

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

**RFP-NIH-NIAID-DAIT-08-13**  
**NIH Tetramer Facility**

**OMB Control Number 0990-0115**

1. <b>OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE FOLLOWING WEBSITE FOR ANY SOLICITATION AMENDMENTS. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.</b> <a href="http://www.fedbizopps.gov/">http://www.fedbizopps.gov/</a>		
2. <b>SECTION A – SOLICITATION/CONTRACT FORM -- PURCHASE AUTHORITY: FAR 1.602-1</b> <b>NOTE: The issuance of this solicitation does not commit the government to an award.</b>		
3. <b>Issue Date:</b> 01/31/2007	4. <b>Due Date:</b> April 30, 2007 <b>Time:</b> 4:30PM Local Time Bethesda, MD	5. <b>Small Bus. Set-Aside:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <b>8(a) Set-Aside:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <b>NAICS #:</b> 541710 (See Part IV, Section L.)
6. <b>Just In Time:</b> <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes (See Part IV, Section L.)	7. <b>Number of Awards:</b> <input checked="" type="checkbox"/> Only 1 Award <input type="checkbox"/> Multiple Awards	8. <b>Technical Proposal Page Limits:</b> <a href="#">See Section J, Attachment 5,</a> <a href="#">Packaging and Delivery of Proposal</a> <a href="#">Section J, Attachment 1</a>
9. <b>Issued By:</b> Aglae Cantave Contract Specialist Office of Acquisitions, NIAID, NIH 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	<input checked="" type="checkbox"/> <b>NIAID reserves the right to make awards without discussion.</b>	
	10. <b>Options:</b> <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes (See Part IV, Section L.)	11. <b>Period of Performance:</b> <b>12/31/2007-12/30/2012</b>
12. <b>Primary Point of Contact:</b> <b>Name :</b> Aglae Cantave <b>Phone:</b> 301-402-5825 <b>Fax:</b> 301-480-4675 <b>E-Mail:</b> <a href="mailto:ACantave@niaid.nih.gov">ACantave@niaid.nih.gov</a>	13. <b>Secondary Point of Contact:</b> <b>Name:</b> Charles Grewe <b>Phone:</b> 301-496-0612 <b>Fax:</b> 301-402-0972 <b>E-Mail:</b> <a href="mailto:grewec@niaid.nih.gov">grewec@niaid.nih.gov</a>	14. <b>Protest Officer:</b> See Section L.1., Paragraph j. Service of Protest.
15. <b>COLLECT CALLS WILL NOT BE ACCEPTED. FACSIMILE SUBMISSIONS ARE NOT ACCEPTABLE.</b>		
16. Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See Attachment 13, Proposal Summary and Data Record, NIH, 2043)		
17. <b>Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract.</b> ( <a href="http://www.ccr.gov">http://www.ccr.gov</a> )		
<b>18. DELIVERY ADDRESS INFORMATION</b>		
19. <b>Hand Delivery or Overnight Service:</b> Aglae Cantave Office of Acquisitions, NIAID, NIH 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	20. <b>U.S. Postal Service or an Express Delivery Service</b> Aglae Cantave Office of Acquisitions, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612	
21. The <b>Official Point of Receipt</b> for the purpose of determining timely delivery is the address provided in Block 19, above. The original paper copy with original signatures is the official copy for recording timely receipt. If the original paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with FAR 15.208 entitled " Submission, Modification, Revision, and Withdrawal of Proposals." <b>FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.</b>		

## DETAILED TABLE OF RFP CONTENTS

PART I - THE SCHEDULE	4
SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS .....	5
ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES .....	5
ARTICLE B.2. PRICES/COSTS .....	5
ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS .....	5
ARTICLE B.4. ADVANCE UNDERSTANDINGS.....	5
SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT .....	5
ARTICLE C.1. STATEMENT OF WORK .....	5
ARTICLE C.2. REPORTING REQUIREMENTS .....	5
ARTICLE C.3. INVENTION REPORTING REQUIREMENT.....	6
SECTION D - PACKAGING, MARKING AND SHIPPING.....	6
SECTION E - INSPECTION AND ACCEPTANCE .....	7
SECTION F - DELIVERIES OR PERFORMANCE .....	7
ARTICLE F.1. DELIVERIES.....	7
ARTICLE F. 2. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998).....	7
SECTION G - CONTRACT ADMINISTRATION DATA.....	7
ARTICLE G.1. PROJECT OFFICER.....	7
ARTICLE G.2. KEY PERSONNEL.....	8
ARTICLE G.3 . INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT .....	8
ARTICLE G.4 . GOVERNMENT PROPERTY .....	9
ARTICLE G.5 . POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE .....	9
SECTION H - SPECIAL CONTRACT REQUIREMENTS .....	10
ARTICLE H.1 . HUMAN SUBJECTS .....	10
ARTICLE H.2 . HUMAN MATERIALS .....	10
ARTICLE H.3. RESEARCH INVOLVING HUMAN FETAL TISSUE .....	10
ARTICLE H.4 . RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (Including Human Gene Transfer Research).....	11
ARTICLE H.5 . CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH .....	11
ARTICLE H.6 . NEEDLE EXCHANGE.....	12
ARTICLE H.7 . ANIMAL WELFARE .....	12
ARTICLE H.8 . SUBCONTRACTING PROVISIONS .....	12
ARTICLE H.9 . SALARY RATE LIMITATION LEGISLATION PROVISIONS .....	13
ARTICLE H.10 . INFORMATION SECURITY .....	13
ARTICLE H.11 . ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS .....	16
ARTICLE H.12 . ENERGY STAR REQUIREMENTS .....	17
ARTICLE H.13. PUBLICATION AND PUBLICITY .....	17
ARTICLE H.14 . PRESS RELEASES.....	17
ARTICLE H.15 . REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE .....	17
ARTICLE H.16 . YEAR 2000 COMPLIANCE .....	18
ARTICLE H.17 . ANTI -LOBBYING.....	19
ARTICLE H.18 . LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES .....	19
ARTICLE H.19 . OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES .....	20
ARTICLE H.20 . SHARING RESEARCH DATA.....	20
ARTICLE H.21 . HOTEL AND MOTEL FIRE SAFETY .....	21
ARTICLE H.22 . PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES .....	21
ARTICLE H.23. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH	
ARTICLE H.24 . NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH .....	22
ARTICLE H.25 CONSTITUTION DAY.....	22
ARTICLE H.26. PRIVACY ACT.....	22
PART II - CONTRACT CLAUSES	23
SECTION I - CONTRACT CLAUSES .....	23
ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES.....	23

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES .....	234
ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT.....	25
PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS	28
SECTION J - LIST OF ATTACHMENTS.....	28
PART IV - REPRESENTATIONS AND INSTRUCTIONS .....	30
SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS.....	300
SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS .....	31
SECTION M - EVALUATION FACTORS FOR AWARD .....	72

## PART I - THE SCHEDULE

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

## **SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS**

### **ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES**

This contract provides for the operation of a Major Histocompatibility Complex (MHC) Tetramer Facility. This facility will provide synthesis and distribution of soluble MHC-peptide tetramer and related reagents to the global research community. Such reagents include mouse, non-human primate, and human MHC class I monomers and tetramers; custom-made mouse, non-human primate, and human class II tetramers; non-classical MHC TL, Qa-1, and mouse and human CD1 monomers and tetramers; CD1d and other MHC ligands; and fluorophores for tetramer detection

### **ARTICLE B.2. PRICES/COSTS**

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

### **ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS**

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

### **ARTICLE B.4. ADVANCE UNDERSTANDINGS**

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

## **SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT**

### **ARTICLE C.1. STATEMENT OF WORK**

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 December 19, 2006, 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.

#### **1. Technical Progress Reports**

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

Please refer to Section J, List of Attachments, Attachment 4, "Reporting Requirements and Deliverables" under this solicitation.

For proposal preparation purposes only, it is estimated that in addition to the required electronic version(s),

1 hard copy 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. Other Reports/Deliverables

- a. **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.
- b. **System Security Plan (SSP)**- for the website and backend infrastructure. The SSP will identify the system and detail the management, operational, and technical controls of the system. This report shall be due to the Government within 60 calendar days of contract award. If a major change is made to the web site and/or backend infrastructure, the Government requires an updated SSP.

### **ARTICLE C.3. INVENTION REPORTING REQUIREMENT**

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

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

### **SECTION D - PACKAGING, MARKING AND SHIPPING**

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and

contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

## **SECTION E - INSPECTION AND ACCEPTANCE**

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, the Project Officer in Article G.1. , is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at, 6610 Rockledge Drive, Bethesda Maryland 20892.

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

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

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

## **SECTION F - DELIVERIES OR PERFORMANCE**

### **ARTICLE F.1. DELIVERIES**

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in SECTION C, Article C.1 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:

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

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

## **SECTION G - CONTRACT ADMINISTRATION DATA**

Any contract awarded from this solicitation will contain the following:

### **ARTICLE G.1. PROJECT OFFICER**

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

[To be specified prior to award]

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

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

The Government may unilaterally change its Project Officer designation.

**ARTICLE G.2. KEY PERSONNEL**

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

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

NAME	TITLE
[To be specified prior to award]	

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

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

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

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

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

Contract No. (This is the 17 digit number that appears in Block 2 of the SF-26, i.e. HHSN2662007xxxxx.)

ADB Contract No. (This is the 10 digit number that appears in the upper left hand corner of the SF-26, i.e. N01-AI-7xxx.)

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

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

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

#### **ARTICLE G.4. GOVERNMENT PROPERTY**

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

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

#### **ARTICLE G.5. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE**

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim 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 (ASSURANCE OF OHRP COMPLIANCE)**

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

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

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

### **ARTICLE H. 3. RESEARCH INVOLVING HUMAN FETAL TISSUE**

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

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

#### **ARTICLE H.4. 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 May 28, 2002 Notice, Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.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](http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm#_Toc7255836)).

