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

RFP-NIH-NIAID- DAIDS-07-31
"IMMUNOLOGY QUALITY ASSESSMENT PROGRAM"

OMB Control Number 0990-0115

1. **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.** http://www.fedbizopps.gov/

2. **SECTION A – SOLICITATION/CONTRACT FORM --** PURCHASE AUTHORITY: FAR 1.602-1
NOTE: The issuance of this solicitation does not commit the government to an award.

3. **Issue Date:**	4. Due Date: **02/05/2007**	5. **Small Bus. Set-Aside:** [ ]Yes [X] No
11/03/2006	**Time:** 4:30 p.m. Local Time	**8(a) Set-Aside:** [ ]Yes [X] No
		NAICS: 541710
		(See Part IV, Section L.)

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

9. **Issued By:**	10. [x] **NIAID reserves the right to make awards without discussion.**	
Elizabeth J. Shanahan Contracting Officer Office of Acquisitions, DEA, NIH, NIAID 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	11. **Options:** **[ ] No** **[X] Yes** (See Part IV, Section L.)	12. **Period of Performance:** **August 24, 2007** **through** **August 23, 2014**

13. **Primary Point of Contact:**	14. **Secondary Point of Contact:**	15. **Protest Officer:**
Name : Elizabeth J. Shanahan	**Name:** Eileen Webster-Cissel	**Name:** Charles Grewe
Phone: 301-496-0612	**Phone:** 301-496-0612	Director, OA
Fax: 301-402-0972	**Fax:** 301-402-0972	Address: (See Block 9.)
E-Mail: shanahane@niaid.nih.gov	**E-Mail: webstere@niaid.nih.gov**	

16. **COLLECT CALLS WILL NOT BE ACCEPTED. FACSIMILE SUBMISSIONS ARE NOT ACCEPTABLE.**

17. Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See Part III, SECTION J – Attachments)

18. **DELIVERY ADDRESS INFORMATION**

19. **Hand Delivery or Overnight Service:**	20. **U.S. Postal Service or an Express Delivery Service**
Office of Acquisitions DEA, NIH, NIAID 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	Office of Acquisitions DEA, NIH, NIAID 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612

21. The **Official Point of Receipt** for the purpose of determining timely delivery is the address provided in Block 19, above. The original paper copy with original signatures is the official copy for recording timely receipt. If the original paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with FAR 15.208 entitled "Submission, Modification, Revision, and Withdrawal of Proposals." FACSIMILE AND E-MAIL SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

PART I - THE SCHEDULE

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

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The purpose of this contract is to assess and enhance the quality, reliability and comparability of immunological laboratory tests performed on samples from subjects enrolled in National Institute of Allergy and Infectious Diseases (NIAID)-supported and/or collaborative multi-site therapeutic, vaccine and prevention studies.

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

a. The estimated cost of the Base Period of this contract is $_____.

b. The fixed fee for the Base Period of this contract is $____. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer. Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract. Payment of fixed fee shall not be made in less than monthly increments.

c. The Government's obligation, represented by the sum of the estimated cost plus the fixed fee for the Base Period of this contract is $_____.

d. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total obligation represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

	Estimated Cost ($)	**Fixed Fee ($)**	**Estimated Cost Plus Fixed Fee ($)**
Base Period	To be negotiated	To be negotiated	To be negotiated
Option Period(s):	To be negotiated	To be negotiated	To be negotiated
Total [Base Period and Option(s)]	To be negotiated	To be negotiated	To be negotiated

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

f. It is estimated that the amount currently allotted will cover performance of the contract through _____.

g. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

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

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. DESCRIPTION-SPECIFICATION/STATEMENT OF WORK]

a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated August 1, 2006, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

a. Technical Progress Reports

1. In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award. *(Please refer to Attachment 4 of the RFP entitled "Reporting Requirements and Deliverables").*

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

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

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

Contracting Officer
Office of Acquisitions
National Institute of Allergy and Infections Diseases
6700B Rockledge Drive
Room 3214, MSC 7612
BETHESDA MD 20892-7612

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

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating

to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the 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 indicated in SECTION G, ARTICLE G.1, is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at the address listed for the Project Officer in Section G, ARTICLE G.1. Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

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

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

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. 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 items in Section C, ARTICLE C.2. in accordance with the stated delivery schedule.

The items described in SECTION C, ARTICLE C.2. will be required to be delivered F.O.B. Destination as set forth in FAR Clause 52.247-35, F.O.B. Destination, Within Consignees Premises (April 1984), and in accordance with and by the date(s) specified in SECTION C, ARTICLE C.2. and any specification stated in SECTION D PACKAGING MARKING AND SHIPPING of the contract. *(Please refer to Attachment 4 of the RFP entitled "Reporting Requirements and Deliverables").*

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

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

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

NAME	TITLE
[To be specified prior to award]	

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

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

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

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

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

Contract No. (This is the 17 digit number that appears in Block 2 of the SF-26, i.e. HHSN261200411000C.)

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

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

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

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

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

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

ARTICLE G.4. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication entitled, **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 evaluations will be prepared annually to coincide with the anniversary date of the contract.

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

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

b. Electronic Access to Contractor Performance Evaluations

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

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

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

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the Contractor has provided to the Contracting Officer 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. The human subject certification can be met by submission of the Contractor's 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).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, 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 research.

ARTICLE H.2. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

The information below is a summary of the NIH Policy Announcement:

The contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

ARTICLE H.3. HUMAN MATERIALS

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

ARTICLE H.4. 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.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. 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 09-25-0200 . This document is incorporated into this contract as an Attachment in SECTION J of this contract.

ARTICLE H.8. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of the Base requirements identified in the Statement of Work as defined in Sections C and F of the contract. Pursuant to clause 52.217-6 set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the intent to exercise the option(s), and the estimated cost of the contract will be increased as set forth in the ESTIMATED COST PLUS FIXED FEE Article in SECTION B of this contract.

ARTICLE H.9. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

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

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

b. Subcontracting Reports

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

(1) Individual Subcontract Reports (ISR)

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

April 30th
October 30th

(2) Summary Subcontract Report (SSR)

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

October 30th

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

Elizabeth Shanahan
Email Address: shanahane@niaid.nih.gov

ARTICLE H.10. SALARY RATE LIMITATION LEGISLATION PROVISIONS

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

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

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

[*Applicable information to be included at award]

ARTICLE H.11. INFORMATION SECURITY

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

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

a. Information Type

[X] Mission Based Information

b. Security Categories and Levels

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

c. Position Sensitivity Designations

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

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

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

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

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

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

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

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

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

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

d. Information Security Training

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

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

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

e. Rules of Behavior

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

f. Personnel Security Responsibilities

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

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

(1) Contractor Agreement

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

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

(2) Contractor-Employee Non-Disclosure Agreements

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

h. NIST SP 800-26 Self-Assessment Questionnaire

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

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

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

i. Information System Security Plan

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

Following approval of its draft ISSP, the contractor shall update and resubmit its ISSP to the Project Officer every three years or when a major modification has been made to its internal system. The contractor shall use the current ISSP template in Appendix A of NIST SP 800-18, *Guide to Developing Security Plans for Federal Information Systems*.

(http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf). The details contained in the contractor's ISSP shall be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels of this Article.

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

ARTICLE H.12. 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.

ARTICLE H.13. 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.14. PUBLICATION AND PUBLICITY

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

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

ARTICLE H.15. 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.16. 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.17. YEAR 2000 COMPLIANCE

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

1. Service Involving the Use of Information Technology

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

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

(End of Clause)

2. Noncommercial Supply Items Warranty

YEAR 2000 WARRANTY--NONCOMMERCIAL SUPPLY ITEMS

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

YEAR 2000 COMPLIANT ITEMS

_____

_____

_____

(End of Clause)

3. Commercial Supply Products Warranty

YEAR 2000 WARRANTY--COMMERCIAL SUPPLY ITEMS

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

YEAR 2000 COMPLIANT ITEMS

_____

_____

_____

(End of Clause)

ARTICLE H.18. 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.19 SHARING RESEARCH DATA

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

The NIH endorses the sharing of final research data to 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.20. 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.21. 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.

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 Negotiated Fixed-Price Architect-Engineer Contract
General Clauses for a Cost-Reimbursement Research and Development Contract
General Clauses for a Cost-Reimbursement Service Contract
General Clauses for a Cost-Reimbursement Supply 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
General Clauses for a Negotiated Fixed-Price Research and Development Contract
General Clauses for a Negotiated Fixed-Price Service Contract
General Clauses for a Negotiated Fixed-Price Supply Contract
General Clauses for a Cost-Reimbursement SBIR Phase II Contract
General Clauses for a Fixed-Price SBIR Phase II Contract
General Clauses for a Time and Material or a Labor Hour Contract

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

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

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

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

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

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

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

Alternate I (February 2002), of FAR Clause 52.232-25, Prompt Payment (February 2002) is deleted.

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 **52.216-15, Predetermined Indirect Cost Rates** (April 1998).
(2) FAR Clause **52.217-6, Option for Increased Quantity** (March 1989).

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

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

"(c) Waiver of evaluation preference.....
[ ] Offeror elects to waive the evaluation preference."

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

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

(6) FAR Clause **52.224-1, Privacy Act Notification** (April 1984).

(7) FAR Clause **52.224-2, Privacy Act** (April 1984).

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

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

(10) **Alternate V** (June 1987), FAR Clause **52.227-14, Rights in Data--General** (June 1987).
Specific data items that are not subject to paragraph (j) include: NONE

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

One or several of the following Cost Accounting Clauses will be included in ARTICLE I.3., depending upon the type of awardee organization.

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

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

(14) FAR Clause **52.230-5, Cost Accounting Standards - Educational Institution** (April 1998).

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

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

(17) FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984).

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.

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

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

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

(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.nlrb.gov.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS:

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal	See Attachment Section at the end of this RFP.
Attachment 2:	Proposal Intent Response Sheet	http://rcb.cancer.gov/rcb-internet/forms/intent.jsp
Attachment 3:	Statement of Work	See Attachment Section at the end of this RFP.
Attachment 4:	Reports/Deliverables	See Attachment Section at the end of this RFP.
Attachment 5:	Information Technology Systems Security - Prospective Offeror Non-Disclosure Agreement	http://rcb.cancer.gov/rcb-internet/forms/IT-security-nondisclosure.pdf
Attachment 6:	Appendix A - Additional Technical Proposal Instructions	See Attachment Section at the end of this RFP.
Attachment 7:	Appendix B -Additional Business Proposal Instructions and Uniform Cost Assumptions	See Attachment Section at the end of this RFP.
Attachment 8:	Appendix C - Advanced Understandings	See Attachment Section at the end of this RFP.
Attachment 9:	Appendix D - List of Government Furnished Property	See Attachment Section at the end of this RFP.
Attachment 10:	Appendix E - Sample Report	See Attachment Section at the end of this RFP.
Attachment 11:	Appendix F -Sample Proficiency Testing Report	See Attachment Section at the end of this RFP.

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

Attachment No.	Title	Location
Attachment 12:	Targeted/Planned Enrollment Table	http://rcb.cancer.gov/rcb-internet/forms/enroll-table.pdf
Attachment 13:	Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Attachment 14:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Attachment 15:	Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf

Attachment 16:	Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (formerly Optional Form 310	http://rcb.cancer.gov/rcb-internet/forms/of310.pdf
Attachment 17:	Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf

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

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

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

Attachment No.	Title	Location
Attachment 23:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 24:	Privacy Act System of Records *System of Records No. 09-25-0200 is applicable to this RFP.*	http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm
Attachment 25:	Safety and Health, HHSAR Clause 352.223-70	http://www.niaid.nih.gov/contract/forms/form10.pdf
Attachment 26:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Attachment 27:	Government Property Schedule	See Attachment Section at the end of this RFP
Attachment 28:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf
Attachment 29:	Commitment To Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf

Attachment 30:	Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Attachment 31:	Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

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

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

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

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

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

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

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

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

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

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

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

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

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

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

(2) The first page of the proposal must show--
- (i) The solicitation number;
- (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
- (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
- (iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
- (v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

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

(ii) (A) Any proposal, modification, or revision received at the Government office designated in

the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(End of Provision)

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

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

b. **NAICS CODE AND SIZE STANDARD**

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

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.

(2) The small business size standard is 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 August 24, 2007. It is anticipated that the award from this solicitation will be a cost reimbursement type contract, completion form, with a 7 year period of performance, and that incremental funding will be used.

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 for the base requirement to be approximately 6 Full Time Equivalents (FTEs), per year. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

e. **COMMITMENT OF PUBLIC FUNDS**

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

f. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

g. **RELEASE OF INFORMATION**

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

h. **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** (AUGUST 1996) - FAR 52.233-2

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

Contracting Officer
Office of Acquisitions
National Institute Of Allergy and Infectious Diseases
6700B Rockledge Drive
Room 3214, MSC 7612
BETHESDA MD 20892-7612

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

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.

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/level of effort)/fixed-price] 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.

III. BUSINESS PROPOSAL

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

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

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

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

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

(5) **Alternate Proposals**

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

(6) **Evaluation of Proposals**

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

(7) **Potential Award Without Discussions**

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

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

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

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

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

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

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

(9) **Privacy Act - Treatment of Proposal Information**

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

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

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

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

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

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

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

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

(10) **Selection of Offerors**

a) The acceptability of the [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

4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

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

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

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

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

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

Include the following information for each contract or subcontract:

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

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

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

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

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

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

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

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

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

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

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

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

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

c) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. TECHNICAL PROPOSAL INSTRUCTIONS

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

(1) **Technical Discussions**

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

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

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

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

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

b) **Statement of Work**

(1) Objectives

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

(2) Approach

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

(3) Methods

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

(4) Schedule

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

c) **Personnel**

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

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

(1) Principal Investigator/Project Director

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

(2) Other Investigators

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

(3) Additional Personnel

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

-The specific items or expertise they will provide.

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

-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) Resumes

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

(2) **Technical Evaluation**

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

(3) **Additional Technical Proposal Information**

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

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

(4) **Other Considerations**

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

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

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

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

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

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

IMPORTANT NOTE TO OFFERORS: The following [10/11/12] paragraphs [(5) through (14)/(15)/(16)] shall be addressed in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

(5) **Human Subjects**

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (MARCH 2005)

(a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protections (OHRP), Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR Part 46.

(c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The OpDiv will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consultation with OHRP, (telephone: 301-496-7005), is recommended.

(e) In accordance with 45 CFR Part 46, prospective Contractors being considered for award shall be required to file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. The contracting officer will direct the offeror/contractor to the OHRP IRB Registration and Assurance Filing website, found at http://www.hhs.gov/ohrp/ or to the physical address if the offeror/contractor cannot access the Internet. HHS regulations for the protection of human subjects may be found at:

http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html

(f) It is recommended that OHRP be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(6) **Instructions to Offerors Regarding Protection of Human Subjects**

Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

(a) Risks to the subjects

Human Subjects Involvement and Characteristics:

- Describe the proposed involvement of human subjects in response to the solicitation.

- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.

- Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.

Sources of Materials:

- Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks:

- Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.

- Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

- Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

Protection Against Risk:

- Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.

- Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.

- In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

(c) Potential Benefits of the Proposed Research to the Subjects and Others

- Discuss the potential benefits of the research to the subjects and others.

- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

(d) Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.

- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Note: If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

Collaborating Site(s)

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

(7) **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled “Protection of Human Research Subjects: Computer-Based Training for Researchers,” available at http://ohsr.od.nih.gov/cbt/. You may download the information at this site at no cost and modify it, if desired. The University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at

http://www.centerwatch.com/order/pubs_profs_protect.html.

In addition, the NIAID sponsors an online training course at:

http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp.

If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the contracting officer with the title of the education program and a one sentence description of the program that the replacement has completed.

(8) **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is NIH policy that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an Institute/Center Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43), ***and applies to research subjects of all ages***.

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research," at:

(http://www.nih.gov/news/crp/97report/execsum.htm).

Information Required for ALL Clinical Research Proposals

This solicitation contains a review criterion addressing the adequacy of: (1) the offeror’s plans for inclusion of women and minorities in the research proposed; or (2) the offeror’s justification(s) for exclusion of one or both groups from the research proposed.

Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic groups and provide a rationale for selection of such subjects in response to the requirements

of the solicitation. The description may include (but is not limited to) information on the population characteristics of the disease or condition being studied in the planned research, and/or described in the statement of work, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned research.

The proposal must include the following information:

- A description of the subject selection criteria
- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group
- The proposed sample composition using the "Targeted/Planned Enrollment Table"(see Section J, Attachments)

NOTE 1: *For all proposals, use the ethnic and racial categories and complete the "Targeted/Planned Enrollment Table in accordance with the Office of Management and Budget (OMB) Directive No. 15, which may be found at: http://www.whitehouse.gov/OMB/fedreg/ombdir15.html.*

NOTE 2: *If this is an Indefinite Delivery, Indefinite Quantity (IDIQ) or Requirements contract as defined in FAR 16.5, the proposal should describe in general terms how it will comply with each bulleted item above for each task order. When the Government issues a task order request for proposal, each of the bulleted information items must be fully and specifically addressed in the proposal.*

Standards for Collecting Data. When you, as a contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in OMB Directive No. 15. The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When you collect race and ethnicity separately, you must collect ethnicity first. You shall offer respondents the option of selecting one or more racial designations. When you collect data on race and ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple responses, you shall make available, at a minimum, the total number of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

In addition to the above requirements, solicitations for **NIH defined Phase III clinical trials**[1] require that*:* a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide: http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference), by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Also, the proposal must include one of the following plans:

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1 See NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, for the Definition of an "NIH-Defined Phase III clinical trial.

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups, OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Use the form entitled, "Targeted/Planned Enrollment Table," when preparing your response to the solicitation requirements for inclusion of women and minorities. (See Section J-List of Documents, Exhibits and Other Attachments of the RFP)

Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

Use the form entitled, "Inclusion Enrollment Report," for reporting in the resultant contract.

(9) **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are *clear and compelling* reasons not to include them. (See examples of Justifications for Exclusion of Children below). For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

All offerors proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

http://www.nih.gov/grants/guide/notice-files/not98-024.html

Offerors also may obtain copies from the contact person listed in the RFP.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. The “Human Subjects” section of your technical proposal should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. This solicitation contains a review criterion addressing the adequacy of: (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

When children are included, the plan also must include a description of: (1) the expertise of the investigative team for dealing with children at the ages included; (2) the appropriateness of the available facilities to accommodate the children; and, (3) the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation.

Justifications for Exclusion of Children

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

- The objective of the solicitation is not relevant to children.

    - There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.

    - The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.

