific staff to attend one to two (1-2) domestic scientific meetings per year to present the Resource and gather community feedback.

SECTION 4 - OPTIONS

Assume options to extend services as described for the base period of the contract will be exercised two (2) times for one (1) year each.

SECTION 5 - 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) 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.