#### **ARTICLE H.5. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH**

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

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

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

[Applicable information to be included at award]

**ARTICLE H.6. NEEDLE EXCHANGE**

a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

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

[Applicable information to be included at award]

**ARTICLE H.7. 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.8. SUBCONTRACTING PROVISIONS**

a. Small Business Subcontracting Plan

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

b. Subcontracting Reports

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

(1) Individual Subcontract Reports (ISR)

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

April 30th  
October 30th

(2) Summary Subcontract Report (SSR)

Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:  
October 30<sup>th</sup>

For both the Individual and Summary Subcontract Reports, the [Contracting Officer/Contract Specialist/or title of alternate designee] shall be included as a contact for notification purposes at the following e-mail address:

[Contracting Officer/Contract Specialist/ or Title of alternate designee, OA, NIAID]  
*Will be included at award*

#### ARTICLE H.9. SALARY RATE LIMITATION LEGISLATION PROVISIONS

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

b. <b>Public Law and Section No.*</b>	<b>Fiscal Year*</b>	<b>Dollar Amount of Salary Limitation*</b>
---------------------------------------	-------------------------	--

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

[\*Applicable information to be included at award]

#### ARTICLE H.10. INFORMATION SECURITY

The Statement of Work (SOW) requires the contractor to develop a publicly available website for the NIH Tetramer Facility. Pursuant to Federal and HHS Information Security Program Policies, the contractor and any subcontractor performing under this contract shall comply with the following requirements:

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

a. Information Type

[ ] Administrative, Management and Support Information:

[ x ] Mission Based Information:

b. Security Categories and Levels

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

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

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

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

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

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

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

d. Information Security Training

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

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

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

e. Rules of Behavior

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

f. Personnel Security Responsibilities

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

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

(1) Contractor Agreement

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

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

(2) Contractor-Employee Non-Disclosure Agreements

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

h. NIST SP 800-26 Self-Assessment Questionnaire

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

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

The annual update shall be submitted to the Project Officer, with a copy to the Contracting Officer [Date will be indicated as determined by the Project Officer/Contracting Officer].

i. Information System Security Plan

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

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

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

## **ARTICLE H.11. ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS**

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

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

## ARTICLE H.12. ENERGY STAR REQUIREMENTS

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

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

For more information about ENERGY STAR® see <http://www.energystar.gov/>

For more information about FEMP see <http://www.eere.energy.gov/>

## ARTICLE H. 13 PUBLICATION AND PUBLICITY

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

"This project has been funded in whole or in part with Federal funds from the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN2662007xxxx.

## ARTICLE H.14. PRESS RELEASES

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

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

[Applicable information to be included at award]

## ARTICLE H.15. 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.16. YEAR 2000 COMPLIANCE**

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

1. Service Involving the Use of Information Technology

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

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

(End of Clause)

2. Noncommercial Supply Items Warranty

### **YEAR 2000 WARRANTY--NONCOMMERCIAL SUPPLY ITEMS**

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

### **YEAR 2000 COMPLIANT ITEMS**

(End of Clause)

3. Commercial Supply Products Warranty

### **YEAR 2000 WARRANTY--COMMERCIAL SUPPLY ITEMS**

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

**YEAR 2000 COMPLIANT ITEMS**

(End of Clause)

**ARTICLE H.17. ANTI -LOBBYING**

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

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

[Applicable information to be included at award]

**ARTICLE H.18. LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES**

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

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

[Applicable information to be included at award]

**ARTICLE H.19. 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.20. 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 expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

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

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

**ARTICLE H.21. 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.22. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES**

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

## **ARTICLE H.23. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH**

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

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

## **ARTICLE H.24. GOVERNMENT CONTROL OVER UNDELIVERED AND/OR UNPUBLISHED RECORDS AND DATA**

- (a) As used in this clause, "records and data" means: (1) any handwritten, typed, or printed documents (including, but not limited to, memoranda, letters, writings, books, brochures, transcripts, minutes, electronic transmissions, study findings, laboratory note books, chromatograms, spectra, and maps); (2) documentary material in other forms (such as punchcards, magnetic or paper tapes, instrumentation cards, computer discs, electronically stored information, audio or video recordings, motion pictures, photographs, slides, microfilm, and microfiche); and, (3) biological samples and pathology materials (pathology slides, paraffin blocks, and wet tissues). Records and data may or may not constitute a specific deliverable defined under the terms of the contract.
- (b) The purpose of this clause is to define the Government's control over records and data that are produced by the Contractor under this contract, but are not defined as a deliverable under the terms of the contract, or are not yet in the Government's physical possession if a deliverable under the terms of the contract. This clause is designed to serve public policy by limiting the disclosure of certain records and data if disclosure is made at a time when such records and data remain unvalidated and unreliable (i.e. may not have undergone a quality control nor subsequent audit and inspection as part of a quality assurance process) and could thereby lead to erroneous conclusions which might threaten public health or safety.
- (c) The Government shall be deemed as having no control over, or direct ownership of records and data created or produced by the Contractor in the performance of this contract until such time as the records and data have been: (1) subjected to an acceptable method of quality control and quality assurance; (2) delivered to the Government or obtained by the Government under the terms of this contract; (3) published in accordance

with the terms of this contract; or (4) used by the Federal Government in developing an agency action that has the force and effect of law.

- (d) In the event of a contract termination, this clause does not relieve the contractor of its obligations set forth elsewhere in this contract to transfer title and deliver to the Government work in process, completed work, supplies, and other material produced or acquired for the work terminated, or, the completed or partially completed plans, drawings, information, and other property that, if the contract had been completed, would be required to be furnished to the Government.
- (e) This clause shall have no effect on the Government's rights during the performance of the contract as specified elsewhere herein, including the Government's rights and abilities to request access to or be provided with such records and data for the purpose of conducting any inspections, examinations or audits as set forth in the contract.

#### **ARTICLE H.25. CONSTITUTION DAY**

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

#### **ARTICLE H.26. PRIVACY ACT**

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

**The Privacy Act System of Records applicable to this project is Number 0925-0216. This document is incorporated into this contract as an Attachment in SECTION J of this contract.**

## PART II - CONTRACT CLAUSES

### SECTION I - CONTRACT CLAUSES

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

**General Clauses for a Cost-Reimbursement Research and Development Contract**  
**General Clauses for a Cost-Reimbursement Contract with Educational Institutions**  
**General Clauses for a Cost-Reimbursement Contract with Non-Profit Organizations Other Than Educational Institutions**

The complete listing of these clauses may be accessed at:

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

#### **ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES**

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

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

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

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

Alternate I of FAR Clause 52.216-11, Cost Contract--No Fee (April 1984), is added.

**Alternate II** (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (September 2006) is added.

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

### ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

- (1) FAR Clause **52.204-9, Personal Identity Verification of Contractor Personnel** (November 2006)
- (2) FAR Clause **52.227-14, Rights in Data - General** (June 1987).
- (3) **Alternate IV** (June 1987), FAR Clause **52.227-14, Rights in Data - General** (June 1987).
- (4) FAR Clause **52.227-16, Additional Data Requirements** (June 1987).
- (5) FAR Clause **52.230-5, Cost Accounting Standards - Educational Institution** (April 1998).
- (6) FAR Clause **52.230-6, Administration of Cost Accounting Standards** (April 2005).
- (7) FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).
- (8) FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984).
- (9) 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 **352.223-70, Safety and Health** (January 2001). [This clause is provided in full text in Section J - Attachments.]
- (2) HHSAR Clause **352.224-70, Confidentiality of Information** (March 2005).
- (3) HHSAR Clause **352.270-9, Care of Live Vertebrate Animals** (March 2005).

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

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

- (1) **NIH (RC)-7, Procurement of Certain Equipment** (April 1984) (OMB Bulletin 81-16).
- (2) **NIH(RC)-11, Research Patient Care Costs** (4/1/84).

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

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

This contract incorporates the following clauses in full text.

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

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

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

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

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

### Notice to Employees

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

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

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

National Labor Relations Board  
Division of Information  
1099 14th Street, N.W.  
Washington, DC 20570

1-866-667-6572  
1-866-316-6572 (TTY)

To locate the nearest NLRB office, see NLRB's website at <http://www.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 20210, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;
  - (2) Download a copy of the poster from the Office of Labor-Management Standards website at <http://www.olms.dol.gov>; or
  - (3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.

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

## PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

### SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

#### SOLICITATION ATTACHMENTS:

<b>Attachment No.</b>	<b>Title</b>	<b>Location</b>
Attachment 1:	Packaging and Delivery of Proposal	See Attachment Section at the end of this RFP
Attachment 2:	Background	See Attachment Section at the end of this RFP
Attachment 3:	<a href="#">Statement of Work</a>	See Attachment Section at the end of this RFP
Attachment 4:	<a href="#">Reporting Requirements and Deliverables</a>	See Attachment Section at the end of this RFP
Attachment 5:	<a href="#">Additional Technical Proposal Instructions and Format for Technical Proposal</a>	See Attachment Section at the end of this RFP
Attachment 6:	<a href="#">Additional Business Proposal Instructions and Uniform Cost Assumptions</a>	See Attachment Section at the end of this RFP
Attachment 7:	Proposal Intent Response Sheet	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>

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

<b>Attachment No.</b>	<b>Title</b>	<b>Location</b>
Attachment 8:	Technical Proposal Cost Summary	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>
Attachment 9:	Summary of Related Activities	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>
Attachment 10:	Government Notice for Handling Proposals	<a href="http://www.niaid.nih.gov/contract/forms/form7.pdf">http://www.niaid.nih.gov/contract/forms/form7.pdf</a>
Attachment 11:	Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (formerly Optional Form 310)	<a href="http://rcb.cancer.gov/rcb-internet/forms/of310.pdf">http://rcb.cancer.gov/rcb-internet/forms/of310.pdf</a>
Attachment 12:	Project Objectives, NIH 1688-1	<a href="http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf">http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf</a>

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

<b>Attachment No.</b>	<b>Title</b>	<b>Location</b>
Attachment 13:	Proposal Summary and Data Record, NIH-2043	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>
Attachment 14:	Small Business Subcontracting Plan	<a href="http://rcb.cancer.gov/rcb-internet/forms/SBA Plan Nov 2005.pdf">http://rcb.cancer.gov/rcb-internet/forms/SBA Plan Nov 2005.pdf</a>
Attachment 15:	Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet	<a href="http://oamp.od.nih.gov/contracts/BUSCOST.HTM">http://oamp.od.nih.gov/contracts/BUSCOST.HTM</a> <a href="http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls">http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls</a>
Attachment 16:	Offeror's Points of Contact	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>
Attachment 17:	Disclosure of Lobbying Activities, OMB Form SF-LLL	<a href="http://rcb.cancer.gov/rcb-internet/forms/sfllin.pdf">http://rcb.cancer.gov/rcb-internet/forms/sfllin.pdf</a>