        - A separate, age-specific study in children is warranted and preferable. Examples include:
        - The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
        - The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
        - Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or
        - Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or
        - Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);
        - Other special cases justified by the offeror and found acceptable to the review group and the Institute Director

Definition of a Child

For the purpose of this solicitation, a child is defined as an individual under the age of 21 years.
The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a “child,” and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of “child” for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

(10) **Research Involving Prisoners as Subjects**

a. HHS Regulations at 45 CFR Part 46, Subpart C provide additional protections pertaining to biomedical and behavioral research involving prisoners or those individuals who, during the period of the contract become prisoners, as subjects. These regulations also set forth the duties of the Institutional Review Board (IRB) where prisoners are involved in the research. HHS-funded research involving prisoners as subjects may not proceed until the Office for Human Research Protections (OHRP) issues approval, in writing, as required by 45 CFR 46.306(a)(2). In addition, OHRP Guidance on the Involvement of Prisoners in Research may be found at:
http://ohrp.osophs.dhhs.gov/humansubjects/guidance/prisoner.htm

b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

On June 20, 2003 the Secretary of HHS waived the applicability of certain provisions of Subpart C of 45 CFR Part 46, (Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects) to specific types of epidemiological research involving prisoners as subjects.

The applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain epidemiological research conducted or funded by DHHS is waived when:

1. The sole purposes are:

   a) to describe the prevalence or incidence of a disease by identifying all cases, or
   b) to study potential risk factor associations for a disease, and

2. The Institution responsible for the conduct of the research certifies to the OHRP that the Institutional Review Board (IRB) approved the research and fulfilled its duties under 45 CFR 46.305(a)(2-7) and determined and documented that:

   a) the research presents no more than minimal risk, and
   b) no more than inconvenience to the prisoner-subjects, and
   c) prisoners are not a particular focus of the research.

For more information about this Waiver see http://www.hhs.gov/ohrp/special/prisoners/Prisoner waiver 6-20-03.pdf

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

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

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

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

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

(12) **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 (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)
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.
(http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm#_Toc7255836)

(13) **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.]

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

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

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

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

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

(a) Information Type

[ ] Mission Based Information:

(b) Security Categories and Levels

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

(c) Position Sensitivity Designations

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

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

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

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

Upon award, the contractor will be required to submit a roster of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a

federal information system(s). The Government will determine and notify the Contractor of the appropriate level of suitability investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: http://ais.NIAID.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 "NIAID Information Technology Security Policies, Background Investigation Process" website: http://ais.NIAID.nih.gov.

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

(d) Information Security Training

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

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

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

(e) Offeror's Official Responsible for Information Security

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

(f) Draft Information System Security Plan

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

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

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

(g) References

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

c. BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

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

(2) Proposal Cover Sheet

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

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;

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

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

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

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

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation. Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.

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

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

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

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

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

5. **Purchased Parts**
Includes material items not covered above. Provide priced quantities of items required for the proposal.

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

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

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

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

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

(4) **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.

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 2006**

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

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

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

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

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

(6) **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the apparent successful offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, Attachment 13 to this RFP is an example of such a plan.

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

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

c) The offeror understands that:

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

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

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

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

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

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

d) Each plan must contain the following:

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

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

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

Owned Small Business Concerns.

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

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

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

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

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

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

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

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

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

(7) **HUBZone Small Business Concerns**

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

(8) **Extent of Small Disadvantaged Business Participation**

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

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

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) code, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). TheNAICS codes can be found at:
http://www.sba.gov/size

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

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

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

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

EXAMPLE

Targets for SDB Participation - NAICS Subsector 223

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

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

(9) **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.

(10) **Other Administrative Data**

a) **Property**

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

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

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

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

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

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

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

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

d) **Financial Capacity**

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

e) **Incremental Funding**

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

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire

project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

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

(11) **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a) Willingness to perform as a subcontractor for specific duties (list duties).
b) What priority the work will be given and how it will relate to other work.
c) The amount of time and facilities available to this project.
d) Information on their cognizant field audit offices.
e) How rights to publications and patents are to be handled.
f) A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:
http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

(12) **Proposer's Annual Financial Report**

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

(13) **Representations and Certifications**

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

(14) **Travel Costs/Travel Policy**

a) **Travel Costs - Commercial**

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

b) **Travel Policy**

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

SECTION M - EVALUATION FACTORS FOR AWARD

a. **GENERAL**

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

The evaluation will be based on the demonstrated capabilities of the potential offerors 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.

b. **EVALUATION OF OPTIONS**

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

c. **HUMAN SUBJECT EVALUATION**

This research project involves human subjects. NIH Policy requires:

(a) **Protection of Human Subjects from Research Risks**

The offeror’s proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by NCI that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated “unacceptable” (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or “acceptable.” If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

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

(b) **Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged), OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will consider the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:

    - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
    - overriding factors dictate selection of subjects); or
    - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.

- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:

    - inclusion of those groups would be inappropriate with respect to their health,;or
    - inclusion of those groups would be inappropriate with respect to the purpose of the research.

- For NIH-defined Phase III clinical trials, reviewers will also consider whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research

Based on the evaluation of the response to this criterion, this section of the proposal may be rated “unacceptable” (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or “acceptable.” See Section L of the solicitation for the requirements of women/minorities inclusion. If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

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

(c) **Children**

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them.

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers’ evaluation of the offeror’s response, this section of the proposal may be rated “unacceptable” (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror’s response regarding the inclusion of children; or the plan is not in accordance wit h NIH policy guidelines) or “acceptable.” If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

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

d. **EVALUATION OF DATA SHARING PLAN**

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

e. **TECHNICAL EVALUATION CRITERIA**

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

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

CRITERIA	**WEIGHT**
A. **CRITERION 1: TECHNICAL APPROACH**	**50 points**

Understanding of the scope, purpose, and complexity of the Statement of Work requirements as evidenced by the Offerors proposed technical plan to perform the following functions:

1. Proficiency Testing and Assay Research and Development

   a) Adequacy, soundness, appropriateness, feasibility and thoroughness of the plans and operating procedures to efficiently and effectively implement proficiency testing programs for CD4 testing, CFSE dye dilution assay and for freezing cells at remote Sites, including: characterization and distribution of Quality Control Material (QCM); distribution of instructions; analysis of results from Sites and reporting results and monitoring site performance.

   b) Adequacy, soundness, appropriateness, feasibility and thoroughness of the plans and procedures to: conduct in-house and facilitate multi-site comparative evaluations of new and existing immunological assays, reagents, and the studies on the effect of sample/reagent handling and storage conditions on assay results; analyze, report and disseminate results.

   c) Adequacy, soundness, appropriateness, feasibility and thoroughness of the plans and procedures to: establish a donor program of HIV infected and non-infected subjects, and to obtain, characterize, store and distribute QCM and reagents.

2. Site Assistance, Training and Information Dissemination

   a) Soundness, appropriateness and feasibility of the plans and demonstrated ability to: interact with Sites to investigate causes of poor performance and provide assistance, assemble, create and provide training materials, and conduct training workshops.

   b) Appropriateness, adequacy and feasibility of the plans to disseminate technical and scientific data, including the design, maintenance and updating of the IQA website.

B. **CRITERION 2: PERSONNEL QUALIFICATIONS** **25 points**

1. Principal Investigator
   Adequacy and relevance of the documented education, training, expertise, experience, and level of effort to oversee all contract requirements; evidence of related experience and technical training in the principles and practices of immunology quality assessment for HIV and HIV-associated viral co-pathogens; and demonstrated ability to coordinate, manage and oversee staffing requirements, timelines and project initiation and implementation in a flexible manner responsive to changing needs.

2. Project Manager
   Adequacy and relevance of the documented education, training, experience, expertise to efficiently manage and coordinate multi- task projects related to the assessment of laboratory performance for proficiency qualification and testing; the development and implementation of approaches to correct deficiencies in Site performance; and the provision of Site assistance in coordinating training and associated technical assistance.

3. Other Scientific and Technical Personnel
   Adequacy and relevance of the documented education, training, experience, expertise and level of effort of other scientific and technical staff in the area of immunologic methodologies, statistical analysis, and software systems design and management.

C. **CRITERION 3: PROJECT MANAGEMENT** **15 points**

1. Adequacy, soundness and appropriateness of the infrastructure proposed for accomplishing the Statement of work, including clear lines of authority and responsibilities.

2. Adequacy, soundness, appropriateness, feasibility and thoroughness of the staffing plans for the conduct of the project, including the clarity and appropriateness of assigned roles, time commitment, and lines of authority; adequacy of back-up staffing.

3. Adequacy, thoroughness and appropriateness of plans for communication with Project Officer and with Site Investigators.

4. Adequacy, soundness and thoroughness of plans for maintaining confidentiality of data.

5. Adequacy of the plans to execute a safe and orderly initial and final transition of all materials and data to a successor contractor.

D. **CRITERION 4: FACILITIES, EQUIPMENT AND OTHER RESOURCES** **10 points**

1. Documented availability and adequacy of facilities, equipment, and other resources necessary for this project; adequacy of the plan to maintain and update computerized inventory and database systems to support the acquisition, testing, storage and disbursement of QCM, and to capture Site capability and performance.

2. Documentation of appropriate approvals/certifications to conduct operations in Good Clinical Laboratory Practices (GCLP), under Clinical Laboratory Improvement Amendments (CLIA) certification, and Institutional Review Board (IRB) approval.

3. Documented security of the physical facility and of data and computerized systems; adequacy of emergency back-up measures; adequacy of the plan to comply with all safety guidelines and regulations, including training and monitoring of personnel for exposure to infectious and hazardous reagents.

TOTAL BASE PERIOD: **100 points**

E. **OPTIONS** **25 points**

Demonstrated ability of the Principal Investigator and the Project Manager to implement, oversee and manage the addition of U.S. and non-U.S. sites for proficiency testing, site assistance and training; ability to recruit qualified personnel in a timely manner; adequacy of the resources and facilities to provide services to additional sites.

TOTAL BASE PERIOD + OPTIONS: **125 points**

F. **PAST PERFORMANCE FACTOR**

An evaluation of offeror's past performance information will be conducted subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal would not be selected for award based on 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.

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-DAIDS-07-31**
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
Elizabeth Shanahan Contracting Officer Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20817	Elizabeth Shanahan Contracting Officer Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612

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

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

C. NUMBER OF COPIES:

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

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

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

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

CREATING AND NAMING ELECTRONIC FILES:

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

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

** if multiple files are submitted for the technical proposal, please include the name of the section in the file name. *EXAMPLE: XYX Company/07-31/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. E*XAMPLE: XYX Company/07-31/Business/Staffing/3-6-06*

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

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

Document	Number of Copies	Page Limits
Technical Proposal and all Appendices	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** Twenty (20) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices) in a Portable Document Format (PDF)	**Not to Exceed 200 pages**
Business Proposal	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** Three (3) Compact Disks containing an electronic copy of the Business Proposal in a Portable Document Form (PDF).	N/A
Breakdown of Proposed Estimated Cost using Electronic Cost Proposal EXCEL Workbook	This Attachment to the Business Proposal should be submitted as a separate EXCEL file on the Business Proposal Compact Disk. **See Section J, Attachment entitled Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet to access the Excel Workbook.**	N/A

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DAIDS-07-31

RFP Title: **IMMUNOLOGY QUALITY ASSESSMENT PROGRAM**

Please review the attached Request for Proposal. Furnish the information requested below and return this page by no later than January 5, 2007. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

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

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

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

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

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

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

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

Attn: Elizabeth Shanahan
RFP-NIH-NIAID-DAIDS-07-31
FAX# (301) 402-0972
Email: shanahane@niaid.nih.gov

STATEMENT OF WORK
IMMUNOLOGY QUALITY ASSESSMENT PROGRAM

BACKGROUND AND INTRODUCTION

The Division of Acquired Immunodeficiency Syndrome (DAIDS), National Institute of Allergy and Infectious Diseases, National Institutes of Health, was formed in 1986 to address the national research needs created by the advent and spread of the HIV/AIDS epidemic. Specifically, the Division's mission is to increase basic knowledge of the pathogenesis, natural history, and transmission of HIV disease and to support research on detection, treatment, and prevention. DAIDS accomplishes this through planning, implementing, managing, and evaluating programs in (1) fundamental basic research, (2) discovery and development of therapies for HIV infection and its complications, and (3) discovery and development of vaccines and other prevention strategies.

Reliable laboratory endpoint data are necessary for meaningful interpretation of clinical trials/studies, and immunological endpoints are employed in most DAIDS-supported therapeutic and preventive clinical trials. Therefore, it is important to evaluate objectively the ability of laboratories to perform such tests reliably, and to ensure the quality of the testing by providing assistance and training when deficiencies are identified. The DAIDS Immunology Quality Assessment Program (IQA) will continue to design and execute proficiency testing programs that periodically assess the ability of laboratories to perform tests correctly, and to provide assistance and training when laboratories have difficulties. The largest existing proficiency testing program currently evaluates the ability of over 80 laboratories in the United States to correctly enumerate CD4-positive T cell lymphocytes, a key surrogate marker of anti-HIV drug activity and disease progression. Also, the IQA will continue to be a flexible, responsive resource to facilitate the adaptation, standardization and quality assessment of new immunological assay methodologies used in therapeutic, vaccine, prevention, epidemiological and preclinical NIAID investigations. Knowing the broad range of factors affecting assay variability, statisticians are able to determine the appropriate study sample size and design appropriate statistical analysis plans. This, in turn, allows investigators to know if a change in test results is due to an intervention or to inherent assay variability.

Currently, the IQA Program serves approximately 85 U.S. and 60 non-U.S. laboratories. With the growing number of NIAID studies in the developing world, it is expected that the IQA Program will expand to evaluate the ability of approximately 125 U.S. and 100 non-U.S. flow cytometry laboratories to adequately enumerate CD4-positive T Cells and to provide laboratory assistance and training. This potential increase will be accommodated by the exercise of contract options. U.S. and non-US laboratories supported by the IQA Program shall hereinafter be referred to as Sites.

Several NIAID programs and Study Groups have been served by this resource. Groups that will be supported by this resource include: the AIDS Clinical Trials Group (ACTG); the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT); the HIV Vaccine Trials Network (HVTN); the HIV Prevention Trials Network (HPTN); Microbicide Trials Network

(MTN) (http://www3.niaid.nih.gov/news/newsreleases/2006/leadership.htm); the Women and Infants Transmission Study (WITS); the Women's Interagency HIV Study (WIHS); the Multicenter AIDS Cohort Study (MACS); the Comprehensive International Program of Research on AIDS (CIPRA); the Acute Infection and Early Disease Research Program (AIEDRP); and individual grantees (http://www3.niaid.nih.gov/about/organization/daids/). In addition, the contract shall serve as a resource to the Centers for Disease Control and Prevention (CDC) Global AIDS Program (GAP)-affiliated laboratories supporting the President's Emergency Plan for AIDS Relief (PEPFAR) activities http://www.cdc.gov/nchstp/od/gap/default.htm.

Although the structure of the NIAID clinical trial networks is subject to change during the contract period, any such changes are not expected to result in changes to the number of Sites serviced by the IQA Program.

SCOPE

The scope of activities to be carried out under this contract include: 1) design and execute proficiency testing programs to externally assess the ability of U.S. and non-U.S. DAIDS-support clinical trial sites (hereinafter referred to as Sites) to reliably: 1) perform immunological assays (e.g., T-cell subsets and other cytometry-based tests); 2) provide assistance and training to laboratories that are not performing according to established standards, especially to flow cytometry laboratories in non-U.S. resource limited countries; 3) conduct or support comparative evaluations of instruments, methods and reagents; 4) facilitate the development, standardization and assay characterization of new immunological assays, and of cheaper simpler methods to measure CD4, for implementation in multi-center investigations; and 5) evaluate the ability of Sites to adequately freeze viable peripheral blood mononuclear cells (PBMC) for future immunological tests.

To accomplish these aims, the Contractor must: a) have access to a wide range of infected and non-infected donors to obtain human biological materials (e.g. plasma, PBMC, tissue); b) prescreen potential donors for existence of required characteristics (e.g. CD4 count, viral load level, HLA type, antigen response, vaccine titer); c) create panels of samples (coded when used for proficiency testing purposes), including replicates to assess within- and inter-laboratory variability; d) provide data management and statistical analysis capability; e) provide staff and facilities for on-site and off-site training; f) provide the facilities to store samples and reagents; and g) ship and track samples and reagents. In addition, the IQA laboratory shall be Clinical Laboratory Improvement Amendments (CLIA)-certified, conducting operations in accordance with Good Clinical Laboratory Practices (GCLP), and have local Institutional Review Board (IRB) approval for its activities.

Three options, that may be exercised at the discretion of the Government, shall provide for expansion of the IQA Program to additional U.S. and non-U.S. Sites as follows:

Option 1 – CD4 Proficiency Testing Program: Addition of U.S. and Canadian Sites only to the CD4 Proficiency Testing Program

Option 2 – United Kingdom National External Quality Assessment Service (UK NEQAS) Proficiency Testing Program: Addition of non-U.S. Sites participating in the UK NEQAS CD4 proficiency testing program

Option 3 – Peripheral Blood Mononuclear Cells (PBMC) Cryopreservation Proficiency Testing Program: Addition of U.S. and non-U.S. Sites to the PBMC cryopreservation proficiency testing program

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.

I. SUMMARY OF MAJOR FUNCTIONS

A. Initial transition
B. External assessment of Sites test performance
C. Assistance and training
D. Assay evaluation, characterization, optimization and standardization
E. Acquisition, characterization, storage, documentation and disbursement of quality control materials
F. Dissemination of IQA technical and scientific data
G. Maintenance of computerized software systems
H. Technical and administrative project management
I. Final Transition
J. Options

II. SPECIFICATION OF TASKS

A. INITIAL TRANSITION

In the event that the incumbent is not successful in the recompetition, the NIAID Project Officer will provide the new Contractor with a copy of the Final Transition Plan of the incumbent Contractor.

The Contractor shall:

a. Within 15 business days after contract award, submit to the Project Officer an Initial Transition Plan that includes the elements described below and the time frame for their execution, not to exceed 60 days:

1. stored Quality Control Material (QCM)/reagents and donor samples. The Contractor shall perform calibration and lot-to-lot comparisons between QCM/reagents received from the incumbent contractor and any QCM developed by the Contractor;
2. all data files in computer readable format and software systems (with documentation and specifications) including proficiency testing, assay development research data files, inventory files, and statistical analysis data files;
3. laboratory/manufacturer correspondence files; and
4. Government Furnished Property (GFP). Verification of equipment performance standards shall take place prior to and after the transfer.

b. Upon Project Officer approval, implement the Initial Transition Plan to complete all tasks associated with the relocation of contract activities, data and other resources and ensure safe and effective coordination with the incumbent contractor.

c. Coordinate the Initial Transition with the Sites to ensure the orderly provision of Site-specific information and instructions, including providing Sites with:

1. Contractor contact information;
2. instructions for delivery of test results to the Contractor and instructions concerning any temporary schedule changes resulting from the transition; and
3. information and instructions on any changes in the proper use and/or storage of QCM, assay methods or reporting requirements.

d. Submit, within 15 days of contract award, a contract-specific information security plan for review and approval by the Project Officer.