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

<b>Attachment No.</b>	<b>Title</b>	<b>Location</b>
Attachment 18:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	<a href="http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf">http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf</a>
Attachment 19:	Safety and Health, HHSAR Clause 352.223-70	<a href="http://www.niaid.nih.gov/contract/forms/form10.pdf">http://www.niaid.nih.gov/contract/forms/form10.pdf</a>
Attachment 20:	Procurement of Certain Equipment, NIH(RC)-7	<a href="http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf">http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf</a>
Attachment 21:	Disclosure of Lobbying Activities, OMB Form SF-LLL	<a href="http://rcb.cancer.gov/rcb-internet/forms/sfllin.pdf">http://rcb.cancer.gov/rcb-internet/forms/sfllin.pdf</a>
Attachment 22:	Commitment To Protect Non-Public Information Contractor Agreement	<a href="http://irm.cit.nih.gov/security/Nondisclosure.pdf">http://irm.cit.nih.gov/security/Nondisclosure.pdf</a>
Attachment 23:	Roster of Employees Requiring Suitability Investigations	<a href="http://ais.nci.nih.gov/forms/Suitability-roster.xls">http://ais.nci.nih.gov/forms/Suitability-roster.xls</a>
Attachment 24:	Employee Separation Checklist	<a href="http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf">http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf</a>
Attachment 25:	Privacy Act System of Records System of Records No. 0925-0216 is applicable to this RFP	<a href="http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm">http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm</a>

## **PART IV - REPRESENTATIONS AND INSTRUCTIONS**

### **SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS**

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

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

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

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

## SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

### 1. GENERAL INFORMATION

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

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

*Discussions* are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

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

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

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

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

- (b) *Amendments to solicitations.* If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).
- (c) *Submission, modification, revision, and withdrawal of proposals.* (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.
- (2) The first page of the proposal must show--
- (i) The solicitation number;
  - (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
  - (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
  - (iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
  - (v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

- (3) *Submission, modification, revision, and withdrawal of proposals.* (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.
- (ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--
- (1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or
- (2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
- (3) It is the only proposal received.
- (B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.
- (iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.
- (iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.
- (v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.
- (4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.
- (5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

- (6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.
  - (7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.
  - (8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.
- (d) *Offer expiration date.* Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).
- (e) *Restriction on disclosure and use of data.* (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

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

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

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

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

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

- (3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.
  - (9) Offerors may submit proposals that depart from stated requirements. Such proposals shall clearly identify why the acceptance of the proposal would be advantageous to the Government. Any deviations from the terms and conditions of the solicitation, as well as the comparative advantage to the Government, shall be clearly identified and explicitly defined. The Government reserves the right to amend the solicitation to allow all offerors an opportunity to submit revised proposals based on the revised requirements.
- (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)

**b. NAICS CODE AND SIZE STANDARD**

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

- (1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.
- (2) The small business size standard is below 500 employees.

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

**c. TYPE OF CONTRACT AND NUMBER OF AWARDS**

It is anticipated that (One Award will be made from this solicitation and that the award will be made on/about December 31, 2007.

It is anticipated that the award from this solicitation will be a multiple-year cost reimbursement type contract with a 5 year period of performance 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 9.0 Full Time Equivalents (FTEs) per each year of the proposed contract. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

e. **COMMITMENT OF PUBLIC FUNDS**

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

f. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

g. **RELEASE OF INFORMATION**

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

h. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors are specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

i. **PREPARATION COSTS**

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

j. **SERVICE OF PROTEST (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 Acquisition, Division of Extramural Activities

NIAID, NIH, DHHS  
6700-B Rockledge Drive, Rm 3214, MSC 7612  
Bethesda, MD 20892-7612 (Fed Ex zip 20817)

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

(End of Provision)

k. **LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70**

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

(End of provision)

## **2. INSTRUCTIONS TO OFFERORS**

### **a. GENERAL INSTRUCTIONS**

#### **INTRODUCTION**

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

#### **(1) Contract Type and General Clauses**

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

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

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

##### **I. COVER PAGE**

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

##### **II. TECHNICAL PROPOSAL**

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments, and Attachment 5 entitled "Additional Technical Proposal Instructions and Format for Technical Proposal".

##### **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, and Attachment 6 entitled "Additional Business Proposal Instructions and Uniform Assumptions".

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

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

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

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

(5) **Alternate Proposals**

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

(6) **Evaluation of Proposals**

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

(7) **Potential Award Without Discussions**

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

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

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

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

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

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

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

## (9) **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 General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(10) **Selection of Offerors**

- a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d) If the Government intends to conduct discussions prior to awarding a contract-

- (1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

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

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

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

lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

- f) The NIAID reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIAID requirements. Synopses of awards exceeding \$25,000 will be published in FedBizOpps.

(11) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

**EACH INSTITUTION MUST:**

- (a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.
- (b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.
- (c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.
- (d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.
- (e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.
- (f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
- (g) Certify, in each application/proposal for funding to which the regulations applies, that:
  - 1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

- 2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;
- 3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and the Institution will otherwise comply with the regulations.

### **Institutional Management of Conflicting Interests**

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

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

- (i) public disclosure of significant financial interests;
  - (ii) monitoring of research by independent reviewers;
  - (iii) modification of the research plan;
  - (iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
  - (v) divestiture of significant financial interests; or
  - (vi) severance of relationships that create actual or potential conflicts of interests.
- (b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

### **(12) 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.

(13) **Past Performance Information**

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

A list of the last five (5) contracts completed during the past three years and the last three (3) 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 that are newly formed entities without prior contracts and subcontracts as required below for all key personnel

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. Standard Industrial Code

The offeror shall submit comparable information on **all subcontractors** that the offeror proposes to perform a subcontract under this effort.

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

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

(14) **Electronic and Information Technology Accessibility**

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

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

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

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

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a) Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).
- b) Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
- c) Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).
- d) 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.

**In addition, refer to Section J, List of Attachments, Attachments, Attachment 5, entitled, Additional Technical Proposal Instructions and Format for Technical Proposal”.**

**(1) Technical Discussions**

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

- a) **Project Objectives, NIH-1688-1**

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

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

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

b) **Statement of Work**

(1) Objectives

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

(2) Approach

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

(3) Methods

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

(4) Schedule

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

c) **Personnel**

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

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE

IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

(1) Principal Investigator/Project Director

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

(2) Other Investigators

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

(3) Additional Personnel

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

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

(4) Resumes

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

(3) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in SECTION M - Evaluation Factors for Award of this solicitation.

(4) **Additional Technical Proposal Information**

- a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.
- b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

**(5) 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.

## **(6) Care of Live Vertebrate Animals**

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

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

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER, OLAW. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies 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 section 6 the offerors technical proposal as outlined in Attachment 5, Additional Technical Proposal Instructions Format for technical Proposals:

- (1) Identification of the species and approximate number of animals to be used;
- (2) rationale for involving animals, and for the appropriateness of the species and numbers used;
- (3) a complete description of the proposed use of the animals;
- (4) 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
- (5) a description of any euthanasia method to be used.

- c. If an Animal Assurance is already in place, the following information must be included in section 6 of the offerors technical proposal as outlined in Attachment 5, Additional Technical Proposal Instructions Format for technical Proposals:

-The Animal Welfare Assurance number.

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

**(7) Possession, Use and Transfer of Select Biological Agents or Toxins**

**Notice to Offerors of Requirements of:** 42 CFR Part 73, Possession , Use, and Transfer of Select Agents and Toxins (relating to public health and safety):

([http://www.cdc.gov/od/sap/42\\_cfr\\_73\\_final\\_rule.pdf](http://www.cdc.gov/od/sap/42_cfr_73_final_rule.pdf));

7 CFR Part 331, Possession, Use, and Transfer of Select Agents and Toxins (relating to plant health or plant products) ([http://www.aphis.usda.gov/programs/ag\\_selectagent/FinalRule3-18-05.pdf](http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf)); and,

9 CFR Part 121, Possession, Use, and Transfer of Select Agents and Toxins (relating to human and animal health, animal health or animal products)

([http://www.aphis.usda.gov/programs/ag\\_selectagent/FinalRule3-18-05.pdf](http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf)) - March 18, 2005.

These regulations implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and the Agricultural Bioterrorism Protection Act of 2002. They are designed to improve the ability of the United States Government to prevent, prepare for, and respond to bioterrorism and other public health emergencies. These regulations establish requirements regarding registration, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections, and notifications.

Listings of HHS select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at <http://www.cdc.gov/od/sap/>

and <http://www.cdc.gov/od/sap/docs/salist.pdf>. Listings of USDA select agents and toxins as well as information about the registration process for domestic institutions are available on the APHIS/USDA website at [http://www.aphis.usda.gov/programs/ag\\_selectagent/index.html](http://www.aphis.usda.gov/programs/ag_selectagent/index.html) and [http://www.aphis.usda.gov/programs/ag\\_selectagent/ag\\_bioterr\\_forms.html](http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_forms.html). For foreign institutions, see the NIAID Select Agent Award information ([http://www.niaid.nih.gov/ncn/clinical/default\\_biodefense.htm](http://www.niaid.nih.gov/ncn/clinical/default_biodefense.htm)).

If the proposed contract will not involve Select Agents, the offeror must include a statement in its technical proposal that the work does not now nor will it in the future (i.e. throughout the life of the award) involve Select Agents.

**Domestic Institutions**

For prime or subcontract awards to domestic institutions that possess, use, and/or transfer Select Agents under this contract, the domestic institution must:

- include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.
- comply with 42 CFR part 73, 7 CFR part 331 and/or 9 CFR part 121 at: [http://www.aphis.usda.gov/programs/ag\\_selectagent/FinalRule3-18-05.pdf](http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf), as required, before using NIH funds for research involving Select Agents. No NIH funds can be used for research involving Select Agents if the final registration certificate is denied.

## Foreign Institutions

For prime or subcontract awards to foreign institutions that possess, use, and/or transfer Select Agents under this contract, the foreign institution must:

- include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.
- when requested during negotiations, provide information satisfactory to the NIAID/NIH that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: [http://www.aphis.usda.gov/programs/ag\\_selectagent/FinalRule3-18-05.pdf](http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf)
- for U.S. institutions are in place and will be administered on behalf of all Select Agent work under the resulting contract. The process for making this determination includes inspection of the foreign laboratory facility by an NIAID representative. During this inspection, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents.

An NIAID-chaired committee of U.S. federal employees (including representatives of NIH grants/contracts and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will ultimately assess the results of the facility inspection, the regulations, policies, and procedures of the foreign institution for equivalence to the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: [http://www.aphis.usda.gov/programs/ag\\_selectagent/FinalRule3-18-05.pdf](http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf).

The committee will provide recommendations to the DEA Director, NIAID. The DEA Director will make the approval decision and notify the Contracting Officer. The Contracting Officer will inform the prime contractor of the approval status of the foreign institution. No NIH funds can be used for research involving Select Agents at a foreign institution until NIAID grants this approval.

### (8) 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.

**(9) Research Involving Human Fetal Tissue**

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

The governing federal statute is the Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and [http://grants1.nih.gov/grants/guide/notice\\_files/not93\\_235.html](http://grants1.nih.gov/grants/guide/notice_files/not93_235.html) and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

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

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

**(10) Research Involving Recombinant DNA Molecules (including Human Gene Transfer Research)**

Recombinant DNA Molecules are either 1) molecules that are constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or 2) DNA molecules that result from the replication of those described in 1).

The NIH Guidelines for Research Involving Recombinant DNA Molecules at: (<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>) and the May 28, 2002 Notice, Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules at: ([http://grants1.nih.gov/grants/guide/notice\\_files/NOT-OD-02-052.html](http://grants1.nih.gov/grants/guide/notice_files/NOT-OD-02-052.html)) and any subsequent revisions to the Guide Notice) 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 NIH 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 NIH funding for any work related to Recombinant DNA Research or a requirement for the contracting officer's prior approval of any or all Recombinant DNA projects under any contract awarded from this solicitation. 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, at:

([http://www4.od.nih.gov/oba/rac/guidelines\\_02/Appendix\\_M.htm#\\_Toc7255836](http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm#_Toc7255836)).

- (11) **Information Security** is applicable to this solicitation and the following information is provided to assist in proposal preparation.

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

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

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

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

(a) Information Type

[ ] **Administrative, Management and Support Information:**

**Mission Based Information:**

(b) Security Categories and Levels

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

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

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

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

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

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

(d) Information Security Training

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

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

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

(e) Offeror's Official Responsible for Information Security

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

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

The offeror must include in the "Information Security" part of its Technical Proposal, a completed Self-Assessment Questionnaire required by NIST Draft SP 800-26, Revision 1, Guide for Information Security Program Assessments and System Reporting Form at:

(<http://csrc.nist.gov/publications/drafts/Draft-sp800-26Rev1.pdf>, See Appendix B for submission format.) NIST 800-26 assesses information security assurance of the offeror's internal systems security. This assessment is based on the Federal IT Security Assessment Framework and Draft NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems, at:

(<http://www.csrc.nist.gov/publications/drafts/800-53-rev1-clean-sz.pdf>).

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

(g) Draft Information System Security Plan

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

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

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

(h) Prospective Offeror Non-Disclosure Agreement

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

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

**Level 6: Public Trust - High Risk**

**Level 5: Public Trust - Moderate Risk**

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

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

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

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

(i) References

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

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**

**In addition to the requirements below, refer to SECTION J, List of Attachments, Attachment 6, entitled, “Additional Business Proposal Instructions and Uniform Cost Assumptions.”**

**(1) Basic Cost/Price Information**

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

**(2) Proposal Cover Sheet**

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

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

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

**(3) Information Other than Cost or Pricing Data**

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

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

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

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

1. **Direct Labor**

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

2. **Materials**

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

3. **Subcontracted Items**

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over \$650,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. **Raw Materials**

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

5. **Purchased Parts**

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

6. **Fringe Benefits**

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

7. **Indirect Costs**

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

8. **Special Equipment**

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

9. **Travel**

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

10. **Other Costs**

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

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

(a) Exceptions from cost or pricing data.

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

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

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

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

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

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

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does

not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

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

- (1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.
- (2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

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

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

The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission 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 2007**

Offerors are advised that pursuant to P.L. \*\*, no NIH Fiscal Year 2006 (October 1, 2006 - September 30, 2007) 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. \*\* applies only to Fiscal Year 2007 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I\* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. \*\* states in pertinent part:

"None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and

Mental Health Services Administration shall be used to pay the salary of an individual through a grant or other extramural mechanism at a rate in excess of Executive Level I\*."

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

*\*Note to Offerors: The current Fiscal Year Executive Level I Salary Rate should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year 2007 Executive Level I Salary rates.*

*\*\*Pending Passage of Legislation.*

#### **(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 (SF 294 and SF 295) to the Government.
- (11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

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

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

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

#### **19. 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>.

#### **20. Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed \$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) code, 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 Subsector(s). The applicable authorized NAICS Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

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

EXAMPLE

Targets for SDB Participation - NAICS Subsector 223

	<b>SDB Percentage of Total Contract Value</b>	<b>SDB Dollars</b>
Total Contract Value- \$1,000,000	25%	\$250,000
SDB Participation by Prime  (Includes joint venture partners and team arrangements)*	10%	\$100,000
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.

21. **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.

## 22. Other Administrative Data

a) **Property**

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

- (a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.
- (b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.
- (2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.
- (3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) **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.

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**

(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 modification.

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)

**23. 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) A copy of the organization's most recent annual report must be submitted as part of the busproposa 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 a contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost/price, past performance, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, cost/price, past performance, and SDB Participation are also important to the overall contract award decision. All evaluation factors other than cost/price, when combined, are significantly more important than cost or price. The trade-off process described in FAR 15.101-1 may be employed. This process permits tradeoffs among cost/price and non-cost factors and allows the Government to consider award to other than the lowest priced or highest technically rated Offeror. In any event, the Government reserves the right to make an award 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.

### **(1) 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.

### **(2) TECHNICAL EVALUATION CRITERIA**

**OFFERORS AND REVIEWERS ARE ADVISED TO REFER TO, ATTACHMENT 4-ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS OF THIS SOLICITATION FOR GUIDANCE AND INFORMATION RELATED TO THE PREPARATION OF PROPOSALS.**

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.

CRITERIA

WEIGHT

**A. Technical Approach**

**50 points**

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

1. Soundness and feasibility of the proposed technical approaches, troubleshooting and alternative methods, and quality control procedures for tetramer and related reagent production.
2. Feasibility of proposed plans for the distribution, tracking, and reporting system of all approved reagent requests.
3. Appropriateness of plan for the development and maintenance of a public Tetramer Facility website.
4. Feasibility of proposed methods and procedures to identify, develop, and incorporate new processes, approaches, and technologies to ensure a state-of-the-art tetramer reagent production facility.

**B. Personnel**

**15 points**

Description and Factors, as appropriate:

1. Related experience of the PI and Facility Manager for planning, managing, and directing projects of similar scope and size.
2. Documented adequacy and relevance of expertise, and experience of the PI, scientific staff, and technical personnel for performing the scientific requirements of the Tetramer Facility.
3. Adequacy, relevance, and appropriateness of the PI's experience in managing consultants, collaborators, and subcontractors.
4. Adequacy, relevance, and appropriateness of the Offeror's experience to provide research resources to the scientific community.
5. Ability of the Offeror to provide technical assistance to the research community.

**C. Project Management**

**20 points**

Description and Factors, as appropriate:

1. Feasibility and adequacy of proposed plans for managing and coordinating the reagent resource tasks, quality control procedures, reporting requirements, and research and development aspects of the project as a whole.
2. Feasibility and efficiency of proposed organization that delineates clear lines of authority and responsibility.
3. Adequacy and feasibility of the Offeror's plan for project organization, staffing, and management.
4. Feasibility of the plan to manage and coordinate consultant and subcontractor efforts.
5. Efficiency and effectiveness of proposed operating procedures, particularly with regard to timeliness, and decision making processes, including prioritization of important project elements.
6. Ability to develop and implement initial and final transition plans to execute the orderly transfer of this project to a successor contractor.

**D. Facilities**

**15 points**

Description and Factors, as appropriate:

1. Availability and adequacy of facilities, including a detailed floor plan of the proposed facility.
2. Availability and adequacy of equipment to conduct the required tasks in tetramer and related reagent production and quality control methods.
3. Availability and adequacy of IT and other resources for internal request tracking systems and development, operation and maintenance of a public website.

4. Availability and adequacy of space for receipt and storage of peptides from clients, storage of all required materials and reagents for public distribution, and international and domestic shipping capabilities.
5. Adequacy of information regarding ownership, lease, or occupancy of facility for the duration of the contract performance period.
6. Adequacy of the plan for compliance with all safety guidelines and regulations, including training and monitoring of personnel for exposure to infectious and hazardous reagents.

### **(3) PAST PERFORMANCE FACTOR**

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

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

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

The assessment of performance risk is not intended to be the product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers all available and relevant information.

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

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

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

### **(4) EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

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

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

Offers will be evaluated on the following sub-factors:

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

## **SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP**

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

## PACKAGING AND DELIVERY OF THE PROPOSAL

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

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

### **A. EXTERNAL PACKAGE MARKING:**

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

**"RFP NO. NIH-NIAID-DAIT-08-13  
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**

Aglae Cantave  
Contract Specialist  
Office of Acquisitions, DEA, NIAID, NIH  
6700-B Rockledge Drive, Room 3214,  
Bethesda, Maryland 20817

#### **If using U.S. Postal Service**

Aglae Cantave  
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:** Cover/Title Page 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.**

**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.**

### **FORMATTING AND LAYOUT:**

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

- Type size must be 10 to 12 points.
- Type spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
- Print margins must be at least one inch on each edge of the paper.
- Print setup should be single-sided on standard letter size paper (8.5 x 11" in the U.S., A4 in Europe).

- 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. Files on CDs should be named using the following format:

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

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

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

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

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

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

**THE NUMBER OF COPIES AND APPLICABLE PAGE LIMITATIONS REQUIRED OF EACH PART OF YOUR PROPOSAL ARE AS SPECIFIED BELOW. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE PROVIDED TO THE REVIEWERS TO BE READ OR EVALUATED. OFFERORS MUST CERTIFY THAT THE INFORMATION IN THE PAPER AND ELECTRONIC COPIES IS EXACTLY THE SAME.**

<b>Document</b>	<b>Number of Copies</b>	<b>Page Limits</b>
<b>Technical Proposal and all Appendices</b>	One (1) SIGNED ORIGINAL Five (5) Copies <b>ELECTRONIC FILES ON CD</b> Five (5) Compact Disks containing an electronic copy of the Technical Proposal including all appendices.	<b>200 Pages</b>
<b>Business Proposal PAPER</b>	One (1) SIGNED ORIGINAL. Five (5) COPIES <b>ELECTRONIC FILES ON CD</b> Five (5) Compact Disks containing an electronic copy of the Business Proposal.	<b>N/A</b>

## BACKGROUND AND INTRODUCTION

### NIH Tetramer Facility RFP-NIH-NIAID-DAIT-08-13

The National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) supports research on the basic understanding of immune responses leading to the development of vaccines and novel therapeutic agents for the prevention and treatment of infectious and immune-mediated diseases, and improvements in public health. This research includes support of various reagent facilities, repositories, and databases that provide resources for biomedical researchers. As a part of the research program to improve our understanding of the progression, prevention, and treatment of infectious and immune-mediated diseases, the NIAID is competing the renewal of the Major Histocompatibility Complex (MHC) Tetramer Facility contract. This facility provides synthesis and distribution of soluble MHC-peptide tetramer reagents to the global research community.