B. SITE TEST PERFORMANCE ASSESSMENT

1. Proficiency Testing (PT) of Immunological Assays

The Contractor shall test Sites to ensure proficiency in performing preclinical and clinical assays through evaluation of results obtained with panels of coded (unknown to Sites) Quality Control Material, hereafter referred to as QCM, which are tested by the Sites at regular intervals or when needed (e.g. pre-qualification of Sites to participate in a particular clinical study). For each assay specified by the Project Officer, the Contractor shall:

a. Provide participating Sites with coded QCM at intervals specified by the Project Officer. Examples of coded QCM include:

1) *whole blood samples* from HIV-seropositive donors at various disease stages, seronegative donors, HIV-negative immune-compromised donors, or vaccinated donors, to be processed and analyzed at the Site for immunophenotypic lymphocyte subset enumeration (e.g. CD4, CD8, CD38,

CD45RA, CD62L, CD28, CD95), or for lymphocyte function assays (e.g. proliferation or cytokine secretion);

2) *serum/plasma* from HIV-negative donors and HIV-positive donors, immune-compromised donors, and/or spiked plasma from sero-negative donors containing various concentrations of cytokines (e.g., TNFα, IFNγ), chemokines ((MIP-1α, MIP-1β) and soluble markers (e.g., sTNFaRII, sIL-2R, Neopterin, beta-2 microglobulin) for assays that measure serum/plasma cytokines, chemokines and other activation markers; and

3) *other QCM* for evaluating Sites' ability to perform in various matrices a variety of immunological assays, such as T-cell repertoire, apoptosis, and pathogen-specific host cellular and humoral immune responses (e.g. lympho-proliferative assays using well-characterized immunogens such as Cytomegalovirus (CMV), Staphylococcal B Enterotoxemia (SEB) and Corynebacterium Equi (CEF).

b. In collaboration with investigators and statisticians identified by the Project Officer, design new or implement currently available tools to capture assay results and information related to methodology and instrumentation at the Sites.

c. Provide Sites with instructions regarding: i) proper use of QCM in assays; ii) storage of QCMs at the Site; iii) method and format of PT performance and reporting; and iv) deadlines for, and method of, reporting PT results.

d. Receive PT results and related information from Sites via hard copy data forms or electronically (e.g. web-based).

e. Verify the accuracy and completeness of data received from Sites.

f. Analyze assay performance results from the Sites and determine successful performance based on criteria formulated by the Contractor, relevant Study Groups and the Project Officer. This shall require basic and advanced statistical analyses of data, including parametric and non-parametric approaches.

g. Upon determination of Site performance status, submit Site-specific reports to each participating Site and to the Project Officer. Such reports must be provided prior to shipping the next round of proficiency testing. Please see Contract Reporting Requirements for more detail.

h. If performance of a Site results in a change in certification status, submit to such Site and to the Project Officer, a letter of status change notification.

i. After each round of proficiency testing evaluation, prepare and submit to the Project Officer a Cumulative Performance Report delineating performance status of all Sites over time.

j. Summarize above activities and Site performance evaluations in Progress Reports.

2. Assessment of Non-U.S. Flow Cytometry Laboratories

Non-U.S. CD4 flow cytometry Sites that support DAIDS-funded clinical studies must participate in the CD4 Proficiency Testing Program provided by the United Kingdom National External Quality Assessment Service (UK NEQAS) - *www.ukneqasli.org*. The UK NEQAS provides the IQA Program with access to its database to retrieve information about participating Sites and their proficiency testing results. Non-U.S. flow cytometry Sites shall be located mostly in resource limited countries in Africa, Asia, Latin America and the Caribbean. It is possible that DAIDS will allow Sites to participate in other international PT programs for CD4.

The Contractor shall:

a. Ship, via carriers such as Federal Express or DHL, a panel of coded fixed samples, provided by the UK NEQAS, to Sites identified by the Project Officer. Evaluate their initial ability to perform CD4 enumeration using these samples and analyze results received from each Site.

b. Facilitate the enrollment of new Sites identified by the Project Officer into the UK NEQAS CD4 Proficiency Testing Program. This shall require sending to new Sites an existing method/capability survey, receiving the completed survey and communicating with the UK NEQAS to request enrollment.

c. Access the UK NEQAS database to review proficiency testing results of each PT round and/or review Site-specific performance reports produced by the UK NEQAS.

d. Summarize the above activities and Site performance evaluations in Progress Reports.

e. Investigate the nature of various international proficiency testing programs for CD4 and analyze for adequacy and comparability with the UK NEQAS program.

3. Proficiency Testing (PT) of Peripheral Blood Mononuclear Cells (PBMC) Cryopreservation

DAIDS clinical studies often include immunological testing, such as ELISPOT, Intracellular Cytokine (ICC) determinations and T cell subset immunophenotyping, to be performed on frozen samples from subjects enrolled in these studies. Because such samples must contain sufficient numbers of viable Peripheral Blood

Mononuclear Cells (PBMC), it is important to assess the ability of domestic and international Sites to adequately process, viably freeze, and ship PBMC.

The Contractor shall:

a. Provide Sites with instructions for freezing viable PBMC, data forms or electronic means for capturing viability and yield at the Site prior to freezing, and instructions for shipping frozen samples to the IQA.

b. Receive frozen samples from domestic and international Sites at intervals specified by the Project Officer; pay for shipping costs from Sites specified by the Project Officer.

c. Upon receipt, store frozen samples from Sites in liquid nitrogen, thaw and determine viability and yield, analyze results and determine performance success based on criteria formulated by the Contractor, relevant Study Groups and the Project Officer.

d. Submit Site-specific performance reports to each Site prior to receipt of the next round of PT samples.

e. Summarize proficiency testing of PBMC cryopreservation activities and Site performance evaluations in Progress Reports.

C. SITE ASSISTANCE AND TRAINING

The Contractor shall provide assistance and training to U.S. and non-U.S. Sites whose results deviate from accepted, agreed-upon values as follows:

1. After every round of PT, identify and contact those U.S. and non-U.S. Sites whose results deviate from accepted, agreed-upon values.

    a. Request and review additional materials (e.g. histograms, list-mode data, additional aliquots of frozen PBMC, Standard Operating Procedures, and the Sites quality management and corrective action plans) to further investigate the sources and magnitude of difficulties. Use available methods such as telephone, email, and web conferencing to effectively communicate with the Sites and provide assistance and training.

    b. Provide Sites with relevant existing training materials and prepare new training materials when necessary, such as additional language-appropriate procedures/instructions for performing assays, diagrams and pictures, instructional videos, manuals and links to available resources.

2. For Sites with persistent performance difficulties, upon approval from the Project Officer:

a. Send additional QCM such as panels of coded fixed samples provided by the UK NEQAS or frozen PBMC. Analyze and report results to the Site and the Project Officer.

b. Send staff with relevant expertise to Sites to provide on-site trouble-shooting and training, or provide training at the Contractor's site for individual investigators/technicians. The Contractor shall not be responsible for travel costs of Site staff to participate in training activities. Contractor staff must be available to undertake arduous travel within 20 days notice to non-U.S. Sites in resource-limited countries and to remain there for up to two weeks.

3. Organize and conduct technical training workshops for groups of investigators/technicians at the Contractor's site or at other suitable U.S. and non-U.S. locations. This includes providing the teaching staff and materials required for "hands-on" training/demonstrations, including language-appropriate written materials (e.g. French, Spanish, and Chinese). The Contractor shall not be responsible for travel costs of non-Contractor workshop participants.

4. Post training materials, a listing of common problems and/or a trouble-shooting guide, and FAQs on the IQA web site.

5. Summarize assistance and training activities and Site performance evaluations in Progress Reports.

D. ASSAY EVALUATION, CHARACTERIZATION, OPTIMIZATION AND STANDARDIZATION

As new immunological methods are considered by DAIDS for implementation in multi-center clinical studies, and as simpler, cheaper methods are proposed for use in resource-limited settings, the Contractor shall, as directed by the Project Officer, analyze method-switching studies performed at Sites, conduct preliminary in-house evaluations, and facilitate multi-site assessments.

1. Analysis of Switching CD4 Flow Cytometric Methods at Sites

Sites may switch methods used to determine CD4 counts from a dual-platform to a single-platform, from 4-color to a 6-color (or more), and from one instrument type to another. For all Sites participating in switching methods, the Contractor shall:

a. Provide instructions to Sites for performing method-switching studies. Examples of switching studies can be found at: http://aactg.s-3.com/iqa.htm.

b. Analyze the results for method comparability and/or for determining differences between methods.

c. Provide analysis results in a report to the participating Sites and to the Project Officer within 3 weeks of receipt of results.

2. In-house Evaluations

At the Contractor's laboratory, The Contractor shall conduct evaluations and prepare analyses as follows:

a. *Comparative evaluations of assay kits/reagents*: Conduct and analyze the results of up to four comparative evaluations a year of various assay kits/reagents to determine the best performance (e.g. low non-specific activity, stimulation index) in specified assays. Examples include: comparison of various lots of Human AB Serum in functional assays such as lympho-proliferation assays (LPA); comparison of various HIV-specific antigens from commercial and non-commercial sources in functional assays such as LPA and comparison of various blood stabilizers in lymphocyte subset immunophenotyping.

b. *Evaluations of sample handling procedures*: Conduct and analyze the results of up to four evaluations per year on the effect of sample handling procedures on assay results. Examples include: fresh vs. frozen samples of blood or plasma; length of storage; storage temperature; shipping temperature and time; and number of viable cells.

c. *Final Study Reports*: Within three weeks of the completion of each evaluation, prepare a comprehensive Final Study Report consisting of a description of the purpose and design of the evaluation, complete information on QCM acquisition and characterization, and evaluation results. Distribute Final Study Reports to the Project Officer and designated Site investigators.

3. Multi-site Evaluations

The Contractor shall facilitate the following multi-site evaluations:

a. *Evaluation of Immunological Assays*: Evaluate up to four existing or newly developed immunological assays per year. For each evaluation, the Contractor shall provide assay-appropriate coded QCM (e.g. well-characterized patient specimens, HIV-specific antigens, mitogens, CEF peptides) to an average of six Sites. Examples of assays to be evaluated include: phenotypic and functional evaluation of Antigen Presenting Cells; various readouts for measuring HIV-1 reactive $CD8^+$ T cells; multi-color flow cytometry to monitor intracellular expression of various cytokines; and measurements of host immune response to co-infections.

b. *Evaluation of Low-cost Alternative Methods*: Evaluate up to four low-cost, alternative methods for measuring CD4+ T cells and other lymphocyte subsets and compare such methods to standard flow cytometric methods. For each evaluation, the Contractor shall provide coded whole blood samples from donors who have various ranges of CD4 T cell counts to an average of six

selected Sites. Examples of comparative evaluations: lymphocyte gating approaches; simpler flow cytometry instruments; and the use of non-flow cytometry methods such as those based on bead technology.

c. *Evaluation of Specimen Handling, Processing and Storage*: Evaluate and compare specimen handling, processing, and storage procedures. Up to four such studies will be performed per year. For each study, the Contractor shall provide appropriate known standards and coded QCM to and average of six selected Sites. Examples of such evaluations include the effect of cryopreservation on Antigen Presenting Cell (APC) function and the effect of anticoagulants and shipping temperature on the intensity of cellular markers expression.

d. To facilitate the above studies, the Contractor shall:

1) acquire and characterize QCM and distribute to Sites. Examples of QCM include: fixed whole blood, whole blood, plasma, serum and cells from HIV-negative donors or HIV-positive donors at different disease stages, or from CMV-positive; monoclonal antibodies to cell markers such as chemokine receptors; pathogen-specific antigens; cell lines; and commercial reference standards and reagents;

2) in collaboration with evaluation participants and statisticians, design data collection tools to capture assay results and related information about methodology and instrumentation at the Sites;

3) provide the Sites with instructions (written and/or electronic) regarding proper use of QCM in assays, storage of QCM at the Site, format and deadlines for reporting of test results;

4) receive assay results and related information via hard copy or electronically from the Sites, check for accuracy and completeness, and contact Sites for clarification and additional information as needed;

5) collate results, analyze, and forward results to Sites and the Project Officer; and

6) within three weeks of the conclusion of each evaluation, prepare a comprehensive Final Evaluation Report. The report shall include the purpose and design of the evaluation, information on participating Sites and other collaborators, complete information on QCM acquisition and characterization, and evaluation results. Distribute reports to evaluation participants, the Project Officer and Project Officer designated Study Group investigators.

E. QUALITY CONTROL MATERIALS

1. Donor Program

The Contractor shall develop and maintain a donor program for obtaining materials from: well-characterized HIV infected (known CD4 and CD8 cell counts, HIV and/or HCV RNA levels, CMV reactivity, HLA type) and uninfected human subjects. Donor materials shall include whole blood, serum, plasma and PBMC. In addition, the Contractor shall have the capability to process large quantities of donor blood (approximately four liters) through leukophoresis and must:

a. Comply with all applicable regulations on the use of human subjects in research (http://www.hhs.gov/ohrp/)

b. Comply with HIPAA and Privacy Act requirements (http://www.hhs.gov/ocr/hipaa/).

2. Additional QCM/Reagents

a. The Contractor shall obtain additional reagents as needed, as directed by the Project Officer, for QCM (e.g., mitogens, HIV-specific antigens and corresponding controls, labeled monoclonal antibodies, human AB serum, culture media, viral isolates, tetramers, and peptides). These additional reagents shall be obtained from tissue typing laboratories, blood banks, domestic and international research institutions, and reagent/kit manufacturers.

b. Inventory and store, when applicable, aliquots of characterized QCM under optimal conditions to ensure continued integrity of materials. As relevant, retain available aliquots from old lots for comparison to new lots.

c. With funds provided by NIAID-funded Site investigators (http://www3.niaid.nih.gov/about/organization/daids/), centrally obtain study-specific reagents, arrange reagents into kits, store, and ship to requesting participating laboratories. Maintain an inventory of reagents/kits and notify study investigators when supplies are low.

3. Characterization of QCM

Prior to use in Site performance evaluation and in assay/kit evaluation studies, the Contractor shall determine QCM and reagent characteristics and their optimal use and storage conditions. This shall include:

a. hematologic and immunophenotypic profile of whole blood (CBC, CD4, CD8);

b. concentration of cytokines, chemokines, soluble markers and titer of neutralizing antibodies;

c. chemokine receptor expression;

d. HIV-1 RNA plasma levels;

e. reagent/kit activity; and

f. effect of reagent handling conditions (length of storage, storage temperature, shipping temperature and length of shipping) on stability and activity.

4. Storage of QCM

The Contractor shall store aliquots of characterized QCM and reagents under conditions previously demonstrated to ensure the continued integrity of materials. This shall include:

a. uninterruptible power to accommodate refrigerators and freezers;

b. continuously monitored central alarm system connected to refrigerators and freezers, and staff to be notified immediately in the event of equipment malfunction;

c. emergency stand-by refrigerators and freezers to be available in case of mechanical failure of storage space; and

d. equipment maintenance services.

5. QCM/Reagent Shipping

The Contractor shall ship QCM/reagents to Project Officer specified U.S. and non-U.S. Sites under appropriate shipping conditions (e.g., temperature monitoring) and in accordance with International Air Transport Association (http://www.iata.org/index.htm) and International Civil Aviation Organization (http://www.icao.int/) dangerous goods shipping regulations and other relevant shipping regulations. In addition, the Contractor shall:

a. Execute agreements with receiving institutions regarding relevant standards for safe handling and authorized use of QCM/reagents.

b. Arrange for overnight or fastest possible delivery of shipments to the Sites.

c. Obtain and maintain the appropriate interstate, intrastate and foreign shipping licenses and permits for transporting biohazard materials.

d. Coordinate the shipments of QCM/reagents to the Sites, including prior notification of incoming shipments and confirmation of shipment receipt .

6. Safety and Health

The Contractor shall provide its personnel with protective garments, equipment, training and sufficient monitoring to assure safe handling of potentially hazardous and infectious materials in compliance with all applicable health and safety regulations while conducting the work set forth herein, and adhere all safety and health regulations in accordance with HHSAR 352.223-70 (http://www.niaid.nih.gov/contract/forms/form10.pdf).

7. Facilities, Equipment and Other Resources

The Contractor shall provide facilities, equipment and other resources to adequately accommodate acquisition, characterization, storage, distribution, and disposal of potentially hazardous materials, including the following:

a. Adequate space to accommodate:

1) shipping, receiving, and disposal areas and equipment;
2) QCM/reagent storage units (e.g. ultra-low freezers, liquid nitrogen tanks, freezers, refrigerators, back-up freezers);
3) a laboratory work area that includes Biosafety Level 3 containment, and aseptic/sterile conditions for QCM/reagent preparation and testing;
4) office/data entry and analysis stations; and
5) a private room for donor specimen collection

b. Security measures to ensure protection of the facility and equipment against damage by fire, theft, vandalism, invasion of privacy, and intrusion by unauthorized personnel.

F. DISSEMINATION OF IMMUNOLOGY QUALITY ASSESSMENT TECHNICAL AND SCIENTIFIC DATA

The Contractor shall, upon approval of the Project Officer and in collaboration with Site investigators, disseminate technical and scientific data that result from activities conducted under the contract through publications and presentations. Scientific presentations shall include data originating from proficiency testing evaluations, field testing of immunologic assays, assessments of assay parameters, evaluations of commercial kits, comparative methodology studies and other studies. The Contractor shall:

1. Prepare, within three months after study completion, materials to support the preparation of scientific manuscripts for publication in peer-reviewed journals and presentations at scientific meetings, and submit these materials to the Project Officer

2. Present data at NIAID-sponsored meetings and at domestic and international scientific meetings as approved by the Project Officer.

3. Provide NIAID-sponsored Study Groups with consensus protocols for immunologic assays and freezing methods, distribute them to Sites, and compile them into a hard copy and/or electronic manual.

4. Post quality assessment technical and scientific data on the IQA web site (e.g. results of assay comparison studies, new assay protocols, revisions to assay protocols, changes in reagent storage and handling characteristics).

G. COMPUTERIZED SOFTWARE SYSTEMS

The Contractor shall provide and maintain state-of-the-art software systems for data management in support of the IQA program, and shall be responsible for the purchase of all general purpose ADP equipment and related maintenance agreements. Computerized software systems shall include the following:

1. PT Data Tracking System

A computerized software system to track and support the activities required for Proficiency Testing (PT). In the event that the incumbent is not successful in the recompetition, existing data shall be transferred in the form of spreadsheets or a database. The Contractor shall compile the following in the tracking system:

a. participating Site contact information;

b. panel scheme such as number of replicate samples, laboratory grouping;

c. type and characteristics of QCM provided for PT;

d. relevant dates, such as QCM shipping date to Sites, QCM testing date;

e. PT performance and certification status of Sites; and

2. Systems for Evaluation, Characterization, Optimization and Standardization of Assays

Computerized software systems to support assay evaluation, characterization, optimization and standardization activities. Any software used to capture or analyze data shall be designed in a format that will easily permit capture of assay results by the Laboratory Data Management System (LDMS®) for assays implemented in clinical trials and performed on patient specimens. In the event that the incumbent contractor is not successful in the recompetition, existing data shall be transferred in the form of spreadsheets. The Contractor shall compile the

following information for assay evaluation, characterization, optimization and standardization:

a. relevant information about materials used;

b. list of testing Sites; and

c. assay results and data analysis.