T lymphocytes (T cells) are a subset of immune cells that play pivotal roles in host immune responses to infectious diseases, immune-mediated diseases, and cancer including: eliminating infected or aberrant cells; providing help for antibody production; and modulating immune regulation. T cell function can be evaluated by assessing such parameters as cytokine production, calcium influx, and production of cytolytic molecules. These parameters generally provide qualitative measurements of T cell activity. Quantitative assessments can offer valuable insights into the magnitude of immune responses during the course of an infection or an immune-mediated disorder, or after vaccination or immune-based therapies. MHC tetramers are valuable tools for the rapid, highly sensitive quantitation of antigen-specific T cells from blood or tissue samples.

MHC tetramers are composed of four identical MHC molecules, each generally containing an antigen-specific peptide in the MHC peptide binding groove. The MHC molecules are labeled with biotin, allowing for tetramerization through the addition of a streptavidin-linked fluorophore. Tetramers are produced when the biotinylated MHC molecules attach to the four biotin-binding sites on streptavidin. MHC class I tetramer technology was invented at Stanford University by Drs. John Altman, Michael McHeyzer-Williams, and Mark Davis (*Science* 274:94-96 (1996)); and U.S. Patent Number 5,635,363). MHC class II tetramer technology was first described by Drs. John Kappler and Phillipa Marrack (*Nature* 369:151-154 (1994)); and *Immunity* 8:675-682 (1998)); and extended in the laboratories of Drs. Gerald Nepom and William Kwok (*J. Clin. Invest.* 104:63-67 (1999)); Dr. Lawrence Stern (*J Immunol.* 166 (2): 741-745 (2001)); *J Immunol Methods* 268 (1): 51-69 (2002)); and Dr. Kai Wucherpfennig (*J. Clin. Invest.* 112:831-842 (2003)).

In 1999, the NIAID established a tetramer core facility at Emory University, as a two year subcontract to the NIAID AIDS Reagent Program (awarded to McKesson BioServices). The tetramer program continued through a separate contract to Emory University (N01-AI-25456), solicited under RFP DAIT-02-04, which expires in 2008. The main goal of the Tetramer Facility was to provide custom-made MHC class I tetramers to domestic and foreign researchers, and to engage in research and development to improve and expand tetramer technology. Since the commercialization rights for MHC class I tetramer technology are licensed to Beckman Coulter, Inc., NIAID negotiated a Memorandum of Understanding (MOU) with Beckman Coulter as an agreement on supplying tetramers through the NIH Tetramer Facility. This MOU allows the NIH Tetramer Facility to provide MHC class I tetramers for research purposes to the broader research community. A list of MHC class I tetramers that the NIH Tetramer Facility cannot provide is available at the Tetramer Facility website (<http://www.yerkes.emory.edu/TETRAMER/>).

The NIAID Division of Allergy, Immunology, and Transplantation (DAIT), Division of Microbiology and Infectious Diseases (DMID), Division of AIDS (DAIDS), and Division of Intramural Research (DIR); and the National Cancer Institute (NCI) have provided funding for the Tetramer Facility from FY 1999-FY 2008. This funding supported tetramer-related technology development, MHC allele gene expression and protein

purification, tetramer production and quality control testing, order tracking, and website maintenance. Investigators requesting reagents incurred the cost of peptide production, shipping of the peptides to the Tetramer Facility, and shipment of the tetramer or other reagents to their institution.

The DAIT Project Officer oversees Tetramer Facility operations and serves as chairperson of the NIAID Tetramer Resource Committee (TRC). The NIAID TRC is composed of NIAID and NCI program and scientific staff, chosen by the NIAID project officer. The TRC reviews and prioritizes tetramer requests (submitted through the Tetramer Facility website by investigators); as well as provides guidance to the NIAID Tetramer Facility project officer regarding research priorities and novel advances in MHC tetramer production and usage. In addition, an administrative assistant, currently supported through a subcontract to the Tetramer Facility contract, serves on the TRC to organize tetramer requests, track user registration and Material Transfer Agreements, and provides instruction to approved users on shipping peptides and obtaining tetramers/reagents from the Facility.

During the past eight years of operation, the NIH Tetramer Facility expanded its list of available reagents to include: additional mouse, non-human primate, and human MHC class I alleles; pre-made human class II tetramers; custom-made mouse and human class II tetramers; non-classical MHC TL, Qa-1, and mouse and human CD1d tetramers; CD1d ligands; and an expanded range of fluorophores for tetramer detection. Since opening in 1999, the NIH Tetramer Facility produced greater than 3000 tetramer reagents, shipped to over 551 investigators in the US and abroad, including at least 15 different countries. A list of publications that acknowledge the NIH Tetramer Facility for receipt of reagents is available as Attachment F to this Request for Proposal (RFP).

## STATEMENT OF WORK

### NIH Tetramer Facility RFP-NIH-NIAID-DAIT-08-13

#### SCOPE:

The scope of this effort is the operation of a Major Histocompatibility Complex (MHC) Tetramer Facility. This facility will provide synthesis and distribution of soluble MHC-peptide tetramer and related reagents to the global research community. Such reagents include mouse, non-human primate, and human MHC class I monomers and tetramers; custom-made mouse, non-human primate, and human class II tetramers; non-classical MHC TL, Qa-1, and mouse and human CD1 monomers and tetramers; CD1d and other MHC ligands; and fluorophores for tetramer detection.

The major functions to be carried out by the contractor are:

- A. Establish, operate, and maintain a Tetramer Production Facility
- B. Develop and maintain a distribution, tracking, and reporting system of reagents
- C. Create a Tetramer Facility website design and provide related maintenance
- D. Carry out Tetramer Technology Research and Development
- E. Provide Tetramer Facility Program Management

Successful execution of these duties requires solid project management, which shall be integrated into the contract tasks listed below and is described in Section E of the Statement of Work.

Please note that the Tetramer Facility is NOT responsible for supplying the peptides for MHC Class I and II tetramer production. The peptides will be provided by the approved requestors.

#### TECHNICAL REQUIREMENTS:

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work below. Subcontracting agreements are allowable and encouraged to accomplish some of the work outlined in this solicitation, as indicated below.

#### Initial Transition

In the event of transition to a new contractor; the Contractor shall work with the incumbent contractor to ensure a fully implemented and orderly transition of activities and resources from the predecessor contract, within two (2) months of contract award. The initial transition shall include the following:

- A. All Standard Operating Procedures for the distribution, tracking, and reporting of all reagents produced at the NIH Tetramer Facility;
- B. All MHC gene expression vectors, cell lines, peptide and ligand stocks, MHC monomer stocks, and production protocols for all reagents produced for the NIH Tetramer Facility; and
- C. Content and database management system of the NIH Tetramer Facility website.

#### Specific Tasks to be performed by the Contractor shall be:

- A. **Establish, Operate, and Maintain a Tetramer Production Facility:** Operate and maintain a centralized tetramer reagent facility to produce and ship quality-controlled, custom synthesized or pre-made antigenic

peptide/MHC monomeric or tetrameric molecules for use by NIH TRC-approved investigators to detect, enumerate, or isolate antigen-specific T cells. MHC molecules may include any alleles of mammalian class I, class II, or non-classical MHC molecules, with a focus on common alleles of mice, non-human primates, and humans. The Contractor shall establish production capacity for approximately 70-80 tetramers per month and have a plan to expand capacity to up to 100 tetramers per month, to accommodate potential increases in requests. Production time for a novel tetramer reagent, from the time of peptide receipt to the time of shipment, shall not exceed 30 days. The Contractor shall provide each requestor with at least 0.2 milligrams of the final tetramer reagent product. The Contractor may enlist subcontractors to perform some of the tasks listed below (e.g., Quality Control), as needed to ensure appropriate expertise to conduct the work.

The Contractor shall:

1. Produce recombinant MHC molecules *in vitro*: Clone and express genes for human, rodent, non-human primate or other mammalian species' class I, class II, and non-classical MHC molecules; as well as the appropriate beta-2 microglobulin. Genetic cloning procedures shall include the introduction of structural modifications to the genes encoding the MHC molecules to improve MHC-ligand monomer and tetramer production. The Contractor shall express the proteins in the appropriate microbial, insect, or mammalian cell lines for the MHC gene expression vectors used and the desired form of the MHC molecules.
2. Purify recombinant MHC proteins: Isolate the expressed MHC proteins from bacterial inclusion bodies, cell lysates, cell supernatants, or other fractions suitable to the proposed technologies for MHC molecule production. Chromatography or other purification methods shall be optimized for efficient extraction, purification, and concentration of the isolated product for high yield renaturation, as required for final monomer or tetramer production.
3. Fold or exchange peptide or ligands into MHC monomeric proteins: MHC ligand or MHC peptide exchange reactions shall depend on the methods. MHC-peptide/ligand complexes shall be folded (renatured) in a manner that yields the most efficient incorporation of peptides or appropriate ligands into the antigen-binding groove of the purified MHC proteins, resulting in production of fully-refolded, stable complexes of ligand, MHC chain(s), and beta-2 microglobulin.
4. Biotinylate or label MHC/ligand complexes: Biotin or other suitable label for oligomer formation shall be quantitatively incorporated at amino acid side chain residues of the MHC molecules that are non-critical for peptide/ligand, T cell receptor, or CD8/CD4 receptor interactions, using appropriate methodologies.
5. Complex biotinylated/labeled MHC/ligand to specific fluorophores to produce tetrameric or oligomeric reagents: Renatured, labeled MHC-peptide monomers shall be reacted with appropriate fluorophore conjugates, as required for a requestor's use specified in an approved request. Fluorophores shall be purchased from commercial sources, when available, or be produced by the Contractor. All fluorophores shall be tested for their ability to produce labeled tetramers or higher degree oligomers, high fluorescence specific activity, and sensitivity for T cell detection.
6. Quality Control: Establish quality control standards for all reagents produced including MHC class I, MHC class II, and non-classical MHC monomers and tetramers; novel MHC ligands; and non-commercial fluorophores.
  - i. Quality Control of stock batches: The quality control procedures shall ensure purity, product functionality, and reliability of reagents provided to requesting investigators. Control measures shall include analysis of each batch of MHC molecule, beta-2 microglobulin, and fluorophore using appropriate tests to characterize the product's

molecular size as an indicator of proper folding and complex formation. Since MHC class II tetramer production and T cell staining is more variable than MHC class I tetramer production and staining capacity, additional quality control measures shall be established for MHC class II molecules. Each batch of MHC class II monomers shall also be tested for proper CD4 T cell staining, using a well characterized peptide for each batch of MHC class II allele produced. The appropriate MHC class II-peptide tetramer shall be produced and tested with an appropriate CD4 T cell line, clone, or hybridoma by flow cytometry staining or another appropriate method, proposed by the Contractor and approved by the Project Officer. Quality control of CD1 ligands and other reagents shall include biochemical analyses to demonstrate appropriate chemical composition, product purity, and biological activity.