3. QCM Data Tracking System

A computerized software system to track QCM data. In the event that the incumbent is not successful in the recompetition, existing data shall be transferred in the form of spreadsheets or a database. The Contractor shall compile the following QCM data:

a. relevant information for each acquired QCM/reagent, including source/donor, description, lot number, date manufactured or obtained;

b. characterization data for each QCM/reagent such as neutralization titers, CD4 cell count, optimal conditions for use in assays;

c. storage information for each QCM/reagent such as length of time in storage, temperature of storage and number of times frozen and thawed;

d. temperature of shipped QCM/reagents; and

e. disbursement of information for each QCM/reagent, such as date shipped and received at the Site, quantity, name of recipient, and study title/number requiring the QCM/reagent.

4. IQA Web Site

The Contractor shall develop, maintain and update an interactive internet web site for posting relevant IQA information. The following shall be included:

a. description of the proficiency testing programs supported by the IQA, including criteria for acceptable or unacceptable performance;

b. lists of Sites participating in the various proficiency testing programs supported by the IQA;

c. guidelines and instructions for CD4 method switching studies;

d. trouble-shooting guides and Frequently Asked Questions for CD4 testing and PBMC freezing; and

e. reports of in-house and multi-Site evaluations.

5. DAIDS Enterprise System Interface

Provide IQA information, specified by the Project Officer, through the DAIDS Enterprise System including:

a. Site and IQA contact information;

b. Site certification status and assay capability;

c. assay methodologies/protocols; and

d. PT schedules.

6. Electronic Communication

a. Provide the capability to receive and transmit data files electronically, including from the Laboratory Data Management System (LDMS®), and to communicate electronically via secure e-mail with all Sites, the DAIDS Enterprise System, and the Project Officer.

b. Provide and maintain a state-of-the-art computerized software system with capability to manage and expedite the processing of selected data and information and for ready transferal of all data and complete system and data documentation to NIAID (or others at the direction of NIAID) at any point during the contract. The system shall provide sufficient flexibility and accessibility to answer inquiries in a timely manner, typically no longer than one business day.

7. System Security

Provide security needs to meet NIH requirements (http://irm.cit.nih.gov/security/secplantemp.doc). Develop a security plan and submit it to NIAID within 60 business days after the effective date of the Contract, for Office of Technology and Information Systems (OTIS), NIAID approval. Implement and maintain security requirements for the data management to:

a. ensure confidentiality of all subject or donor records (both hard copy and electronic)

b. ensure security of data related to performance evaluation of participating Sites

c. provide security against anticipated risks, including loss of confidentiality of subject records and vital or catastrophic loss of study data or important software

8. System Maintenance And Upgrades

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

b. Maintain and upgrade reliable and secure electronic communication linkages with NIAID, Sites, and investigators who send e-mail and share text and data files.

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

9. Information Technology (IT) Report

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

10. Information Security (InfoSec)

InfoSec consists of:

a. Confidentiality -- the prevention of unauthorized disclosure/use of information

b. Integrity -- the prevention of unauthorized modifications to information

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

With input from NIAID subject matter experts and NIAID Office of Technology and Information Systems (OTIS) staff, conduct a study of the

InfoSec requirements for the entire project, including but not limited to: the privacy requirements of clinical data; physical and electronic security for hardware, software and communications; the question of whether all participants in the contract (subcontractors, NIAID staff, study Site investigators, etc.) need to have secure capability for communication and exchange of information, particularly in the case of a national disaster that could disrupt the ability to interact and exchange needed information. The study shall include a definition of the entire system, such as a complete physical and logical description including hardware, software, communications, InfoSec and other considerations.

H. PROJECT MANAGEMENT

1. The Contractor shall:

a. Provide a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and management of all activities carried out under this contract.

b. Provide the overall management, integration and coordination of all contract activities, including systems for tracking and monitoring progress, timelines and budgets.

c. Conduct effective communications with the Project Officer and the Contracting Officer.

2. Conference Calls And Meetings

The Contractor shall:

a. Participate in a minimum of one conference call per week to include the Project Officer, the Principal Investigator, the Project Manager, statisticians and other IQA personnel specified by the Contractor or the Project Officer.

b. Participate in conference calls with Sites working on comparative evaluations and assay development. When necessary schedule and initiate conference calls, the cost of which will be charged to the contract.

c. Meet with the Project Officer and groups of Site investigators at periodic intervals to review progress, anticipated or existing problems, and to discuss work to be performed. The schedule and location of such meetings/site visits shall be determined by the Project Officer. The Contractor shall make facility and meeting arrangements, which shall be approved in advance by the Project Officer.

I. FINAL TRANSITION

The Contractor shall plan and implement an efficient, orderly and secure transition of contract data, procedures, materials and other resources at the completion of the contract. This shall include the following:

a. Eight months prior to the completion of this Contract, submit to the Project Officer a draft plan detailing the transition to a successor Contractor of all contract-related materials. These materials shall be organized and catalogued in sufficient detail to support an orderly transition to the successor Contractor. The Contractor shall work with the Project Officer and the Contracting Officer to refine and complete this plan. A final plan shall be submitted six months prior to the expiration date of the Contract. The plan shall include recommended steps to sustain the activities provided for in the Contract during transition and shall include delivery to the Government or its designee by the expiration date of this Contract all contract-related items including:

   1) stored QCM/reagents. The Contractor shall perform calibration and lot-to-lot comparisons between QCM/reagents received from the current Contractor and any QCM developed by the contractor;

   2) all data files in computer readable format and software systems (with documentation and specifications) including systems for tracking proficiency testing, assay development research data, inventory data, and statistical analysis data;

   3) laboratory/manufacturer correspondence files; and

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

b. Notify all Sites of the transition as early as possible and provide schedules to the Sites for the transition, and instructions for any changes in testing schedules anticipated during the transition.

J. OPTIONS

The Government anticipates the potential need to provide services to additional Sites. These additional services shall be funded through the exercise of three types of Options:

a. **Option 1 – CD4 Proficiency Testing Program:** Under this option, the Contractor shall add Sites to the CD4 Proficiency Testing Program and provide proficiency testing, technical assistance and training services. Most Sites will be located within the continental U.S,, Puerto Rico and Hawaii, and Canada.

Option 1 may be exercised up to two times, annually for up to an additional 10 sites per option exercised. Option 1 may be exercised a total of four times over the life of the contract.

b. **Option 2 - UK NEQAS CD4 Proficiency Testing:** Under this option, the Contractor shall add non-U.S. Sites participating in the UK NEQAS CD4 Proficiency Resting Program to receive oversight, technical assistance and training. Most non-U.S. Sites will be located in South America, the Caribbean, Africa, and Asia. A small number of Sites may be located in other areas (e.g. Europe and Australia).

Option 2 may be exercised in any year for up to an additional 20 sites per option exercised. Option 2 may be exercised a total of two times over the life of the contract.

c. **Option 3 – PBMC Cryopreservation Proficiency Testing:** Under this option, the Contractor shall add U.S. and non-U.S. sites to the PBMC Cryopreservation Proficiency Testing Program and provide proficiency testing and assistance and training services.

Option 3 may be exercised in any year for up to an additional 20 sites per option exercised. Option 3 may be exercised a total of three times over the life of the contract.

For each Option, the Contractor shall:

1. Option Plan Development

The Contractor shall develop a plan for the staffing, facilities and other resources necessary to provide the services called for in the Statement of Work. The plan shall include timelines for all tasks involved in implementing each option, proposed modifications in organizational structure, management procedures, and other Contractor functions that may be required to carry out the option.

2. Option Plan Implementation

Based on the Project Officer's recommendation to implement an option, the Contracting Officer will authorize the exercise of each Option through a Modification to the contract.

[END OF STATEMENT OF WORK]

REPORTING REQUIREMENTS AND DELIVERABLES
IMMUNOLOGY QUALITY ASSESSMENT PROGRAM

I. 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. The Contractor shall provide the reports and deliverables specified below. All reports shall be submitted in electronic form as PC-formatted computer files in Microsoft Word™ and Microsoft Excel™ and/or searchable PDF format. Electronic versions shall be sent on CD or more current electronic data storage medium, by US mail or courier service. All reports shall be archived on CD or other appropriate media for surrender to the Government at the expiration of the Contract.

A. Trimester Progress Reports

The Contractor shall submit copies of a Trimester Progress Reports on/before the 15th of the month following the end of each trimester. A Trimester Progress Report shall not be required when submitting an Annual or the Final Report. Each report shall consist of:

1. A cover page containing:

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

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

3. Summaries or computer printouts of activities as specified in the SOW:

    a. Performance Evaluation Report [Proficiency Testing (PT)]. For each assay system tested at the Sites the following information shall be included:

        1) Quality Control Material (QCM) acquisition, characterization and distribution, including type, source, amount, characterization data, storage and inventory information, receiving Sites and relevant dates
        2) Analysis of results, noting the statistical methodologies employed
        3) Performance status of Sites including criteria for successful performance
        4) Summary of problems, corrective actions and subsequent performance

b. Research and development of immunological methodologies. For each new assay evaluation, kit/reagent evaluation, methodologies comparison and assessment of assay parameters, the following shall be included:

1) Study objectives
2) QCM/kit acquisition, characterization and distribution, including type, source, amount, characterization data, storage and inventory information, receiving Sites and relevant dates
3) Analysis of results
4) Problems encountered and solutions employed
5) Recommendations based on research results

c. Scientific Activities. This shall include any research not included in 3a. and b. above; a list of scientific meetings and conferences attended; a list of manuscripts published, submitted or in preparation; and a list of abstracts submitted for presentation or in preparation.

4. Summary of facilities/equipment issues

5. Summary of data management issues which shall include problems and solutions related to computer hardware and software

6. Summary of Site-specific issues which shall include difficulties and solutions related to material shipments and transmission of QC data from the Sites

7. Summary of meetings/discussions with the Project Officer regarding issues relevant to the conduct of the contracted work

8. Personnel Report, which shall include name, title, percent effort and responsibility of each individual working on the Contract

B. Annual Progress Reports

Annual Reports shall include the last Trimester Progress Report and an Annual Table of Contents referring to previous Trimester Progress Reports. The Annual Report shall include the annual local Institutional Review Board (IRB) approval for contract operations. The Annual Reports shall be submitted on or before the 30th of the month after each anniversary date of the Contract. An Annual Report is not required for the period when the Final Report is due.

C. Final Progress Report and Summary of Salient Results (Form 1688-1)

The Final Report shall cover the entire Contract performance period and be in sufficient detail to explain comprehensively the accomplished tasks, a brief description of any unfinished projects, and a status report on transition or shut down activities. In addition, the Contractor will provide a 200 word "Summary of

Salient Results" detailing the important accomplishments of the contract studies during the performance of the contract. The Final Report is due 30 Days prior to expiration date of the contract.

II. Progress Reports Delivery Schedule

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

Item	Type of Progress Report	Initial Report Due	Recipients & Number of Copies	Subsequent Reports Due
1.	Trimester Report	4 Months after Effective Date of Contract (EDOC)	Original–CO 1 copy – PO	Due on/before the 15th of the month following each trimester reporting period. Not due when Annual or Final Reports are due.
2.	Annual Report	Anniversary Date of Contract	Original – CO 1 copy – PO	Annually; submitted 30 days after the anniversary date. An Annual Report is not due when a Final Report is due.
3.	Final Report and Summary of Salient Results	30 Days prior to expiration date of the contract	Original – CO 1 copy – PO	N/A

III. Other Reports/Deliverables

A. Site-Specific Proficiency Testing (PT) Assessment Reports

Provide, via electronic mail, each Site with its own Site-specific report of the Proficiency Testing results five business days following data receipt from all participating Sites or five business days following verification of cell viability and yield of frozen cells thawed and counted at the IQA. These reports shall also be submitted to the Project Officer and others, as requested by the Project Officer.

B. CD4 Method Switching Reports

Provide, via electronic mail, each Site that has conducted a CD4 method switching study with a report of study results within 15 business days following

receipt of results from the Site. These reports shall also be submitted to the Project Officer.

C. Assay Research and Development Reports

Submit written reports (either electronic or hard copies) of all research and development studies performed as specified in Paragraph D. of the Statement of Work as follows:

1. Within 15 business days following completion of data analysis, assay study results shall be reported to the Project Officer and relevant Study Group(s) as specified by the Project Officer.

2. Within 3 months of study completion, submit to the Project Officer materials to support preparation of scientific manuscripts for publication in peer reviewed journals. Prior to submission for publication, all manuscripts shall be submitted in hard copy or electronic copy to the Project Officer and others, as specified by the Project Officer.

D. Information Technology (IT) Plan and InfoSec Study

1. Draft a plan for the secure transfer, maintenance, and upgrade of data, hardware and software within 10 business days of the start of the contract.

2. Draft a plan for the Information Technology report and InfoSec study within 60 days of the start of the contract.

E. Transition Plans

1. Initial Transition Plan. If applicable, within 15 business days of the start of the Contract, the Contractor shall provide an Initial Transition Plan and timetable for the safe and orderly relocation of all IQA-related materials from the current Contractor, as outlined in the Statement of Work. This plan shall include staffing requirements and a description of work during the transition. Upon approval by the Project Officer, the contractor shall implement the Initial Transition Plan within 30 days of award of the contract.

2. Final Transition Plan. Eight months prior to the expiration date of the contract, provide a draft Final Transition Plan which describes proposed procedures for an orderly transition to a subsequent Contractor or the NIAID, and the estimated cost.

F. Contract Completion

Subject to NIAID Project Officer approval, deliver to NIAID or its designee, by the completion date of this contract, equipment and reagents, inventory and software systems, including software programs, labeled and inventoried paper files, and Government-Furnished Property (GFP), as outlined in the Statement of Work.

IV. Other Reports/Deliverables Schedule

Item	Type of Report	Report Due	Recipients & Number of Copies	Subsequent Reports Due
1.	Site-Specific (PT) Assessment Reports	within 5 business days of PT data receipt or thaw/count of frozen samples at the IQA	1 copy – Each Site 1 copy – PO	
2.	CD4 Method-Switching Reports	Within 15 business days of results receipt from the Site	1 copy – Site 1 copy - PO	
3.	Immunologic Assay Research and Development Reports	within 15 business days of completion of data analysis	1 copy – PO 1 copy– Study Group	
4.	IT Plan	Within 10 business days after the effective date of the contract	1 copy – PO 1 copy - CO	
5.	InfoSec Study	Within 60 business days after the effective date of the contract	1 copy – PO 1 copy - CO	
6.	Initial Transition Plan (if required)	15 business days after the effective date of the contract	Original – CO 1 copy – PO	Implementation 30 days after contract award

7.	Draft Final Transition Plan	Eight months prior to completion of the Contract	Original –CO 1 copy – PO	
8.	Final Transition Plan	Six months prior to completion of the Contract	Original –CO 1 copy – PO	

V. Addressees:

Project Officer
Drug Development and Clinical Sciences Branch
Division of AIDS/NIAID/NIH
6700-B Rockledge Drive, Room 5207
Bethesda, MD 20892-7624
(email address provided at time of contract award)

Contracting Officer
DAIDS Research Contracts Branch
Office of Acquisitions
Division of Extramural Activities/NIAID/NIH
6700-B Rockledge Drive, Room 3214
Bethesda, MD 20892 (20817 for overnight deliveries)
(email address provided at time of contract award)

IMMUNOLOGY QUALITY ASSESSMENT PROGRAM
ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS
FORMAT FOR TECHNICAL PROPOSAL – TABLE OF CONTENTS

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

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

Offerors are advised to give careful consideration to the statement of work, all reference material, appendices and attachments, the technical evaluation criteria, and, the RFP as a whole, in the development of your proposal.

Offerors who propose 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 between the prime and subcontractor(s), and the expected advantages of such an approach.

Offerors are reminded that the total page limitation for the technical proposal is **200 pages** including all appendices and attachments.

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

SECTION 2: TECHNICAL PLAN/APPROACH

A. Proficiency Testing and Assay Research and Development

1. *Proficiency Testing for Immunological Assays*: Describe your plans and operating procedures for implementing a proficiency testing program for CD4/CD8. The current program is described at http://aactg.s-3.com/iqa.htm. Focus on:

   a. Access to well-characterized (CD4 counts, HIV viral load) donors from whom you can obtain the variety of types of QCM described in the Statement of Work. Include plans for compliance with applicable domestic and international regulations on the use of human subjects (e.g. IRB submission and approval plans, consent procedures, etc.) and with HIPAA and Privacy Act requirements. You are reminded that NIH regulations do not permit contract funds to be expended on customs payments to foreign governments.
   b. Preparation and characterization of QCM.
   c. Preparation and distribution of instructions to Sites.
   d. Shipment of QCM according to regulations and under the appropriate conditions. Provide documentation of relevant permits and licenses currently held or include plans to obtain them prior to contract award.
   e. Analysis of Site performance and reporting of results. See Appendix E for an example. Also, see Appendix C for description of web-based receipt of proficiency testing data from Sites.

2. *Proficiency Testing for PBMC Cryopreservation*: Describe your plans and operating procedures for implementing a proficiency testing program for PBMC cryopreservation. The current program is described at http://aactg.s-3.com/cryo.htm. Focus on:

   a. Preparation and distribution of instructions to Sites.
   b. Receipt and processing of PBMC. See Appendix C for description of the LDMS® used by the IQA and the Sites.
   c. Analysis of performance and reporting of results. See attached examples in Appendix F.

3. *In-house and Multi-site Comparative Evaluations:* Describe proposed approaches and procedures to conduct in-house and facilitate multi-site method/reagent comparative evaluations outlined in the Statement of Work. Example of a multi-site comparative evaluation can be found at: http://aactg.s-3.com/pub/download/imm/IQA/trucount.pdf. Provide an example

of a multi-site comparative evaluation that you have performed in the past, including the purpose of the study, the number of participation Sites, characterization and distribution of QCM to Sites, instructions to Sites, analysis of data received from Sites and publication.

B. Assistance, Training and Information Dissemination

1. Describe proposed plans and approaches for:

a. investigating and providing assistance when Site results deviate from accepted, agreed-upon values, including plans for re-testing sites after implementation of corrective action.
b. providing training to U.S. and non-U.S. Site personnel, including training workshops at Contractor site and visits to Sites. .
c. disseminating trouble-shooting guides, frequently asked questions and guidelines method switching studies..

Include examples of past activities that describe your proposed plans and approaches for providing Site training and assistance.

2. Describe proposed plans and approaches for:

a. developing, distributing, and updating policies, user manuals, and guidelines via hard copy, electronic mail and web site
b. establishing, maintaining and updating an interactive, user-friendly and secure internet website for posting relevant IQA information
c. preparing manuscripts for publication in peer-reviewed journals
d. preparing and presenting data at national and international meetings.

SECTION 3: PROJECT MANAGEMENT

A. Organizational Context

Identify the context of the project within the organization, its mission, and within the organizational portfolio of ongoing and historical activities. Offerors shall describe how projects in general are prioritized within their organization and the level of priority this contract shall receive. Document prior success in the timely completion of tasks done under Government-funded projects of similar nature to the IQA.

B. Project Organization

Provide a plan for project organization and management in relation to the implementation, conduct, monitoring and completion of the tasks identified in the Statement of Work. Propose time schedules for achieving contract objectives, and procedures for maintaining quality control over the implementation and operation of the contract, including plans to keep within budget.

C. Staff Organization

Describe the responsibilities and level of effort for all proposed personnel who will be assigned to the contract and an administrative framework indicating clear lines of authority and responsibility for personnel. A subcontract may be proposed for obtaining statistical expertise. Describe the extent to which outside consultants will be used, as well as assurance of their availability.

D. Personnel Qualifications

Document the education, training, qualifications and experience of proposed staff. Limit CVs to 2-3 pages. Two Key Personnel will be required for this contract, the Principal Investigator and the Project Manager. The following staff will be needed:

1. Principle Investigator (PI) for this project who must possess:

    a. education at the master or doctoral level or equivalent experience, knowledge of clinical immunology and experience in the principles and practices of immunology quality assessment for HIV and HIV-associated viral co-pathogens;
    b. experience in overseeing the overall operations of an IQA program, including design and execution of proficiency testing programs, design and execution of method/reagent comparative evaluations, assistance to Sites and publication of IQA research results; and
    c. ability to hire staff in a flexible manner responsive to changing needs.

2. Project Manager for this project that will manage all aspects of this project, organize in-house training workshops and maintain communication with the Project Officer. The Project Manager shall be trained and experienced with Good Clinical Laboratory Practices and with management and coordination of multi-task projects, customer service, and laboratory trouble-shooting

3. Technicians who shall conduct the testing required for QCM characterization and method/reagent comparative evaluations, freezing and thawing PBMC, storage and distribution of QCM/reagents, and assistance/ trouble shooting. The technical staff shall have experience with the conduct of immunological assays, with providing assistance to Sites and shall possess IATA certification.

4. Statistician at the master or doctoral level who, in collaboration with Site Investigator, shall formulate criteria for acceptable/unacceptable performance of Sites in proficiency testing programs, shall design comparative evaluations and analyze their results.

5. Information technology professional with training and experience in developing and maintaining websites and electronic mail communication linkages.

E. Safety and Health

Provide proposed plans and procedures for the safe handling of potentially hazardous biological specimens, in particular blood borne pathogens such as HIV, HCV. This includes:

1. a summary of your safety and health operating procedures manual;

2. training certificates from Transport of Dangerous Goods training courses for key personnel;

3. documentation of ongoing programs and plans for programs for adequate training of personnel handling infectious biological material, and

4. evidence of training and compliance with applicable guidelines or regulations for a Biosafety Level 2 facility.

SECTION 4: FACILITIES, EQUIPMENT AND OTHER RESOURCES

A. Document the availability, adequacy and security of facilities, equipment, work space, storage space and other resources necessary to carry out the Statement of Work for the duration of the contract, including:

1. a description of the location and features of facilities, including BSL-2 bio-safety level of laboratories and security. Provide a floor plan and lease or ownership information;

2. a list of equipment, equipment maintenance plans and backup equipment; and

3. assurance(s) of ability to conduct operations in accordance with GCLP. Provide proof of CLIA certification and Institutional Review Board approval for this project.

B. Computerized Systems

1. Computerized inventory and database systems

Describe the proposed software system(s) to capture and track data relating to the tasks described in Statement of Work. Include plans to design any software to be used to capture or analyze data in a format that will easily permit further development and inclusion in the LDMS®, should the assays be implemented in clinical trials and performed on patient specimens. The LDMS® will be part of the Government Furnished Property.

2. System Security

Provide proposed plans for ensuring compliance with NIH requirements for computer system security. The successful Offeror will be required to develop a plan and submit it through the NIAID Project Officer to the NIAID Office of Technology and Information Systems (OTIS), for approval, as specified in the Statement of Work. A template for a comprehensive plan and its intended use can be found at http://irm.cit.nih.gov/security/secplantemp.doc . Additional information is also available at:

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

Assigning Security Level Designations

Table 1: Categories of Safeguarded Agency Information

Table 2: Security Level Designations for Agency Information

Table 3: Position Sensitivity Designations for Individuals Accessing Agency Information

NIST Guide for Developing Security Plans

Security Advice for Application Developers
System Security Plan Template

System Development Life Cycle Activities Matrix
Security and the System Development Life Cycle (SDLC) Class Presentation

The Ten Most Critical Web Application Security Vulnerabilities

3. DAIDS Enterprise System Interface

Describe proposed plans for interfacing with the DAIDS Enterprise System (see Appendix C) for transfer of data specified in the Statement of Work.

4. System Maintenance and Upgrades

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

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

5. Information Security (INFOSEC)

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

6. Information Technology (IT) Report

Provide a proposed draft report of the IT requirements (with a complete IT security assessment), including identification of personnel assigned to interact with NIAID IT staff.

SECTION 5: TRANSITION PLANS

1. Initial Transition

If applicable, describe your plan for transition of the IQA Program from the incumbent Contractor, including Government-furnished

property, reagents, donor samples and all data and data systems. Describe the coordination efforts required between the incumbent Contractor and the Offeror for the relocation tasks, include plans for instrument calibration and lot-to-lot comparisons between QCM/reagents received from the incumbent Contractor and any QCM developed by the Offeror. Include plans for the conduct of ongoing operations and coordination with Sites for transition of the IQA Program. Provide timelines for the transition that minimize disruption of the CD4 proficiency testing program which requires sending PT samples to Sites every other month. Currently, the IQA resides in Newark, New Jersey. Refer to Appendix D for a list of Government-Furnished Property to be transferred.

2. Final Transition

Describe general plans for transition of the IQA program to another contractor at the end of the contract period of performance.

SECTION 6: OPTION PLANS

For each of the three Options listed below, provide a proposed plan for staffing, facilities and other resources necessary to provide the services called for in the Statement of Work. The Plans should include the timelines for all tasks involved in initiating and implementing each option, proposed modifications in organizational structure and staffing mix, coordination, management and quality assurance procedures, and other Contractor functions that may be required to carry out such expansions. The Plans should also identify any proposed subcontractors and describe fully their proposed roles and responsibilities in providing services to additional U.S. and non-U.S. Sites.

A. **Option 1 – CD4 Proficiency Testing Program**: Add Sites to the CD4 Proficiency Testing Program and provide proficiency testing and assistance and training services. Most Sites shall be located within the continental U.S., Puerto Rico and Hawaii, and a few in Canada. The base number of Sites participating in the CD4 proficiency testing program is 85, expected to grow to 125 through the exercise of Option 1.

B. **Option 2 – UK NEQAS CD4 Proficiency Testing**: Add non-U.S. Sites participating in the UK NEQAS CD4 proficiency testing program to receive oversight and assistance. Most non-U.S. Sites shall be located in South America, the Caribbean, Africa, and Asia. A small number of Sites may be located in other areas (e.g. Europe and Australia). The base number of Sites participating in the UKNEQAS CD4 proficiency testing program is 60, expected to grow to 100 through the exercise of Option 2.

C. **<u>Option 3</u> – PBMC Cryopreservation Testing** - Add U.S. and non-U.S. sites to the PBMC cryopreservation proficiency testing program and provide proficiency testing and assistance and training services. The base number of Sites participating in the PBMC cryopreservation testing program is 80 (60 in the U.S. and 20 outside the U.S.), expected to grow to 140 Sites (100 in the U.S. and 40 outside the U.S.), through the exercise of Option 3.

SECTION 7: 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. Also 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 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 Subject use. The following information is essential:

a. Human Subjects
Include plans for compliance with applicable domestic and international regulations on the use of human subjects (e.g. IRB submission and approval plans, consent procedures, etc.).
Also include, as applicable, documents relevant to the following:

- Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (MARCH 2005)
- Instructions to Offerors Regarding Protection of Human Subjects
- Collaborating Site(s)
- Required Education in the Protection of Human Research Participants
- Inclusion of Women and Minorities in Research Involving Human Subjects
- Inclusion of Children in Research Involving Human Subjects
- Data and Safety Monitoring in Clinical Trials
- Research Involving Human Fetal Tissue
- Research Involving Prisoners as Subjects

- Research Involving Recombinant DNA Molecules (including Human Gene Transfer Research)
- Human Embryonic Germ Cell (HEGC) Research
- Human Embryonic Stem Cell (HESC) Research
- HIV Antiretroviral Treatment Trials

b. Health Insurance Portability & Accountability Act (HIPAA) Include plans for compliance with HIPAA.

II) 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.

III) Sharing of Model Organisms for Biomedical Research (Plan)

Section L of the RFP specifies the minimum documentation requirements for Model Organism sharing. All related documentation should be included in the proposal in this clearly marked section. The Technical Proposal should include a plan for sharing Model Organisms as required by this RFP.

IV) IT Systems Security

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

IMMUNOLOGY QUALITY ASSESSMENT PROGRAM
RFP NIH-NIAID-DAIDS-07-31
APPENDIX B

ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS

AND

UNIFORM COST ASSUMPTIONS

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

Offerors are advised to give careful consideration to the statement of work, all reference material provided as appendices and attachments, and the technical evaluation criteria, and, the RFP as a whole, in the development of 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

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. Proficiency Testing: The existing CD4 Proficiency Testing (PT) Program is described at http://aactg.s-3.com/iqa.htm. For estimating PT, the Offeror shall assume:

    a. For *lymphocyte subset immunophenotyping*, shipment of a panel containing five, 2-3 ml whole blood samples in EDTA (including duplicate or triplicate samples), obtained from several donors at various HIV disease stages, shipped overnight at room temperature to 82 U.S. Sites and 3 Canadian Sites 6 times/year.

b. For *CFSE dye dilution assay*, shipment of a panel containing three, 10 ml whole blood samples in heparin, obtained from 3 HIV-negative CMV-positive donors, shipped overnight at room temperature to 5 U.S. Sites 4 times/year.

c. For *determination of production of inducible cytokines*, shipment of a panel containing five, 2ml whole blood samples in heparin from uninfected donor(s), shipped overnight at room temperature to 5 U.S. Sites 2 times/year.

d. For *lymphocyte subset immunophenotyping of frozen cells,* shipment of a panel containing 15 millions frozen PBMC in 1 ml, obtained from 4 HIV-infected donors, shipped overnight on dry ice to 5 U.S. Sites 3 times/year.

e. *Shipping of Materials:* Shipped materials are classified as "diagnostics" not as "hazardous". The NIH has a contract with Federal Express for shipping at room temperature at the cost of $6/shipment and for shipping on dry ice at the cost of $8/shipment. Shipping costs shall be assumed by the Contractor.

2. Assessment of Non-U.S. Flow Cytometry Laboratories: For estimating assessment of non-U.S. flow cytometry laboratories, the Offeror shall assume:

a. Shipment of a panel, obtained from the UK NEQAS, containing 20 samples of stabilized whole blood from HIV-negative donors representing various levels of CD4 count, shipped one time/year by air at room temperature to 2 Sites in Africa, 2 Sites in Thailand, 2 sites in China, 2 Sites in Latin America and 2 Sites in the Caribbean.

b. Facilitation of the enrollment in the UK NEQAS CD4 PT Program of 10 Sites/year.

c. Shipped materials shall be classified as "diagnostics" and the cost of shipping should be assumed to be $50 per shipment.

d. The base number of non-US CD4 Sites who benefit from oversight and assistance by the IQA is 60.

4. Proficiency Testing of PBMC Cryopreservation: For estimating proficiency testing of PBMC cryopreservation, the Offeror shall assume:

a. Receiving, storing, thawing and counting up to 5 samples from each of 60 U.S. and 20 non-U.S. Sites 4 times a year; shipping costs shall be borne by the shipping Sites. The base number of participating U.S. Sites is 60 and participating non-U.S. sites is 20.

b. Paying for the cost of dry ice replenished shipments from 6 non-U.S. Sites: 2 in Africa, 2 in Thailand, and 2 in Latin America, 4 times per year.

5. Site Assistance and Training: For estimating Site assistance and training services, the Offeror shall assume:

a. Conducting phone/email/web interactions with 10 U.S. and 20 non-U.S. CD4 Sites six times per year.

b. Conducting phone/email/web interactions with 10 U.S. and 10 non-U.S. cryopreservation Sites four times per year.

c. Shipment once a year, by air at room temperature, to 2 Sites in Africa, 2 Sites in Thailand, 2 sites in China, 2 Sites in Latin America and 2 Sites in the Caribbean, of a panel obtained from the UK NEQAS of 20 samples of stabilized whole blood from HIV-negative donors representing various levels of CD4 count.

d. Shipment once a year to 10 U.S. Sites and to 10 non-U.S. Sites (2 in Africa, 2 in Thailand, 2 in China, 2 in Latin America and 2 in the Caribbean) of a panel of 10 samples containing 10×10^6/ml in 0.5ml each of frozen PBMC from HIV-positive donors.

e. Five visits each year of one person to non-U.S. Sites (1 in Africa, 1 in Thailand, 1 in China, 1 in Latin America and 1 in the Caribbean), for one week each.

f. Conduct of 3 annual CD4 workshops and 3 annual cryopreservation workshops at the contractor site, each hosting 10 Site participants for 2 days.

6. Switching Studies: For estimating studies for switching from one CD4 method to another, the Offeror shall assume ten studies annually.

7. In-house Comparison Studies:

a. Comparative Evaluations of Assay Kits/Reagents: For estimating the 4 in-house studies described in Task D.2.a. of the Statement of Work, the Offeror shall assume the conduct of 4 annual evaluations each comparing 3 lots of human AB serum tested by LPA, using 3 donors and 2 mitogens.

b. PBMC Comparative Evaluations: For estimating the 4 in-house studies described in Task D.2.b. of the Statement of Work, the Offeror shall

assume 4 annual comparative evaluations of the effect of PBMC storage at minus 70^0F vs. storage in LN2, on flow cytometric measurement of intracellular cytokine (IFN-g) production.

8. Assay Evaluation Studies: For estimating each of the 4 annual assay evaluation studies described in Task D.3.a. of the Statement of Work, the Offeror shall assume:

   a. 6 weekly shipments of a panel consisting of 10 samples of 2 ml whole blood in EDTA from HIV-positive subjects, shipped overnight at room temperature to 6 U.S. laboratories.

   b. 6 weekly shipments of a panel of reagents consisting of 4 LFU/ml Tetanus and 200 µg/ml Candida and 0.02 µg/ml PHA, shipped overnight on dry ice to 6 U.S. laboratories.

9. Comparative Evaluations: For estimating each of the 4 comparative evaluations of alternative CD4 methods described in Task D.3.b., the Offeror shall assume 10 weekly shipments of a panel consisting of 10, 2 ml whole blood samples in EDTA from HIV-positive subjects with various CD4 counts, shipped overnight at room temperature to 6 U.S. laboratories.

10. Sample Condition Evaluations: For estimating each of the 4 sample condition evaluation studies described in Task D.3.c., assume shipment of two parallel panels: one "fresh blood" panel consisting of 10, 10ml whole blood samples from HIV-positive subjects, shipped overnight in room temperature; and one "frozen cell" panel consisting of 10 samples each containing 15 million frozen PBMC in 1ml from the same subjects whose blood is used to prepare the "fresh blood" panel. This panel will be shipped overnight on dry ice. Both panels will be shipped one time to 6 U.S. laboratories.

11. Shipping of Centrally-stored IQA Reagents: For estimating shipping of centrally-stored IQA reagents to U.S. Sites, assume 20 overnight shipments each month on dry ice (Task E.2.b.).

12. Sample Shipping: Shipped samples shall be designated as diagnostic specimens, packaged in STP-210 Diagnostic Packaging, shipped via DHL or Fedex. The NIH has a contract with Federal Express for shipping at room temperature at the cost of $6/shipment and on dry ice at the cost of $8/shipment. International shipments that require replenishing dry ice are assumed to cost $450/shipment. The shipping cost shall be assumed by the Contractor.

13. QCM Storage: For estimating storage of QCM, assume storage of 300 vials at minus 20^0F; 4,000 vials at minus 70^0F; 400 bottles each with 100 ml human AB serum at minus 70^0F; and 2,500 vials in liquid nitrogen.

B. Information Resources

1. The Offeror shall assume that the cost for KPMD hosting of CD4 proficiency testing data on a backup server, licensing and support of the CD4 proficiency testing program will be approximately at $7,500 per year, and possible updates will cost approximately $2,500 per year. Please see Appendix C for more information about KPMD.

2. The Offeror shall assume the following minimum requirements for computer hardware and software to be provided by the Contractor:

    a. IBM Compatible computer (PC), with a processor speed of 2.5 GHz, 512 MB RAM, DVD+/-RW (Multi Format Double Layer Drive), 3.5” disk drive, 1.44MB disk drive, 80 GB hard drive, 15" LCD flat panel monitor, 10/100 32-bit Fast Ethernet card, 4 USB ports.

    b. Hewlett Packard (HP) Compatible Laser Jet Printer or other laser printer with USB port capability.

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

    d. Software packages that include Microsoft Windows 2000 Professional or XP Professional, Microsoft Office Professional 2003 Suite, Symantec PC Anywhere-Version 11.5 or higher, Backup capability (examples: Colorado Backup, Iomega, CMS), anti-virus software with up-to-date virus definitions and on-going support for definition updates (e.g. McAfee, Norton Anti-virus, etc.).

3. The Offeror shall assume the cost of complying with computer system security needs to meet NIH requirements and the cost of interacting with the DAIDS Enterprise System as described in Appendix C.

4. The Offeror shall assume the cost to develop and maintain an IQA website.

C. Travel

1. For estimating purposes, assume:

    a. 2 visits/year, 3 days each, by 2 Contractor personnel to Bethesda, Maryland to meet with the Project Officer and attend DAIDS-sponsored meetings.

b. travel by 2 Contractor personnel to present data at 2 domestic meetings, each of 3 days duration.

c. travel once a year by 2 Contractor personnel to present data at 1 international meeting of 5 days duration.

D. Equipment (GFP)

The Offeror is expected to provide flow cytometers, freezers and other instrumentation required to conduct activities described in the Statement of Work. Equipment leasing costs, prorated for the actual use of the equipment on this Contract, may be charged to the Contract. Certain Government Furnished Equipment, data and software systems will be transferred from the incumbent contractor to the Offeror. A list of Government-furnished property is provided in APPENDIX D.

E. Transition Plans

The Offeror shall bear the cost of planning and executing the initial transition and the final transition as described in items A. and I. of the Statement of Work.

F. Options

The Offeror shall estimate each of the three Options described below and include the cost of additional required staff, facilities and other resources necessary to exercise each Option:

a. Option 1 – CD4 Proficiency Testing: add 10 U.S. Sites to the CD4 Proficiency Testing Program and provide the services described in Task B.1. and C. of the Statement of Work.

   Option 1 may be exercised up to two times, annually for up to an additional 10 sites per option exercised. Option 1 may be exercised a total of four times over the life of the contract.

b. Option 2 – UK NEQAS Proficiency Testing: add 20 non-U.S. Sites participating in the UK NEQAS CD4 Proficiency Testing Program, to receive oversight and assistance by the IQA as described in Tasks B.2 and C. of the Statement of Work. These Sites shall be located in South America, the Caribbean, Africa, and Asia. Include the cost of shipping 1 qualification panel (Task B.2.a.) and 1 troubleshooting panel (Task C.2.a.) per year to 3 Sites in Africa.