- ii. Quality Control of final custom-made reagents: Production of customer orders of MHC class I, non-classical class I and class II tetramer reagents shall include quality control that minimally consists of verifying proper MHC folding, peptide binding to the requested MHC molecules, and tetramerization of the product, using such techniques as Enzyme-linked Immunosorbent Assays (ELISA) using anti-beta 2 microglobulin antibodies specific for properly folded MHC I, and FPLC chromatogram of the protein indicating its size to demonstrate proper folding and multimerization of the tetramer reagent, or other similar procedures that ensure product quality.

- B. **Develop and Maintain a Distribution, Tracking, and Reporting System:** Operate a distribution, tracking, and reporting system for all requested and approved reagents that include the following tasks: A Facility manager shall assist the contract Principal Investigator in the overall project management and an administrative component shall assist in tetramer order review and tracking tasks, as outlined below.

**Administrative Component:**

Tasks 1-4, described below, shall be conducted in a manner that ensures the scientific confidentiality of the requestors' proposed research. Confidentiality may be preserved by assigning these tasks to a subcontractor or through another method chosen by the Contractor, with final approval by the Project Officer. The administrative component shall work directly with the Project Officer to organize reagent requests prior to the NIH TRC meetings, and conduct tasks 2-4, outlined below. Task 5 shall be conducted by the Contractor.

1. The requestors complete the online tetramer/reagent requests available at the NIH Tetramer Facility website. The completed requests are sent directly to the NIH Tetramer Resource Committee staff and the appropriate administrative component staff via electronic mail. To maintain requestor scientific confidentiality, the full request shall NOT be sent to the NIH Tetramer Facility staff.
2. The administrative component shall compile all of the tetramer request information, which shall include: Requesting Investigator name and email address; Institution; funding source (if provided by requestor); phrase documenting research focus (e.g., HIV vaccine, cancer immune therapy, etc); MHC allele or other reagent requested; beta-2 microglobulin; fluorophore requested; and peptide or ligand sequence, antigen source, and pathogen (if applicable), into a spreadsheet and distribute to the NIH TRC members by 4pm Eastern Time on the day prior to the next TRC meeting.
3. The administrative component shall attend face-to-face meetings with the TRC, which will occur every other week (average of twice per month) in Bethesda, MD. The administrative component shall take notes and provide a summary of the request decisions to the TRC members within one (1) business day of the meeting.
4. For tracking pending and approved tetramer requests, the administrative component shall:

- i. Obtain and store Materials Transfer Agreements (MTAs) from all approved requestors, which will serve as a registration form and be signed by the principal investigator (i.e., primary senior scientist responsible for the research project) and the Institution's business official. The MTAs will be provided by the Project Officer, after approval from the NIAID Office of Technology Development. The signed MTAs will be valid for 2 years from the time of receipt, unless the Investigator changes Institutions during this time frame. In this case, the subcontractor will obtain a new MTA from the Investigator. In order to keep requestor MTAs up-to-date, the administrative component staff shall contact all registered Tetramer Facility users two (2) months before their MTA expires to request an updated MTA.
- ii. Submit the following TRC-approved request information, including a tetramer/reagent task order number for each approved request (for tracking purposes), to the NIH Tetramer Facility staff within one (1) business day of approval of the tetramer request by the TRC or the Project Officer:
  - a. Investigator name
  - b. Institution name and address
  - c. Shipping company and account information
  - d. MHC allele
  - e. Peptide/ligand amino acid/molecule sequence
  - f. Organism and source protein/molecule of the peptide/ligand
  - g. Beta-2 microglobulin requested (for class I tetramers only)
  - h. Fluorophore label choice
  - i. Feedback and refill comments provided by requestors, when applicable
  - j. Comments provided by TRC, when applicable
- iii. Send the task order number(s) to approved requestors with instructions on how to ship the appropriate amount of peptide ligands and peptide/ligand purity information, and provide shipping information to the NIH Tetramer Facility staff, within three (3) business days of the TRC meeting.

5. Administration and Production of Approved Tetramer Requests: The Contractor shall:

- i. Receive all approved requests for tetramer reagents from the subcontractor, and establish a standard operating procedure for the administrative and manufacturing activities associated with each type of approved request. Action on each approved request shall occur no later than seven (7) business days after receipt of the approved request order by the Facility. Required actions are outlined in steps ii – viii of this section.
- ii. Contact approved requestors regarding fulfillment of orders, as needed. This task includes verifying the peptides that the requestor will supply and, for refill requests, indicating whether peptides or biotinylated monomers are available from previous orders; identifying genetic plasmids containing MHC genes not currently available through the NIH Tetramer Facility that the requestor must supply; and confirming the availability of specific fluorophores, as needed.
- iii. Initiate and complete reagent production. Production and shipping of all final products shall not take longer than an average of thirty-five (35) calendar days from time of receipt of the approved request, for pre-made reagents and refill requests not requiring additional peptide, or of the peptide, for new requests and refill requests requiring additional peptide. Quality control procedures shall follow the procedures outlined in section A.6 of the Technical Requirements.

- iv. Address any queries from approved investigators regarding the status of their approved orders. Information regarding pending or new requests shall be directed to the Project Officer.
- v. Distribute reagents to NIH TRC-approved investigators within five (5) business days of completion of quality control testing and tetramer production. Requesting investigators will pre-pay for express mail parcel delivery costs. The Contractor shall provide shipping containers and wet or dry ice packs, as appropriate, and ship the reagent(s) by express mail parcel delivery to the appropriate address. The shipping procedure shall include providing the proper package handling and customs documentation for domestic and foreign destinations. A package insert describing the enclosed reagent(s), including identification of the MHC molecule, peptide or ligand, and beta-2 microglobulin species (for MHC class I reagents), fluorophore label, protein concentration, buffer composition, and suggested use protocol; proper reagent storage methods; and results of quality control testing. In certain cases where the tetrameric or oligomeric reagents may be unstable during prolonged transit on wet ice (e.g., shipment to foreign sites or based on MHC allele stability variations), the Contractor shall ship monomeric labeled (biotin or other compound) MHC-peptide complexes on dry ice with detailed instructions for tetramerization with appropriate fluorophores.
- vi. Store excess peptides or specific MHC-peptide monomeric complexes from tetramer/reagent task orders, to be used for production of refill requests for the same client that provided the original peptide stock. Peptide stocks shall not be used to fill requests from other clients unless permission is given by the original client, since the original client incurred a cost for peptide production and shipping of the peptide to the Tetramer Facility.
- vii. Contact a sampling of users, in addition to those users that complete on-line feedback forms, to obtain feedback on tetramers and other reagents provided by the NIH Tetramer Facility. Feedback will be used to improve overall customer service and the quality of distributed reagents.
- viii. Maintain a computerized spreadsheet database (or other appropriate computer-based method) to track all tetramer reagent requests received, pending completion, and filled; and to maintain an inventory of available reagents and materials, including excess peptides and monomeric MHC-peptide complexes stored from previous orders.

- C. **Website Design and Maintenance:** The Tetramer Facility public Website shall contain complete information on reagent availability, technical specifications, and use protocols; tetramer history and applications; standard operating procedures for tetramer production; request, review, and order completion process; as well as provide online help for technical and administrative issues; and include an online customer feedback form. The Website shall also contain a order tracking feature so that clients can check the status of their orders online. Website content shall require approval by the Project Officer prior to public posting, and shall be updated regularly as new reagents, methodologies, or information becomes available.
- D. **Tetramer Technology Research and Development:** Identify, develop, and incorporate new processes, approaches, and technologies to ensure a state-of-the-art tetramer reagent production facility. Subcontractors may be employed, as needed to obtain appropriate expertise and incorporate cutting edge technologies.

1. Optimize current manufacturing methods to improve production, quality control, and reliability of tetramer and other Facility reagents.
2. Evaluate and implement new technologies to improve upon or replace current tetramer/oligomer production methods.
3. Develop new reagents related to tetramer usage, including novel fluorophores; expanded MHC alleles; expanded pre-made reagents including CD1d ligands and CD1 tetramers; and novel MHC-ligand complex oligomers to improve T cell detection methods for detection of rare or low avidity T cells, especially CD4 T cells.
4. Sponsor and organize an annual workshop to develop new reagents, improve and standardize use protocols, and promote technology development/transfer to the Facility. Proposed workshop date/place, goals, draft agenda, and draft participant list shall be submitted to the NIAID Project Officer for review, discussion, and concurrence at least eight (8) months prior to the proposed workshop date. After NIAID concurrence, the contractor shall contact approved participants and finalize plans for the workshop. A summary of the workshop shall be submitted to the Project Officer within thirty (30) calendar days of the workshop end date.

#### E. **Project Management and Administration**

##### 1. Overall Project Management

Provide a technical and administrative management infrastructure to ensure the efficient planning, implementation, oversight, and completion of all projects carried out under this contract. This infrastructure shall include:

- i. A Principal Investigator (PI) with ultimate responsibility for the scientific and technical leadership of the Tetramer Facility and the management, coordination and integration of all contract activities, including directing tetramer production and technology development, managing subcontracts and equipment purchases and making a wide range of decisions about staffing, standard protocols, pipeline priorities, intellectual property issues, preparing required reports, deliverables and other official documentation.
- ii. A Facility Manager (FM) with overall responsibilities for project management, including communicating with approved requestors and addressing technical questions from the scientific community; tracking approved tetramer requests; overseeing the annual workshop, in conjunction with the PI and the Project Officer; updating website content (after approval by the Project Officer); monitoring the budget; and preparing progress reports and other deliverable documentation to be submitted to the Project Officer and Contracting Officer.

##### 2. Contract Meetings and Teleconferences

- i. The PI or designate assigned by the PI (e.g., FM) shall plan and conduct weekly meetings with the Contractor's personnel to review overall progress and discuss any technical issues related to tetramer production and technology development.
- ii. The PI or designate assigned by the PI (e.g., FM) shall plan and conduct monthly meetings of the Contractor's PI and FM with the Project Officer and Contracting Officer, either in person or via teleconference, to review overall program progress, and

to discuss any issues that are relevant to the current scientific and financial administration of the Tetramer Facility and future activities. The exact schedule for those meetings will be established by the Project Officer and the Contracting Officer after contract award. The Contractor shall prepare and distribute the agenda and meeting/teleconference materials to all meeting participants at least two (2) business days before the meeting; and shall provide a summary of all meetings and teleconferences in the Quarterly Progress Reports.