   Option 2 may be exercised in any year for up to an additional 20 sites per option exercised. Option 2 may be exercised a total of two times over the life of the contract.

c. Option 3 – PBMC Cryopreservation Proficiency Testing: add 20 Sites to the PBMC Cryopreservation Proficiency Testing Program and provide the services described in sections B.3 and C. of the Statement of Work.

Option 3 may be exercised in any year for up to an additional 20 sites per option exercised. Option 3 may be exercised a total of three times over the life of the contract.

Offerors are instructed to propose costs assuming the exercise of options as follows:

Option	Contract Year Option Exercised	Quantity of Options Exercised
1	**Year 1**	**2**
2	**Year 1**	**1**
3	**Year 1**	**1**

SECTION 4 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED

I) 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.

II) 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.

III) 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.

APPENDIX C: ADVANCED UNDERSTANDINGS

IMMUNOLOGY QUALITY ASSESSMENT PROGRAM

CONFIDENTIALITY OF INFORMATION

Information and data provided to or generated by the contractor under this contract shall be treated confidentially and protected by an Advanced Understanding to be included in the resulting contract and worded as follows: "Because there is a likelihood that the contractor will be utilizing and evaluating bioanalytical methods provided to the Government by third party suppliers (commercial, non-commercial, and research resources), it is essential to include provisions that will protect the proprietary rights of the suppliers. Whenever these materials and methods generally are provided to the Government as proprietary and confidential, the contractor shall be bound by the same terms and conditions as the Government in these agreements, with respect to the proprietary and confidential nature of the information provided by the laboratory. All information provided by the supplier or Project Officer shall be assumed to be confidential unless specifically identified as non-confidential in writing by the Project Officer. Confidential information may not be revealed without written permission. All materials and methods supplied to the contractor shall be utilized solely for contract-related research purposes and no unauthorized use or distribution of these materials will be permitted.

All other data provided to the contractor under the contract similarly are to be considered confidential. All data provided to the contractor shall be utilized solely for contract-related research purposes and no unauthorized use or distribution of these data will be permitted. Any manuscript or scientific meeting abstract generated under this contract must be submitted for review and written approval by the Project Officer before submission for public presentation or publication. Contract support shall be acknowledged in such publications. A "publication" is defined as an issue or printed material offered for distribution or any communication or oral presentation of information. The Project Officer will review all manuscripts/abstracts in a period of time not to exceed 20 calendar days from receipt, and will either grant clearance for publication/disclosure, recommended changes, or, as applicable, refer the document to the supplier of the materials and methods for their review. When the supplier does not consent to publication of the manuscript or abstract, the Project Officer shall withhold approval to publish in accordance with the terms and conditions of any existing Agreement between NIAID and the contractor, or the laboratory. NIAID will use its best efforts to assist and expedite the review and approval process by the supplier and laboratories."

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

Secure One HHS

"HHS is responsible for implementing a Department-side information security program to assure that each information system and associated facility provides a level of security that is commensurate with the risk and magnitude of the harm that could result from the loss, misuse, disclosure, or modification of information contained in the system. Each system's level of security shall protect the confidentiality, integrity, and availability of the information and comply with all security and private-related laws and regulations. The HHS Information Security

Program Policy and Handbook, known as 'Secure ONE HHS', provide baseline of security policies for the Department. These policies apply to the Department, which includes Operating Division (OPDIV) and Staff Division (STAFFDIV) personnel, contractors, and other authorized users. All information technology related issues such as technical security, information security, personnel security, web management, application management, database management, electronic communications, electronic reporting, etc., defined within this RFP is subject to the prescribed methods defined within 'Secure ONE HHS.' The contractor shall provide a description of security program that is in place in the contractor's facility that will assure compliance with 'Secure ONE HHS,' and describe any other components of your security system used to keep data and access to it, secure."

COMPUTERIZED SYSTEMS

During the contract period of performance, the NIAID may have a need to convert existing systems, databases, and applications to a functionally equivalent and compatible environment. These Advanced Understandings apply to the computerized systems described below.

Laboratory Data Management System (LDMS®)

Most Sites are currently linked through an electronic network which is used to manage specimens and/or generate data from the Sites to a remote central database. This system, the Laboratory Data Management System (LDMS®), tracks specimens, provides assay templates, calculates derived quantities, produces reports, creates bar-coded labels with a unique identifier, and generates data files for export from the Site. Sites that participate in the PBMC Cryopreservation Proficiency Testing (PT) Program utilize the LDMS® to enter viability and yield information, to produce a diskette which is sent to the IQA where it is uploaded into IQA's own LDMS®. The IQA enters its viability and yield data after thawing samples and downloading the information to Frontier Science Foundation - FSTRF (www.fstrf.org) – the data center for two large clinical trial networks.

DAIDS anticipates that software requirements will change over the course of the 7-year contract and that another software program will replace the LDMS®. When that occurs, the Offeror will be required to use software that provides continued support for the PBMC Cryopreservation PT Program.

United Kingdom National External Quality Assessment Service (UK NEQAS)

To support the CD4/CD8 PT Program, the current contractor utilizes a software program created by KPMD, a software engineering company that creates customized software packages. KPMD is based in Sheffield, South Yorkshire, UK (http://www.kpmd.co.uk/). The KPMD customized software program is owned by the Government and will be transferred to the successful Offeror. In this CD4/CD8 PT Program, Site-testing results are entered by the Site on an available internet website. The system generates statistical analyses; Site-specific performance reports are generated automatically, produced in Acrobat, and made available to participating sites on the IQA website. The system was developed in Microsoft .Net using Visual Basic Windows Forms and .Net Web Services.

The data can is held in Microsoft Access databases. The annual cost for KPMD hosting, licensing and support is approximately $7,500 per year, and potential updates will cost approximately $2,500 per year. It is expected that the IQA contractor will host PT results on its own server and the KPMD server will be utilized as backup.

Division of AIDS Enterprise System (DAIDS-ES)

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

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

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

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

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

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

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

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

Depending upon the architecture and implementation of the Contractor's data management system(s), the following activities may be required to be compatible with the DAIDS-ES:

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

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

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

INTELLECTUAL PROPERTY

Contractors acknowledge that:

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

- Prior to, during, and subsequent to the award, the U.S. Government is not required to obtain for the contractor any proprietary rights, including intellectual property rights, or any materials needed by the contractor to perform the project.

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

- The contractor is encouraged to reach early consensus with any proposed partners regarding any appropriate intellectual property or other legal issues that may arise during

the project. In addition, contractors are expected to exercise their Bayh-Dole rights in a manner that does not conflict with the goals of this award or the intent of the Bayh-Dole Act to promote the utilization, commercialization and availability of U.S. Government-funded inventions for public benefit. Finally, the contractor is expected to make new information and materials known to the research community in a timely manner through publications, web announcements, and reports to the NIAID or other mechanisms consistent with laws, regulations, and NIH policies.

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

One of the goals of this contract is to facilitate the optimization and standardization of immunological methods for implementation in multi-site clinical trials. It is expected that the great majority of methods will be proprietary to third parties. It is clear from the NIAID's experience that third party providers ("provider") will not provide their proprietary methods without assurance that the intellectual property rights associated with their methods will be protected. Accordingly, to encourage providers to provide their methods for evaluation under this contract the contractor agrees to the Article pertaining to the Intellectual Property Option to the Provider, which requires the contractor and its subcontractors to provide a research use license and a commercialization license option to Subject Inventions made under the contract to the Providers as follows:

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

(1) Single Provider

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

The contractor will allow provider three (3) months from the date the contractor sends written notice to the provider of the existence of a contractor invention (or such additional period as the provider and the contractor may agree) to notify the contractor in writing, whether or not it wants to obtain an exclusive license to the contractor invention. If the provider fails to notify the contractor in a timely fashion then the contractor's obligation to offer the provider a license option with respect to that contractor Invention will expire, and the contractor will be free to dispose of its interests in such contractor Invention in accordance with the contractor's policies. If the contractor and the provider fail to reach agreement within ninety (90) days, (or such additional period as the provider and the contractor may agree) on the terms for an exclusive

license for a particular contractor Invention, then for a period of six (6) months thereafter the contractor will not offer to license that contractor Invention to any third party on materially better terms than those last offered to the provider without first offering such terms to the provider, in which case the contractor will offer the provider a period of thirty (30) days in which the provider can accept or reject the offer.

(2) Multiple Providers

With respect to a contractor invention resulting from the use of "Materials and method" provided by multiple providers, but which is an improvement only to a "Material or Method" of a specific provider, the contractor agrees to grant to that provider the rights described above in (1).

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

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

Provider Inventions

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

Protection of Proprietary Data

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

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

APPENDIX D: GOVERNMENT-FURNISHED MATERIALS/PROPERTY

IMMUNOLOGY QUALITY ASSESSMENT PROGRAM

1. Equipment/Property

Equipment	Vendor/Model/SN#[Qty]	Placed in Service	Serial Number
Phlebotomy Chair		Feb-99	
Plate Reader	Molecular Devices Versamax	May-03	BN2434
Beta Counter Wallace TriLux 1450	Perkin Elmer	Sep-00	4501651
Blood Collector/Mixer	Genesis	Feb-99	95345
Centrifuge Avanti Floor	Beckman AVANTI JE	Apr-03	JSE03B14
Centrifuge Counter Top	Beckman ALLEGRA 6	Apr-03	ALS03A36
Computer for TriLuxBeta Counter 1450	Perkin Elmer	Sep-00	FJMXI
Cryo Rack Scanner PC Computer	Matrix Vision Mate Repository Sys.	May-04	
Cryo Tube reader	Matrix Vision Mate Repository Sys.	May-04	
ELIspot Reader	CTL		S1A100332
Flowcytometer: Coulter FC500*	Beckman Coulter FC500	Jul-03	OAG23101
Flowcytometer: BD FASCalibur*	Becton Dickinson	May-03	E5638
Freezer #1 -70oc	Harris HLT 25V 85SID 34	Apr-03	W16M5999452 XM
Freezer #2 -70oc	ACTG Forma Scientific 923	Apr-03	96972-4746
Freezer #3 -70oc	Harris HTL 21V 85D 29	Apr-03	J04J438767 TJ
Freezer #4 -70oc	Napco UF650	Sep-04	50310091
Freezer : Liquid Nitrogen	Taylor Wheston 24K Series	Apr-03	
Freezer Racks [22]	VWR	Jul-05	
Harvester: Mach 3	TomTec	Sep-00	96-3500
Harvester: Mach 3 Autotraps [2]	TomTec	Sep-00	

Heat Sealer	Perkin Elmer	Sep-00	2953714
Hematology Analyzer	Beckman Coulter AcT 5	Apr-03	AF22093/ SysID# 455089
Hot Plate/ Stirrer	Corning PC420	Apr-03	440936
Ice Machine	Scottsman	Apr-03	N00162622
Incubator Oven	Imperial III LabLine 310	Apr-03	0303-3031
Incubator: NuAire CO2 Incubators F525	NuAire NU-8700 IR	Feb-03	SN# 81767011703
Incubators CO2 Incubators	NuAire CO2 NU-8700 IR Left	Apr-03	82848-031203
Incubators CO2 Incubators	NuAire CO2 NU-8700 IR Right	Apr-03	82849-031203
Laminar hood #1	NuAire 425-600	Apr-03	835-23042203
NuAire Portable UV Lights for Hood [2]	NuAire -Labrepco [2]	Jul-03	
pH Meter	Corning	Dec-03	
Pipette Aids [6]	VWR [6]	Mar-03	
Pipettes Multi Electronic	Rainin [12]	Sep-02	
Pipettes Multi Manual	Thomas Scientific [2] Rainin [4]	Sep-03	
Pipettes Single Manual	VWR [4]	Jul-03	
Plasma Extractor	Baxter	Feb-06	T28908
Refrigerator: Counter Top		Apr-03	
Refrigerator/Freezer	Crosley CT21GKKQ	May-03	EM0632817
Scale: Analytical #AX204	Mettler Toledo AX204	Apr-03	1122090119
Scale: Balance PB 3002	Mettler Toledo PB 3002	Apr-03	1114032442
Sonicator		Nov-02	
Thermo Mixer	Eppendorf VWR	May-03	
Thermo Mixer	Eppendorf VWR	May-03	
Thermo Mixer Block	Eppendorf VWR	Aug-03	
Vi Cell PC*	Beckman Coulter	May-03	
Vi-Cell*	Beckman Coulter Vi-Cell A	Apr-03	AF47087
Vortex	VWR [2]	May-03	

Water Bath -Dual	LabLine	Apr-03	0203 0305
Computer	Dell	May-03	
Computer	Dell	May-03	
Computer	Dell	May-03	
Computer	PC next to Plate reader	Jan-99	
Copier*	Sharp ARM450UT	May-03	37116252
Desk Chairs [3]	Labrepco	May-03	
Desks/drawers		May-03	
File Cabinets	various	May-03	
File Cabinets	various	May-03	
Lab Stool Chairs [6]	Labrepco	Mar-03	
Fax		Jan-99	
Printer: Xerox Wkstation	Xerox Workstation DWC657	Jan-99	
Printer HP Printer 4200	HP 4200	May-03	CNBY711223
Printer: HP Laser Jet		May-03	
Printer: HP Color Printer		May-03	
Molecular Devices Plate Validation	Molecular Devices	May-03	
Amega Scientific Temp Alarm Sys	Temp Monitor Sys	Nov-03	

* Leased items

2. DATA AND SOFTWARE SYSTEMS

	System	Item	Form
1	PT data tracking	Data	Spreadsheets, MS-Word files, Access database
2	Assay research	Data	Spreadsheets, MS-Word files
3	QCM data tracking	Data	Spreadsheets, MS-Word files
4	Data management system	Software	LDMS
5	CD4 PT web-based system	software	KPMD

NIAID DAIDS QUALITY ASSESSMENT

FLOW CYTOMETRIC IMMUNOPHENOTYPING AND HEMATOLOGY WITH ABSOLUTE CD4/CD8 COUNTS

SUMMARY REPORT

March 2006

If you have any questions please contact:	
Mr./Ms.	
IQA	
NIAID-DAIDS	
Phone:	Email:
Fax:	Website:

ND – No Data NC- Not Calculated (e.g. div by zero)

NIAID DAIDS QUALITY ASSESSMENT

March 2006

CERTIFICATION CRITERIA Based on CD3+CD4+% and CD3+CD8+%

Every other month, laboratories receive a shipment comprised of 5 coded HIV+ Whole blood specimens. For these coded specimens, laboratories are required to measure and report the same phenotypes that they perform on specimens from patients enrolled in NIAID-DAIDS sponsored investigations. Laboratories are evaluated every four months (a trimester) for their ability to perform CD3+CD4+% and CD3+CD8+% subset phenotyping on a total of 10 coded specimens.

Some of the 10 specimens are replicates, allowing for evaluation of both inter-lab (between-lab) performance and intra-lab (within-lab) performance.

Inter-lab performance for a specimen is bad if residual values for CD3+CD4+% or CD3+CD8+% are >= 5%, or <= 5%, with deviates >= 2 or <= -2. The residual value is the lab's value minus the median of all participating laboratories analyzing that specimen. The deviate is the residual divided by the inter quartile range (IQR). The IQR is three-quarters of the difference between the 25th and the 75th percentiles of results in laboratories analyzing that specimen. The median and the IQR of a replicate set are determined by including all labs and all specimens in that set of replicates.

Intra-lab performance is bad if the range of the replicate values (highest minus lowest) within a given lab is >= 4%.

In each trimester there are a total of 6 possible inter-lab determination and 2 intra-lab determination s. Each determination receives a mark of "good" or "bad". A set of replicate specimens is counted as only one mark, no matter how many replicates are in the set. Thus, there are a total of 8 possible marks for the trimester. A lab that has one-third or more bad CD3+CD4+% marks or one-third or more bad CD3+CD8+% marks has failed the trimester. If a lab fails for either phenotype (CD3+CD4+% or CD3+CD8+%), the lab is considered to have failed the trimester.

CD3+CD4+% and CD3+CD8+%

Specimens	CD4 T-Cells	CD8 T-Cells
060101	ND	ND
060102	ND	ND
060103, 060104, 060105	ND	ND
060302, 060303, 060304	Good	Good
INTER-LAB EVALUATIONS: (residual >= 5% and deviate >= 2) = BAD		
060301	Good	Good
060302, 060303, 060304	Good	Bad
060305	Good	Good
Bad Marks/Total Marks	0/8	1/8
Percent Bad Marks	0%	12.50%
Trimester Performance	Satisfactory	Satisfactory

ND - No Data NC - Not Calculated (e.g. div by zero)

NIAID DAIDS QUALITY ASSESSMENT

March 2006

Mock Analysis of CD4 and CD8 Absolute Counts

In addition to flow cytometric immunophenotyping of CD3+CD4+% and CD3+CD8+%, labs are also required to submit either lymphocyte% and WBC data from a hematology analyzer so that CD4 and CD8 count data can be calculated or the lab must be approved to obtain CD4 and CD8 count data via a single platform flow cytometric method. CD4 and CD8 count data are analyzed but DO NOT COUNT TOWARD CERTFICATION at this time.

Inter-lab performance for a specimen for CD4 count is bad if the residual value is >= 100 or <= -100 and the deviates are >= 2 or <= -2. Inter-lab performance for a specimen for CD8 count is bad if the residual value is >= 200 or <= -200 and the deviates are >= 2 or <= -2. The residual value is the lab's value minus the median for all the participating laboratories analyzing that specimen. The deviate is the residual value divided by the inter quartile range (IQR). The IQR is three-quarters of the difference between the 25th and 75th percentiles of results in laboratories analyzing the specimen. The median and IQR of a replicate set are determined by including all labs and all specimens in that set of replicates.

Intra-lab performance is bad for CD4 counts if the range of the replicate values (highest minus lowest) within a given lab is >= 75.
Intra-lab performance is bad for CD8 counts if the range of the replicate values within a given lab is >= 150.

In each trimester there are a total of 6 possible inter-lab determinations and 2 intra-lab determinations. Each determination receives a mark of "good" or "bad". A set of replicate specimens is counted as only one mark, no matter how many replicates are in the set. Thus, there are a total of 8 possible marks for the trimester. A lab that has one-third or more bad CD4 count marks or one-third or more bad CD8 count marks has MOCK failed the trimester. Please be advised that if you are unhappy with your results and wish to switch to single platform methodology, you must do a DAIDS comparison study. See documentation at aactg.s-3.com/iqa.htm or contact Mr.

CD4 and CD8 Counts

Specimens	CD4 T-Cells	CD8 T-Cells
060101	ND	ND
060102	ND	ND
060103, 060104, 060105	ND	ND
060302, 060303, 060304	Bad	Bad
INTER-LAB EVALUATIONS ***CD4: (Residual <= -100 or >= 100 and deviate <= -2 or >= 2)*** ***CD8: (Residual <= -200 or >= 200 and deviate <= -2 or >= 2)***		
060301	Bad	Bad
060302, 060303, 060304	Bad	Bad
060305	Good	Bad
Bad Marks/Total Marks	3/8	4/8
Percent Bad Marks	37.50%	50.00%
Trimester Performance	Unsatisfactory	Unsatisfactory

ND - No Data NC - Not Calculated (e.g. div by zero)

NIAID DAIDS QUALITY ASSESSMENT

March 2006

FLOW CYTOMETRIC IMMUNOPHENOTYPING

CELL PREPARATION METHOD : FACS Lysing Solution

FLOW CYTOMETER : FACSCalibur

PHENOTYPE	Specimen-Donor 060301 - D	Specimen-Donor 060302 - A	Specimen-Donor 060303 - A	Specimen-Donor 060304 - A	Specimen-Donor 060305 - E
CD3+	78.0	79.0	78.0	79.0	34.0
CD3+/CD4+	21.0	16.0	15.0	15.0	0.0
CD3+/CD8+	58.0	60.0	62.0	60.0	27.0
Total CD19+	8.0	7.0	6.0	7.0	42.0
CD3-/CD19+	7.0	7.0	6.0	6.0	41.0
CD3-/CD(16+56)+	ND	ND	ND	ND	ND

ND - No Data NC - Not Calculated (e.g. div by zero)

NIAID DAIDS QUALITY ASSESSMENT

March 2006

FLOW CYTOMETRIC IMMUNOPHENOTYPING

TRIPLICATE ANALYSIS

PHENOTYPE		Specimen-Donor 060302 - A	Specimen-Donor 060303 - A	Specimen-Donor 060304 - A		RANGE
CD3+		79.0	78.0	79.0		1.0
CD3+/CD4+		16.0	15.0	15.0		1.0
CD3+/CD8+		60.0	62.0	60.0		2.0
Total CD19+		7.0	6.0	7.0		1.0
CD3-/CD19+		7.0	6.0	6.0		1.0
CD3-/CD(16+56)+		ND	ND	ND		ND

Replicate Specimens (from the same donor) are evaluated for a range as a measure of reproducibility. The range is the difference between the highest and lowest reported values on a replicate specimen. A range >= 4 is considered to be a failure by the Immunology Quality Assurance Programme.

ND - No Data NC - Not Calculated (e.g. div by zero)

NIAID DAIDS QUALITY ASSESSMENT

March 2006

FLOW CYTOMETRIC IMMUNOPHENOTYPING

Donor A		CD3+%	CD3+ CD4+%	CD3+ CD8+%	Total CD19+%	CD3- CD19+%	CD3- CD(16+56)+%
Specimen	**Parameter**						
060302	Group N	84.0	84.0	84.0	39.0	63.0	63.0
	Reported	79.0	16.0	60.0	7.0	7.0	ND
	Upper Quartile	76.0	15.0	57.0	9.0	9.0	13.0
	Median	74.0	14.0	57.0	8.0	8.0	12.0
	Lower Quartile	73.8	14.0	55.0	7.0	7.0	9.0
	IQR	1.7	0.8	1.5	1.5	1.5	3.0
	Residual	5.0	2.0	3.0	-1.0	-1.0	ND
	Deviate	3.0	2.7	2.0	-0.7	-0.7	0.0
060303	Group N	84.0	84.0	84.0	39.0	63.0	63.0
	Reported	78.0	15.0	62.0	6.0	6.0	ND
	Upper Quartile	76.0	15.0	57.0	9.0	9.0	13.0
	Median	74.0	14.0	57.0	8.0	8.0	12.0
	Lower Quartile	73.8	14.0	55.0	7.0	7.0	9.0
	IQR	1.7	0.8	1.5	1.5	1.5	3.0
	Residual	4.0	1.0	5.0	-2.0	-2.0	ND
	Deviate	2.4	1.3	3.3	-1.3	-1.3	0.0
060304	Group N	84.0	84.0	84.0	39.0	63.0	63.0
	Reported	79.0	15.0	60.0	7.0	6.0	ND
	Upper Quartile	76.0	15.0	57.0	9.0	9.0	13.0
	Median	74.0	14.0	57.0	8.0	8.0	12.0
	Lower Quartile	73.8	14.0	55.0	7.0	7.0	9.0
	IQR	1.7	0.8	1.5	1.5	1.5	3.0
	Residual	5.0	1.0	3.0	-1.0	-2.0	ND
	Deviate	3.0	1.3	2.0	-0.7	-1.3	0.0

Donor D		CD3+%	CD3+ CD4+%	CD3+ CD8+%	Total CD19+%	CD3- CD19+%	CD3- CD(16+56)+%
Specimen	**Parameter**						
060301	Group N	62.0	63.0	63.0	35.0	47.0	42.0
	Reported	78.0	21.0	58.0	8.0	7.0	ND
	Upper Quartile	79.0	21.0	57.5	8.0	8.0	14.0
	Median	78.0	20.0	56.0	8.0	8.0	13.0
	Lower Quartile	77.0	19.0	55.0	7.0	7.0	11.0
	IQR	1.5	1.5	1.9	0.8	0.8	2.3
	Residual	0.0	1.0	2.0	0.0	-1.0	ND
	Deviate	0.0	0.7	1.1	0.0	-1.3	0.0

Donor E		CD3+%	CD3+ CD4+%	CD3+ CD8+%	Total CD19+%	CD3- CD19+%	CD3- CD(16+56)+%
Specimen	**Parameter**						
060305	Group N	61.0	62.0	62.0	35.0	46.0	42.0
	Reported	34.0	0.0	27.0	42.0	41.0	ND
	Upper Quartile	31.0	1.0	26.8	48.0	48.8	23.0
	Median	29.0	1.0	25.0	46.0	46.5	22.0
	Lower Quartile	28.0	1.0	24.0	44.5	45.0	20.0
	IQR	2.3	0.0	2.1	2.6	2.8	2.3
	Residual	5.0	-1.0	2.0	-4.0	-5.5	ND
	Deviate	2.2	0.0	1.0	-1.5	-2.0	0.0

RESIDUAL = REPORTEDVALUE - MEDIAN
IQR = THREE-QUARTERS OF THE DIFFERENCE BETWEEN THE UPPER AND LOWER QUARTILES
DEVIATE = RESIDUAL / IQR

Appendix E

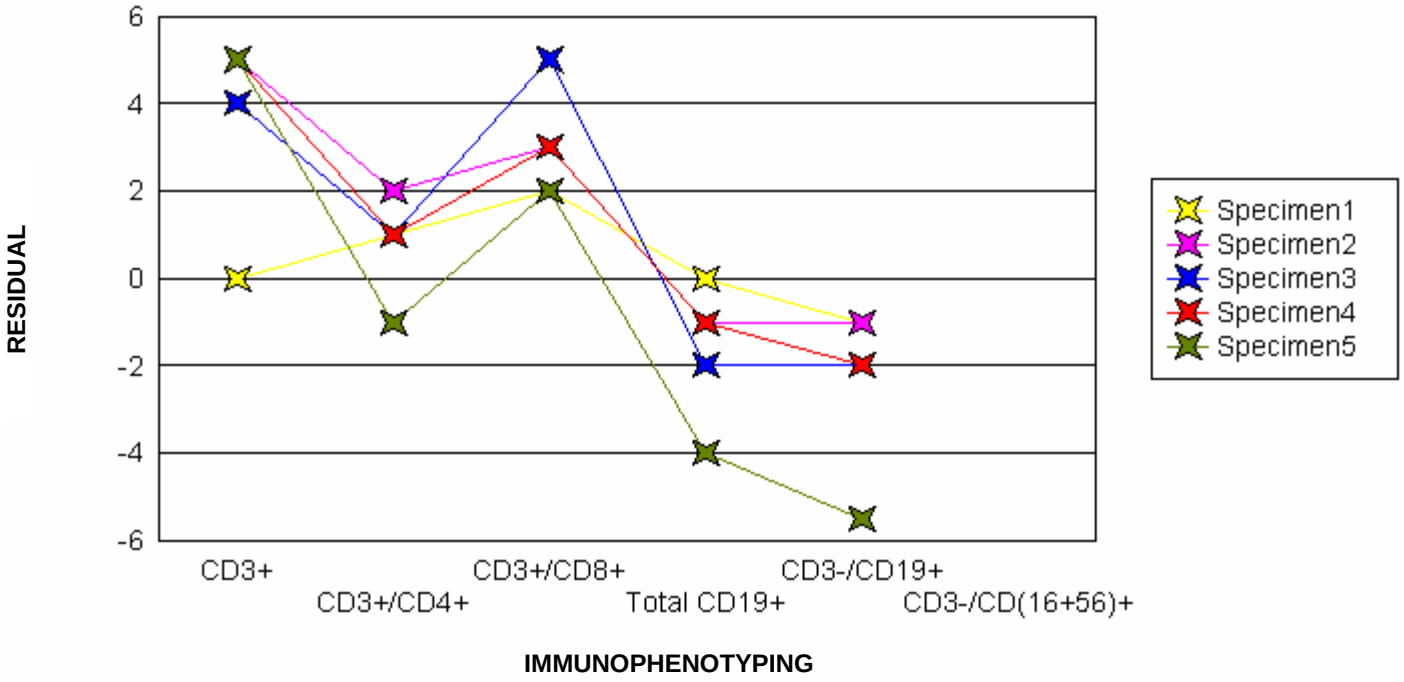
ND - No Data NC - Not Calculated (e.g. div by zero)

NIAID DAIDS QUALITY ASSESSMENT

March 2006

FLOW CYTOMETRIC IMMUNOPHENOTYPING

	Specimen1-Donor	Specimen2-Donor	Specimen3-Donor	Specimen4-Donor	Specimen5-Donor
	060301 - D	060302 - A	060303 - A	060304 - A	060305 - E
CD3+	0.0	5.0	4.0	5.0	5.0
CD3+/CD4+	1.0	2.0	1.0	1.0	-1.0
CD3+/CD8+	2.0	3.0	5.0	3.0	2.0
Total CD19+	0.0	-1.0	-2.0	-1.0	-4.0
CD3-/CD19+	-1.0	-1.0	-2.0	-2.0	-5.5
CD3-/CD(16+56)+	ND	ND	ND	ND	ND



Appendix E

ND - No Data *NC - Not Calculated (e.g. div by zero)*

NIAID DAIDS QUALITY ASSESSMENT

March 2006

HEMATOLOGY AND ABSOLUTE CD4/CD8 COUNTS

HEMATOLOGY ANALYZER : Other

ANALYTE	Specimen-Donor 060301 - D	Specimen-Donor 060302 - A	Specimen-Donor 060303 - A	Specimen-Donor 060304 - A	Specimen-Donor 060305 - E
WBC	4.5	3.0	3.0	3.1	3.4
% Lymphocytes	2,662.0	1,328.0	1,286.0	1,337.0	947.0
Absolute CD4 Count	25,155.9	6,374.4	5,787.0	6,217.1	0.0
Absolute CD8 Count	69,478.2	23,904.0	23,919.6	24,868.2	8,693.5

ND - No Data NC - Not Calculated (e.g. div by zero)

NIAID DAIDS QUALITY ASSESSMENT

March 2006

HEMATOLOGY AND ABSOLUTE CD4/CD8 COUNTS

TRIPLICATE ANALYSIS

ANALYTE		Specimen-Donor 060302 - A	Specimen-Donor 060303 - A	Specimen-Donor 060304 - A		RANGE
WBC		3.0	3.0	3.1		0.1
% Lymphocytes		1,328.0	1,286.0	1,337.0		51.0
Absolute CD4 Count		6,374.4	5,787.0	6,217.1		587.4
Absolute CD8 Count		23,904.0	23,919.6	24,868.2		964.2

Replicate Specimens (from the same donor) are evaluated for a range as a measure of reproducibility. The range is the difference between the highest and lowest reported values on a replicate specimen. There is no definition of failure regarding hematology in the Immunology Quality Assurance Program.

ND - No Data NC - Not Calculated (e.g. div by zero)

NIAID DAIDS QUALITY ASSESSMENT

March 2006

HEMATOLOGY AND ABSOLUTE CD4/CD8 COUNTS

Donor A		**WBC**	**% Lymphocytes**	**Absolute CD4 Count**	**Absolute CD8 Count**
Specimen	**Parameter**				
060302	Group N	39.0	30.0	231.0	231.0
	Reported	3.0	1328.0	6374.4	23904.0
	Upper Quartile	3.0	43.9	763.0	765.5
	Median	3.0	42.0	186.5	577.5
	Lower Quartile	2.9	41.0	151.7	152.8
	IQR	0.1	2.2	458.5	459.6
	Residual	0.0	1286.1	6187.9	23326.5
	Deviate	0.0	586.2	13.5	50.8
060303	Group N	39.0	30.0	231.0	231.0
	Reported	3.0	1286.0	5787.0	23919.6
	Upper Quartile	3.0	43.9	763.0	765.5
	Median	3.0	42.0	186.5	577.5
	Lower Quartile	2.9	41.0	151.7	152.8
	IQR	0.1	2.2	458.5	459.6
	Residual	0.0	1244.1	5600.5	23342.1
	Deviate	0.0	567.1	12.2	50.8
060304	Group N	39.0	30.0	231.0	231.0
	Reported	3.1	1337.0	6217.1	24868.2
	Upper Quartile	3.0	43.9	763.0	765.5
	Median	3.0	42.0	186.5	577.5
	Lower Quartile	2.9	41.0	151.7	152.8
	IQR	0.1	2.2	458.5	459.6
	Residual	0.1	1295.1	6030.6	24290.7
	Deviate	1.2	590.3	13.2	52.9

Donor D		**WBC**	**% Lymphocytes**	**Absolute CD4 Count**	**Absolute CD8 Count**
Specimen	**Parameter**				
060301	Group N	46.0	41.0	110.0	110.0
	Reported	4.5	2662.0	25155.9	69478.2
	Upper Quartile	4.2	56.7	1291.0	1391.4
	Median	4.2	55.4	463.8	1248.0
	Lower Quartile	4.0	53.4	399.0	433.0
	IQR	0.2	2.5	669.0	718.8
	Residual	0.3	2606.6	24692.1	68230.2
	Deviate	1.8	1053.2	36.9	94.9

Donor E		**WBC**	**% Lymphocytes**	**Absolute CD4 Count**	**Absolute CD8 Count**
Specimen	**Parameter**				
060305	Group N	46.0	41.0	109.0	109.0
	Reported	3.4	947.0	0.0	8693.5
	Upper Quartile	3.1	28.9	213.5	238.0
	Median	2.9	27.0	120.0	188.0
	Lower Quartile	2.1	24.0	6.0	138.1
	IQR	0.8	3.7	155.6	74.9
	Residual	0.5	920.0	-120.0	8505.5
	Deviate	0.7	250.3	-0.8	113.5

RESIDUAL = REPORTEDVALUE - MEDIAN
IQR = THREE-QUARTERS OF THE DIFFERENCE BETWEEN THE UPPER AND LOWER QUARTILES
DEVIATE = RESIDUAL / IQR

Appendix E

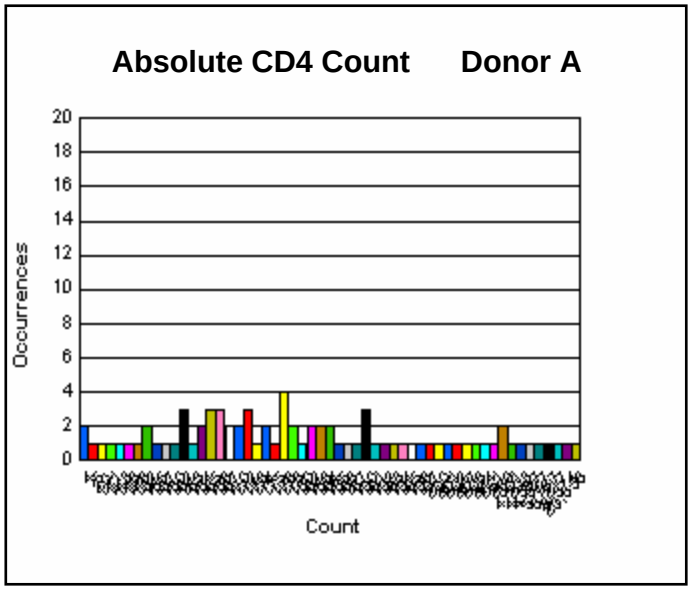
ND - No Data NC - Not Calculated (e.g. div by zero)

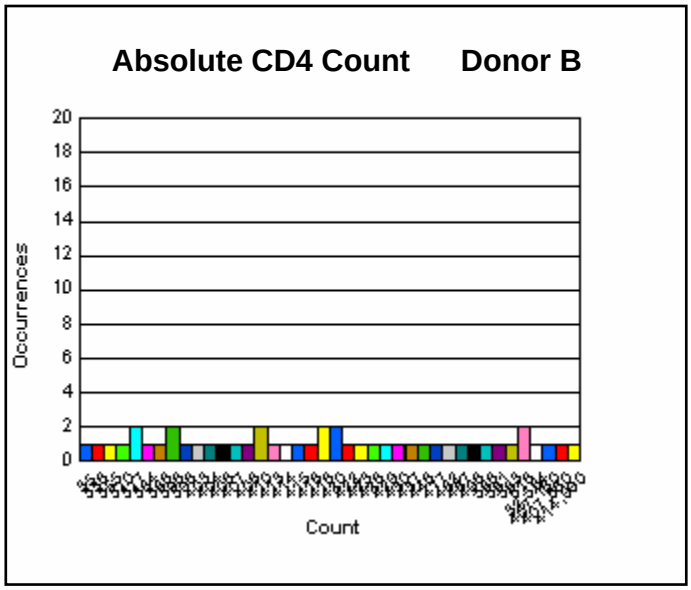
NIAID DAIDS QUALITY ASSESSMENT

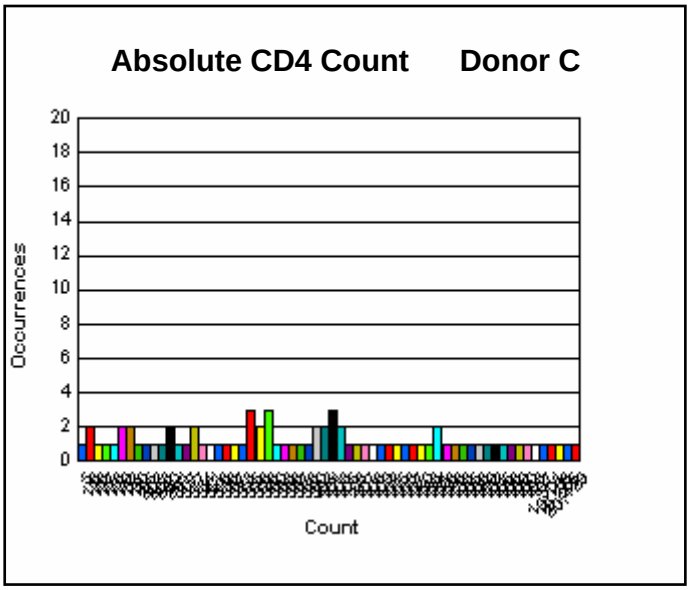
March 2006

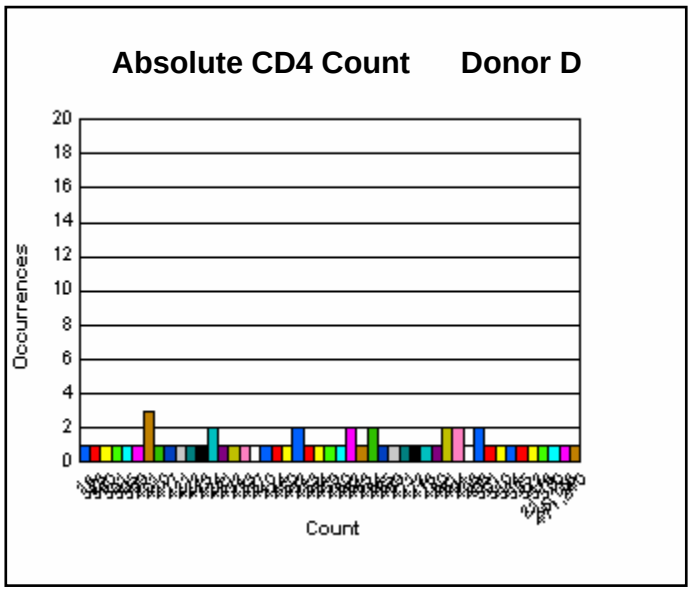
OVERALL DISTRIBUTION OF ALL ABSOLUTE CD4 RESULTS BY DONOR