### 3. Scientific and Technical Team

Provide a scientific and technical team with the expertise required to develop and maintain a tetramer production facility including, at a minimum, expertise in protein expression, purification and high-yield production; molecular biology and gene cloning; T cell immunology related to MHC-TCR interactions and MHC-peptide complex formation; and IT administration. The Contractor's team must be qualified to perform the Statement of Work and include strong scientific leadership, as well as significant experience in the management, design, and execution of a state-of-the art structural biology center.

### 4. Research Facilities, Equipment, Safety and Training

Provide all the facilities, state-of-the-art laboratory equipment, and standard operating procedures (SOPs) to operate and manage the Tetramer Facility.

### 5. Final Transition

Plan and implement an orderly, safe and efficient transition to a subsequent contractor or to the Government, by the expiration date of the contract, including the transfer and movement of stored reagents, data, web portals, databases, software applications and algorithms, SOPs, technologies, purchased supplies and equipment, and any other resource generated under this contract.

- i. Prepare and submit, for review and approval by the Project Officer and the Contracting Officer, a written draft Final Transition Plan twelve (12) months prior to the expiration date of the contract. The Draft Final Transition Plan shall detail how the resources generated under this contract shall be transferred in an orderly manner to a subsequent contractor or the Government.
- ii. Prepare the Final Transition plan four (4) months prior to expiration date of the contract. Implement the Final Transition Plan as approved by the Project Officer and the Contracting Officer.

### 6. Project Reporting in accordance with the SOW and Reporting Requirements and Deliverables (Attachment4).

## **REPORTING REQUIREMENTS AND DELIVERABLES**

### **NIH Tetramer Facility RFP-NIH-NIAID-DAIT-08-13**

#### **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 ARTICLE F.1. DELIVERIES of this contract:

##### **1. Monthly Progress Report**

This report shall include a full description of the tetramer production activities for processing and fulfillment of requests, during the reporting period (number of task orders received, list of successfully and unsuccessfully produced tetramers, and any important issues that were encountered with tetramer production). The Contractor shall submit one (1) electronic version on the 5th of the month, following the end of each reporting period, directly to the Project Officer. The electronic version will be distributed to the NIAID Tetramer Review Committee by the Project Officer. A Monthly Progress Report is not due in a month where a Quarterly or Annual Progress Report is due. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

##### **2. Quarterly Progress Report**

The detailed reporting requirements are listed below. 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. Quarterly Progress Reports are not required for periods in which an Annual Progress Report or Final Report is due.

Contents of the Quarterly Progress Report are:

- a. Face page to include contract number, contract title, performance period covered, Contractor's name and address, telephone and telefax numbers, E-mail address and submission date.
- b. An executive summary, to include but not limited to:
  - i. An overview of the status of the NIAID Tetramer Facility, including personnel, tetramer requests processed, research and development activities (including subcontract status);
  - ii. A brief overview of the work completed during the current reporting period, obstacles to completing part or all of the proposed work, justification for failure to complete intended work or performance on unintended work, and a summary of any Key Personnel changes since the previous reporting period, including a biosketch of the new key personnel and documentation of prior approval by the Contracting Officer and Project Officers (as required by (Section G. Article G.2);
  - iii. A brief overview of the activities that occurred during the current reporting period and any problems (technical or financial) that occurred during the current reporting period; and the fulfillment of production goals and of the specific aims set forth in the Statement of Work.
  - iv. A list of publications from clients, since the last reporting period, that cite the NIH Tetramer Facility for supplying reagents.
  - v. A summary of client feedback received by Tetramer Facility staff since the last reporting period.

3. A full description of:
  - i. The work performed during the reporting period;
  - ii. The relation between the accomplishments and the goals and objectives of the contract; and
  - iii. A full disclosure of the results and their relevance, explanations of any differences between planned and actual progress, and, if necessary, what corrective steps are planned or have been implemented.
4. Copies of manuscripts (published or unpublished) derived from research performed under the contract and copies of all abstracts, manuscripts, preprints, and publications that resulted from work conducted or any protocol or method developed specifically under this contract during the performance period.
5. A full disclosure of intent to file patent applications or copyrights within or outside of the U.S. on procedures 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>

### **3. Annual Progress Report**

This report shall include a summation of the results of the entire contract work for the period covered. The report shall be submitted thirty (30) days after the anniversary date of the contract. An annual report will not be required for the period when the Final Report is due. The annual report shall consist of the following information:

1. Face page to include contract number, contract title, performance period covered, Contractor's name and address, telephone and telefax numbers, E-mail address and submission date;
2. An executive summary, to include the fulfillment of production goals and of the specific aims set forth in the Statement of Work.
3. A detailed description of the work performed in the year; the results obtained in all tetramer related technology development; explanations of any differences between planned and actual progress, and, if necessary, what corrective steps are planned or have been implemented; summary of tetramer and other reagents produced and shipped in the year, and summary of feedback obtained from clients; discussion of the relevance of the results of technology development and reagent production and their relation to work being conducted in the area by other groups; and
4. A summary and update of all intentions to file patent applications or copyrights within or outside of the U.S. on procedures utilized, derived, or established by the work supported under this contract; and filed within the previous year.

### **4. Draft Final Report**

The Contractor shall provide the Project Officer with one (1) hard copy and one (1) electronic version of the Final Report in draft form sixty (60) calendar days prior to the delivery date of the final version of the report. The project officer will review the draft report and provide the Contractor with comments within fourteen (14) calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary.

### **5. Final Report**

This report shall consist of the work performed and results obtained for the entire contract period of performance as stated in Section F of the contract. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted on or before the last day of the contract performance period. An Annual Progress Report shall not be required for the period when the Final Report is due.

**6. Summary of Salient Results – use in all R&D contracts**

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

**B. Technical Reports Delivery Schedule**

Satisfactory performance of the contract is defined as satisfactorily performing the statement of work and delivering the following items.

Progress Reports				
Item	Type of Report	Initial Report Due	Recipient & Number of Hard & Electronic Copies	Subsequent Reports Due
1.	Monthly Progress Reports	Fifth (5 <sup>th</sup> ) business day of the month, following the first month after contract award date.	1 electronic version to PO	Monthly, on the 5 <sup>th</sup> business day of the month, following the end of each reporting period. A Monthly Progress Report is not due for a month where a quarterly or annual report is due.
2.	Quarterly Progress Reports	Fifteenth (15 <sup>th</sup> ) of the month following the end of the first quarterly performance period.	1 hard copy and 1 electronic version to PO; 1 hard copy to CO	Quarterly, submitted on the 15th day of the month following the end of each quarterly performance period.
3.	Annual Progress Report	Thirty (30) calendar days after the first Anniversary Date of the contract	1 hard copy and 1 electronic version to PO; 1 hard copy to CO	Annually; submitted 30 calendar days after the anniversary date. An Annual Progress Report is not due when a Final Report is due.
4.	Draft Final Report	Sixty (60) calendar days prior to the completion date of the contract.	1 hard copy and 1 electronic version to PO; 1 hard copy to CO	
5.	Final Report	On or before the completion date of the contract.	1 hard copy and 1 electronic version to PO; 1 hard copy to CO	

### C. Other Reports/Deliverables

1. **Invention Report Requirement** – In addition to the requirements of Article C.3. invention disclosures shall be reported to the NIAID within two months after the inventor provides written disclosure to their authorized organizational official. The disclosure to NIAID must be in writing. Identify the contract number and name of the inventor or inventors, and provide a complete technical description and other information as required by CFR's Standard Patent Rights Clauses, 37 CFR 401.14(c)(1). Follow all procedures as outlined at the NIAID invention disclosure website: <http://www.niaid.nih.gov/ncn/sop/contracts/invention.htm>

2. **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 for use in tetramer request/reagent tracking and the Tetramer Facility public website system.

3. **System Security Plan (SSP)** for the website and backend infrastructure. The SSP will identify the system and detail the management, operational, and technical controls of the system. This report shall be due to the Government within 60 calendar days of contract award. If a major change is made to the web site and/or backend infrastructure, the Government requires an updated SSP.

Other Reports				
Item	Type of Report	Initial Report Due	Recipient & Number of Hard & Electronic Copies	Subsequent Reports Due
1.	Annual Workshop Summary	Thirty (30) calendar days after the workshop end date, to be held within the first year of the contract award and yearly thereafter.	1 hard copy and 1 electronic version to PO; 1 hard copy to CO	Annually; submitted 30 calendar days after the workshop end date.
2	Invention Reporting	Within two (2) months of written disclosure to the contractor's authorized organizational official	2 hard copies and 1 electronic version to PO; 1 hard copy to CO	As required, for the life of the contract
3.	Draft Transition Plan	Twelve (12) months prior to expiration date of the contract.	1 hard copy and 1 electronic version to PO; 1 hard copy to CO	
4.	System Security Plan	Within sixty (60) calendar days of contract award.	1 hard copy and electronic version to PO; 1 electronic copy to CO and ISSO	As required for the life of the contract.
5.	Final Transition Plan	Four (4) months prior to expiration date of the contract	1 hard copy and 1 electronic version to PO; 1 hard copy to CO.	

## D. ARTICLE F. 1. DELIVERIES

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

The items specified below as described in SECTION C, 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 the contract:

Deliverables					
Item	Type of Deliverable	SOW Reference	Due	Recipient	Subsequent Deliverables Due
1.	Shipment of Tetramer Facility provided reagents (e.g., oligomers, tetramers, monomers, ligands, etc) to approved investigators	SOW Task B, item 5, iv.	Within five (5) business days of completion of reagent production and all quality control testing	TRC-approved investigators (i.e., requestors)	As required by approved request list workload
2.	All MHC gene expression vectors, cell lines, peptide and ligand stocks, MHC monomer stocks, and production protocols for all reagents produced for the NIH Tetramer Facility	SOW Task A	At contract completion	To be specified 60 days prior to contract completion	N/A
3.	All computer programs, written documentation for all programs, Tetramer Facility website content and access codes	SOW Task C	At contract completion	To be specified 60 days prior to contract completion	N/A
4.	All Standard Operating Procedures for reagent production, protocols for novel technologies developed under this contract, and	SOW Task D	At contract completion	To be specified 60 days prior to contract completion	N/A

	all novel reagents developed under this contract (and not specified in item 2 above).				
5.	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 Tasks A, B, C, D, and E	At contract completion	To be specified 60 days prior to contract completion	N/A
6.	All laboratory equipment (e.g., freezers, tissue culture hoods, incubators, protein purification equipment) purchased and used solely for tasks required by the contract.	SOW Tasks A, B, and D	At contract completion	To be specified 60 days prior to contract completion	N/A

**E. Copies of reports shall be sent to the following addresses:**

Project Officer

Address: Basic Immunology Branch  
Division of Allergy, Immunology, and Transplantation (DAIT)  
NIAID, NIH, DHHS  
6610 Rockledge Drive, MSC 6601  
Bethesda, MD 20892-6601 (Fed Ex zip 20817)

Contracting Officer

Address: DAIT Research Contracts Branch  
Office of Acquisition, Division of Extramural Activities  
NIAID, NIH, DHHS  
6700-B Rockledge Drive, Rm 3214, MSC 7612  
Bethesda, MD 20892-7612 (Fed Ex zip 20817)

NIAID ISSO

Address: NIAID Information System Security Officer  
National Institutes of Health  
National Institute of Allergy and Infectious Diseases  
Office of the CIO  
10401 Fernwood Road, Room 2C11  
Bethesda, MD 20892

**F. Special Shipping and Packaging**

- 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) \_\_\_\_\_

**ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS  
FORMAT FOR TECHNICAL PROPOSAL  
NIH Tetramer Facility  
RFP-NIH-NIAID-DAIT-08-13**

**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. 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 in this Appendix.

Offerors are advised to give careful consideration to the Statement of Work, all reference materials, appendices 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 200 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**

- I. 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.
- II. PROJECT OBJECTIVES (NIH FORM 1688-1)
- III. GOVERNMENT NOTICE FOR HANDLING PROPOSALS
- IV. PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)
- V. TABLE OF CONTENTS

**SECTION 2: TECHNICAL APPROACH**

**I. TECHNICAL PROPOSAL OVERVIEW (2-3 pages)**

Provide a brief overview of the proposed program, including descriptions of the following:

- A. The scope of MHC tetramer reagents and related resources that the Offeror is proposing to provide;

- B. The activities to be performed by the Offeror and those that shall be provided by any proposed subcontractors, including the identification of the proposed subcontractors and a list of key personnel of the Offeror and the proposed subcontractors with degrees and titles; and
- C. The facilities and other resources to be made available by the Offeror and any proposed subcontractors.

## **II. TECHNICAL PLAN**

Offerors shall provide the information outlined below as part of their technical proposal. For each proposed subcontract, the technical proposal must provide a detailed description of the subcontract research plan and contribution to the overall proposal, a complete description of the facilities, and the professional backgrounds of proposed personnel, within the appropriate sections of the research proposal.

### **A. Initial Transition – For all new offerors (excluding current Contractor)**

A detailed description of the plans for ensuring an orderly transition of activities and resources from the predecessor contract to the successful offeror within 2 months of contract award.

### **B. Key SOW Activity: Establish, Operate, and Maintain a Tetramer Production Facility**

A detailed description of:

1. The types of reagents to be provided by the Tetramer Facility, including: MHC class I, class II, and non-classical MHC alleles; any pre-made tetramers; CD1d or other MHC ligands and peptides; fluorophores; etc.
2. The scientific basis for the proposed experimental approaches for production of tetramers and related reagents and quality control methods.
3. The experimental approaches for production and quality control of all tetramers and related reagents, including a detailed description of the source of human, mouse, or non-human primate T cells that will be used for testing MHC class II tetramers.
4. Alternative approaches to be employed, or methods for problem solving, if the proposed experimental approaches and quality control methods do not achieve the defined goals.
5. Subcontract activities needed to address the specific tasks, and methods to identify and add new subcontracts as needed to perform any of the contract duties.

### **C. Key SOW Activity: Develop and Maintain a Distribution, Tracking, and Reporting System**

A detailed description of:

1. Methods and procedures for tracking tetramer and other reagent requests as outlined in the Technical Requirements, Section B: Develop and Maintain a Distribution, Tracking, and Reporting System.
2. Subcontract or other proposed activities needed to address the specific tasks associated with the administrative component of the TRC, including how requestor research confidentially will be maintained.
3. Procedures for administration, production, quality control, and shipping of approved tetramer/reagent requests.
4. Methods for obtaining client feedback on provided reagents.
5. Plans for client interactions that minimize costs to the client and the facility, while maximizing customer service.

### **D. Key SOW Activity: Website Design and Maintenance**

A detailed description of:

1. The types of information to be included on the public NIH Tetramer Facility website.
2. Procedures for updating website information, including process for NIAID approval of website content.
3. Sample screen shots of the proposed NIH Tetramer Facility website and key features of the website to improve usability and information dissemination.
4. Subcontract activities needed to address any of the required tasks, and methods to identify and add new subcontracts as needed to perform the contract duties.

#### **E. Key SOW Activity: Tetramer Technology Research and Development**

A detailed description of:

1. Procedures to identify, develop, and incorporate new processes and methodologies for optimized production, quality control, and reliability of tetramers and related reagents manufactured at the facility.
2. Methods for developing and optimizing new tetramer-related reagents for public distribution, including alternative approaches to be employed, or methods for problem solving, if the proposed experimental approaches do not achieve the defined goals.
3. Subcontract activities needed to address any of the specific tasks, and methods to identify and add new subcontracts as needed to perform the contract duties.
4. Plans for the organization of an annual workshop to provide state-of-the art information and promote technology development. Provide a list of possible workshop topics for year 1 and methods for selecting future workshop topics.

#### **E. Provision of Contract-Generated Resources**

Provide a plan for sharing data and novel tetramer-related research protocols with the scientific research community, for methodologies developed under the contract. The NIH policy on the sharing of data can be found at <http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>. Stating that results will be published is not an adequate plan. Additional information about data sharing, including examples, can be found at [http://grants.nih.gov/grants/policy/data\\_sharing/](http://grants.nih.gov/grants/policy/data_sharing/). The NIH Policy statement on the Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Biomedical Research Resources is available at: [http://grants.nih.gov/grants/policy/nihgps\\_2001/part\\_ia\\_6.htm#\\_Toc504811860](http://grants.nih.gov/grants/policy/nihgps_2001/part_ia_6.htm#_Toc504811860).

### **SECTION 3: PERSONNEL**

#### **A. Principal Investigator (PI)**

Describe the training, education, experience and qualifications of the PI as well as the percentage of the total time the PI will be committed to the project. Please provide relevant documentation to describe:

- CV, limited to 2-3 pages
- Qualifications and relevant training
- Previous experience with projects of similar size and complexity including management of subcontractors (limited to the past 5 years)
- References to relevant publications
- Summary of related activities, including ability to: assess progress, in accordance with established tasks and timelines; recommend modifications to reagent 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 assess

performance, identify performance problems and design and implement remedial actions when necessary.

**B. Facility Manager (FM)**

Describe the training, education, experience and qualifications of the proposed FM, including the percentage of the total time the FM will be committed to the project. Please provide relevant documentation to describe:

- CV, limited 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, including communicating with approved requestors and addressing technical questions from the scientific community; tracking approved tetramer requests; overseeing the annual workshop, in conjunction with the PI and the Project Officer; updating website content (after approval by the Project Officer); monitoring the budget; and preparing progress reports and other deliverable documentation to be submitted to the Project Officer and Contracting Officer.

**C. 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 Statement of Work.

**SECTION 4: PROJECT MANAGEMENT**

- A. 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 Statement of Work. Describe in detail the responsibilities and level of effort for all proposed personnel who will be assigned to the contract, including the Facility Manager, proposed subcontractors and consultants, and administrative and technical framework indicating clear lines of authority and responsibility for all proposed personnel.
- B. Outline how the contract Principal Investigator and Facility Manager will communicate with the Project Officer and Contracting Officer and how the Principal Investigator will communicate, monitor, and manage the project both internally and externally (e.g., at subcontractor facilities), including methods for prioritization of important project tasks.

**SECTION 5: FACILITIES AND OTHER RESOURCES**

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

Attachment 5

Additional Technical Proposal Instructions

- A. 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).
- B. Identification and description of ALL support resources (including Information Technology systems) which will be required to effectively complete the technical requirements of the contract.

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

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.

**I) Human Subjects**

Section L of the RFP specifies the minimum documentation requirements for Human Material/Subjects use. All related documentation should be included in the proposal in a clearly marked section. The Technical Proposal should document all information necessary to evaluate Human Material/Subject use.

**II) Animal Welfare**

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.

**III) 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.

**IV) Biohazard Safety**

The Technical Proposal should include a plan for biohazard safety and security requirements.

**ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS**  
**NIH Tetramer Facility**  
**RFP-NIH-NIAID-DAIT-08-13**

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

Offerors are advised to give careful consideration to the statement of work, all reference material provided as appendices and attachments, 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 in this appendix, as well as **any other** information which will benefit the proposal.

**BUSINESS PROPOSAL – TABLE OF CONTENTS**

**SECTION 1 – PROPOSAL COVERSHEET** (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**

1. Tetramer production costs shall include a workload estimate of 70-80 requests per month, with approximately 30% of requests for CD1d monomers and tetramers, and the remaining requests for custom MHC class I and class II tetramers, for the first year of the contract. These cost estimates shall include a projected increase in production capacity up to 100 tetramer reagents per month, by the end of the second year of award.
2. For each proposed subcontract, the business proposal must provide a detailed description of the subcontract associated costs to include Direct Labor, Fringe Benefits, Materials and Supplies, Equipment, Consultants, Travel, and Overhead (and other categories as apply to the specific subcontract tasks).

**B. Travel**

1. Annual Workshop: Meeting costs shall include hotel meeting space, audio visual and logistical support, light refreshments and travel costs for 25 participants, including relevant Tetramer Facility staff, to a 1.5 day meeting at a hotel in Bethesda, Maryland. Travel costs shall include airfare (coach – assume that half of the travelers will come from the West Coast, one quarter from the North, and one quarter from the South), per diem (government rate), ground transportation, and hotel accommodations (government rate) for 2 nights.
2. Scientific Meetings: Offerors shall include travel costs for the Principle Investigator and 1-2 scientific

staff to attend 1 domestic scientific meeting per year, on a topic related to the contract Statement of Work.

**C. Storage**

Offerors should include a uniform assumption of 480 new peptide stocks, MHC ligands, and MHC monomers to be stored each year.

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

**1) Small Business Subcontracting Plan**

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

**2) Extent of Small Disadvantaged Business Participation**

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

**3) Past Performance Data, including references**

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