Specimen1-Donor	Specimen2-Donor	Specimen3-Donor	Specimen4-Donor	Specimen5-Donor
060301 - D	060302 - A	060303 - A	060304 - A	060305 - E









Appendix E

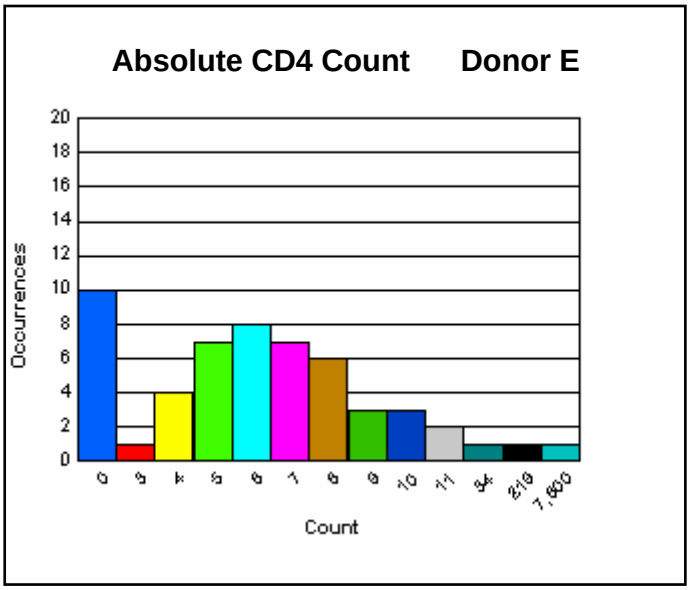
ND - No Data *NC - Not Calculated (e.g. div by zero)*

NIAID DAIDS QUALITY ASSESSMENT

March 2006

OVERALL DISTRIBUTION OF ALL ABSOLUTE CD4 RESULTS BY DONOR

Specimen1-Donor	Specimen2-Donor	Specimen3-Donor	Specimen4-Donor	Specimen5-Donor
060301 - D	060302 - A	060303 - A	060304 - A	060305 - E



Appendix E

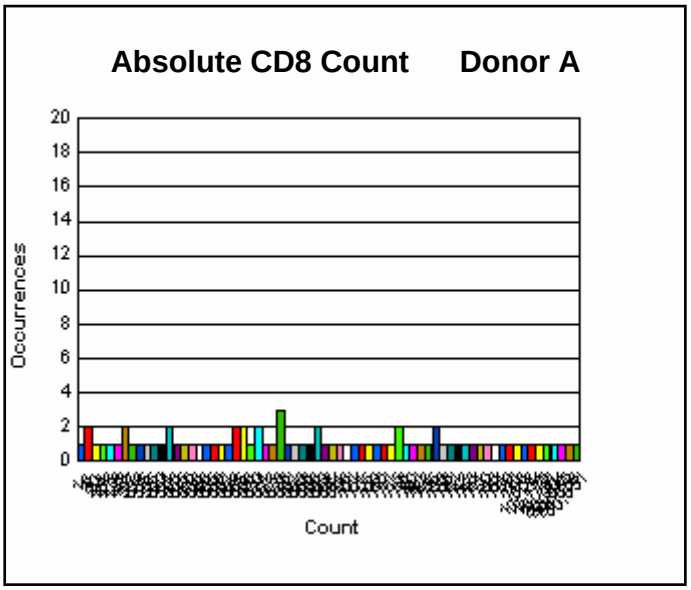
ND - No Data *NC - Not Calculated (e.g. div by zero)*

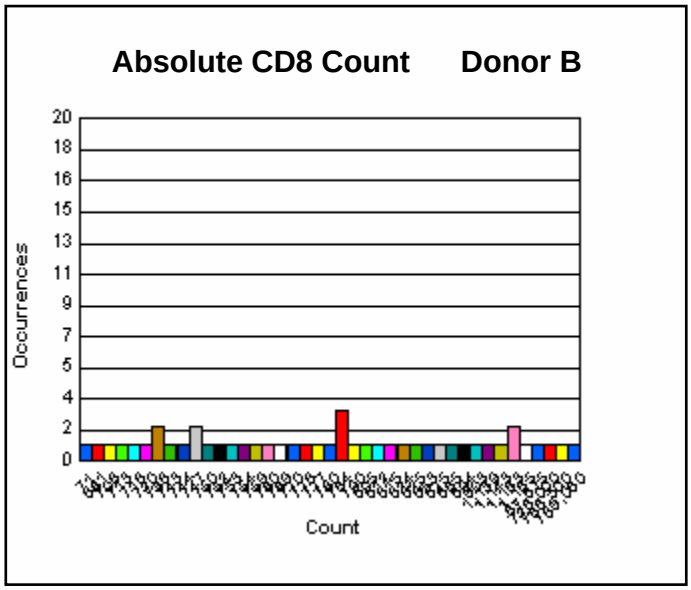
NIAID DAIDS QUALITY ASSESSMENT

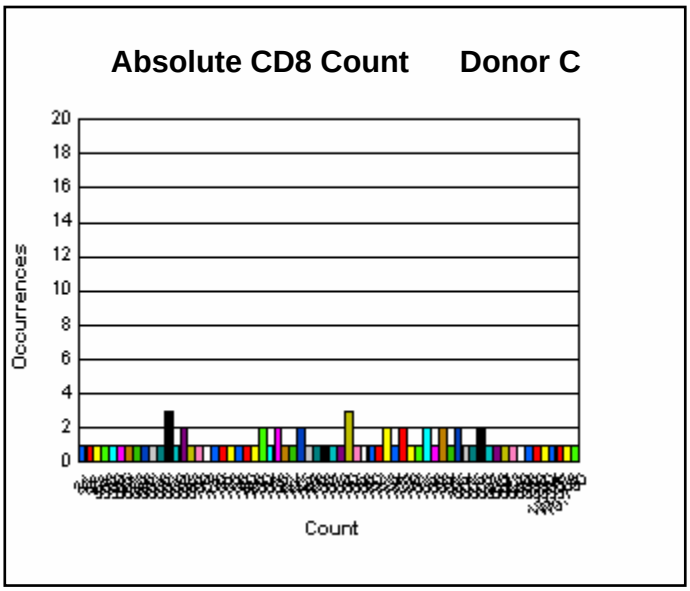
March 2006

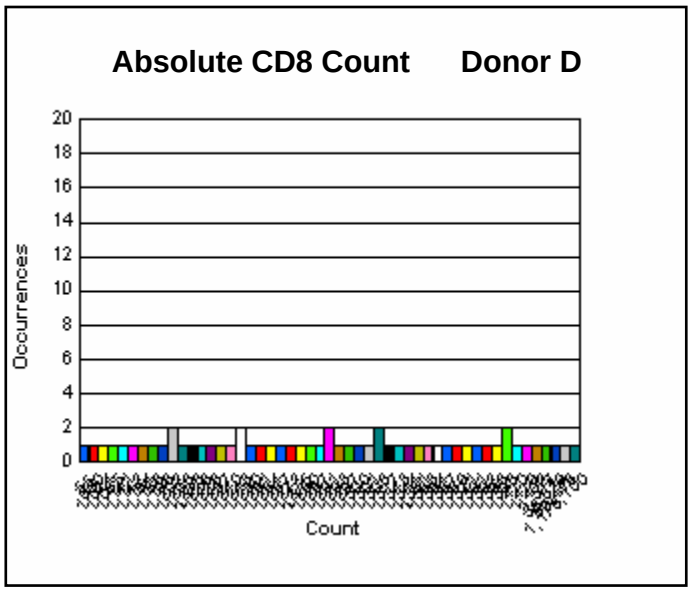
OVERALL DISTRIBUTION OF ALL ABSOLUTE CD8 RESULTS BY DONOR

Specimen1-Donor	Specimen2-Donor	Specimen3-Donor	Specimen4-Donor	Specimen5-Donor
060301 - D	060302 - A	060303 - A	060304 - A	060305 - E









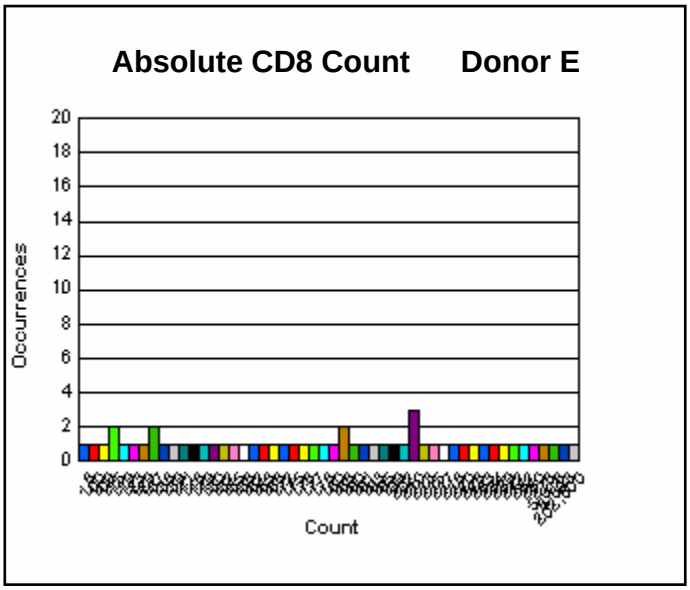
ND - No Data *NC - Not Calculated (e.g. div by zero)*

NIAID DAIDS QUALITY ASSESSMENT

March 2006

OVERALL DISTRIBUTION OF ALL ABSOLUTE CD8 RESULTS BY DONOR

Specimen1-Donor	Specimen2-Donor	Specimen3-Donor	Specimen4-Donor	Specimen5-Donor
060301 - D	060302 - A	060303 - A	060304 - A	060305 - E



IMMUNOLOGY QUALITY ASSESSMENT PROGRAM
APPENDIX F

Site Cryopreservation Proficiency Testing Report

Memorandum

To: ….

From: Immunology Laboratory Steering Committee

Re: Cryopreservation Study Results for …

Date: April 7, 2006

In April of 1999 the Immunology Research Agenda Committee initiated a program to evaluate the ability of all ACTU's that perform cryopreservation for Immunology studies and sub studies to adequately cryopreserve PBMC's. For the March 2006 Cryopreservation Study, samples were received from 37 sites. One to two donors were received from each site at the Immunology Quality Assessment Contract Laboratory at the New Jersey Medical School. One vial was thawed from each donor to test the viability and viable cell recovery. Results were then compared to the information provided by each site. Figure 1. Shows the frequency distribution of viabilities of aliquots received from sites. **The mean and median viability of all aliquots was 90% and 96%. All participating labs should achieve 80% viability and 80% viable cell recovery as established by the Performance Evaluation Guidelines Group.**

Figure 1

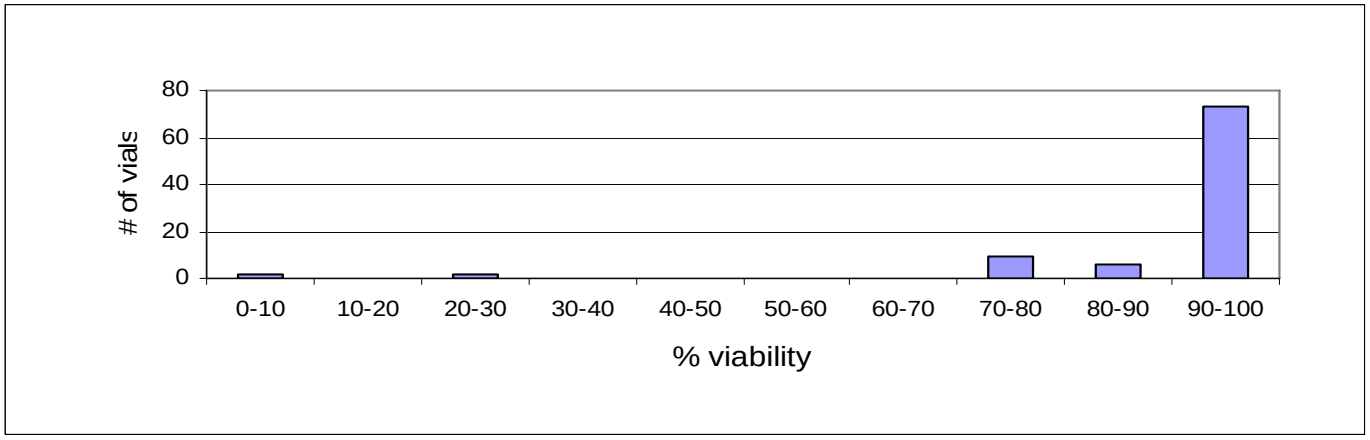
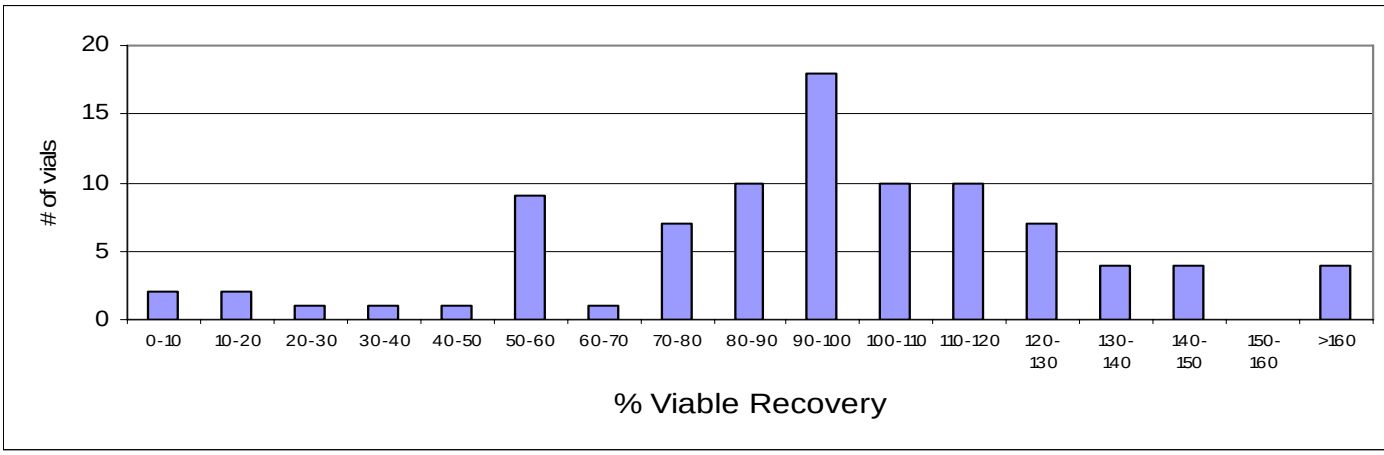


Figure 2, shows the viable cell recovery as a percentage of the number of viable cells indicated to be present in the vial when it was shipped to the IQA. **The mean and median viable recovery of all aliquots was 117% and 98% respectively.**

Figure 2



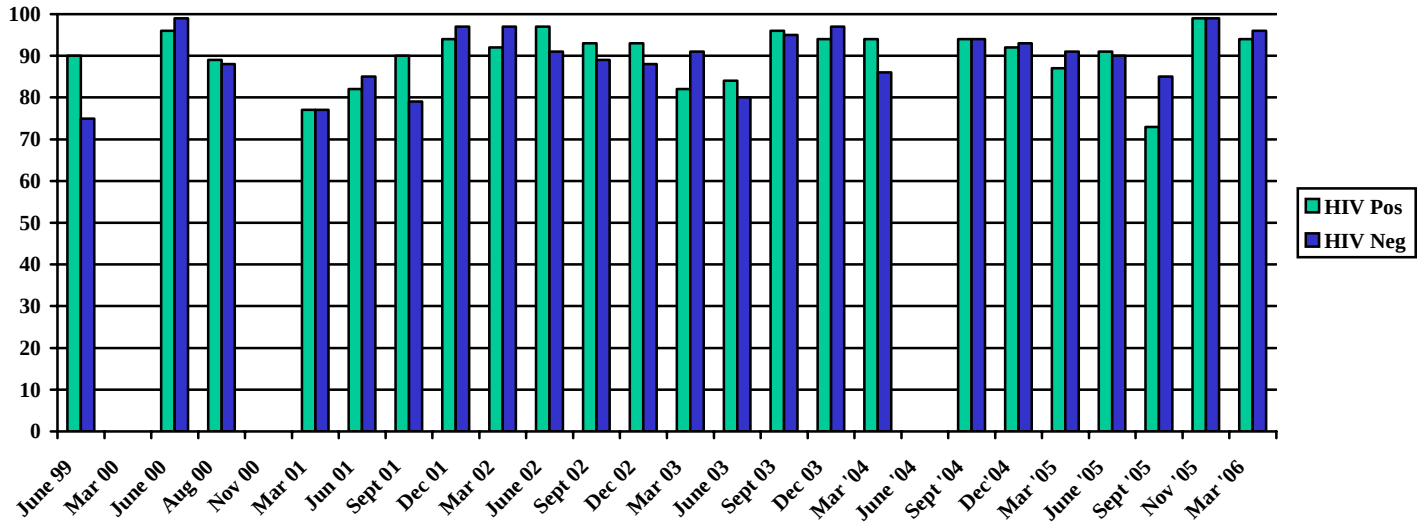
As you can see the viable recovery was quite variable among the sites. The data obtained from the vials sent by your site are shown below in Table 1.

Table 1.

Site	Vial ID	Viability	Viable Recovery
	731	94%	130%
	761	96%	123%

Figure 3, shows your sites cumulative viability results for the quarterly rounds that your site has participated in.

Figure 3.



The next round of submission will take place on June 2006. Sites should initiate IRB review for these quarterly submissions to ensure continuing participation in this program. Detailed instructions are available on the AACTG web site (http://aactg.s-3.com/cryo.htm). It is expected that this ongoing program will result in an overall improvement in the ability of AACTG sites to Cryopreserve PBMC's for future immunologic studies.

The Staff at the IQA lab are available for technical consultation concerning specific laboratory techniques for these procedures, to help you and your laboratory staffs improve and maintain high quality procedures for preparing and storing viable PBMC. You may contact us at (973)-972-1500 or by email at: louzaora@umdnj.edu

Again, thank you for your participation