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

RFP-NIH-NIAID-DAIDS-08-33
"NIAID HIV/AIDS Scientific and Operations Support"

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:** **June 8, 2007**	5. **Small Bus. Set-Aside:** [ ]Yes [X] No
April 20, 2007	**Time:** 4:00 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.**	
Eileen Webster-Cissel Contracting Officer Office of Acquisitions, DEA, NIAID, NIH 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:** **Base Period: 12/1/07 - 11/30/09** Annual Option Periods from 12/1/09 – 11/30/14

13. **Primary Point of Contact:**	14. **Secondary Point of Contact:**	15. **Protest Officer:**
Name: Anita Hughes	**Name: Eileen Webster-Cissel**	**Charles Grewe**
Phone: 301-496-0612	**Phone:** 301-496-0612	Director, Office of Acquisitions, NIAID
Fax: 301-402-0972	**Fax:** 301-402-0972	**Address (see Block 9.)**
E-Mail: **hughesan@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**
Anita Hughes, Contract Specialist Office of Acquisitions DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	Anita Hughes, Contract Specialist Office of Acquisitions DEA, NIAID, NIH 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.

13. DETAILED TABLE OF RFP CONTENTS

PART I - THE SCHEDULE

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 PROPOSED CONTRACT DOCUMENT. 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. HOWEVER, THE ENCLOSED CONTRACT SCHEDULE PROVIDES ALL THE NECESSARY INFORMATION FOR THE OFFEROR 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 provide scientific, technical and operational expertise for NIAID HIV and AIDS research activities, particularly clinical research, conducted through grants and contracts.

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 direct ratio to the level of effort expended; that is, the percent of fee paid shall be equal to the percent of total effort expended. Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract. Payment of fixed fee shall not be made in less than monthly increments.

c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee for the Base Period 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 estimated contract amount represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

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

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 any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

The following Advance Understandings will be included in any resultant contract award:

a. **Non-Personal Services and Inherently Government Functions**

(1) Pursuant to FAR 37.1, no personal services shall be performed under this contract. All work requirements shall flow only from the Project Officer to the Contractor's Project Manager. No Contractor employee will be directly supervised by the Government. All individual employee assignments, and daily work direction, shall be given by the applicable employee supervisor. If the Contractor believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.

(2) Pursuant to FAR 7.5, the Contractor shall not perform any inherently Governmental actions under this contract. No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. In all communications with other Government contractors in connection with this contract, the Contractor employee shall state that they have no authority to in any way change the contract and that if the other contractor believes this communication to be a direction to change their contract, they should notify the Contracting Officer for that contract and not carry out the direction until a clarification has been issued by the Contracting Officer.

(3) The Contractor shall insure that all of its employees working on this contract are informed of the substance of this article. Nothing in this article shall limit the Government's rights in any way under the other provisions of the contract, including those related to the Government's right to inspect and accept the services to be performed under this contract. The substance of this article shall be included in all subcontracts at any tier.

b. **Confidential Treatment of Sensitive Information**

The Contractor shall guarantee strict confidentiality of the information/data that it is provided by the Government during the performance of the contract. The Government has determined that the information/data that the Contractor will be provided during the performance of the contract is of a sensitive nature.

Disclosure of the information/data, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated April 2007, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

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

a. Technical Progress Reports

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

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

- Contract Number and Project Title
- Contractor's Name and Address
- Date of Submission
- Delivery Address
- Reporting Period
- Executive Summary

(1) Monthly Progress Report

The Monthly Progress Report shall include a discussion of the major activities undertaken during the reporting period and the activities planned for the ensuing reporting period. This report shall also list any travel completed during the reporting period and any travel anticipated during the next reporting period. A discussion of major problems encountered during the reporting period and actions taken to address these problems, including actions taken to prevent the problems from re-occurring shall be included. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month. Monthly Progress Reports shall not exceed 20 pages in length.

(2) Annual Progress Report

The Annual Progress Report shall also include a summation of the monthly progress and the activities planned for the ensuing reporting period. Furthermore, a list of any travel completed during the reporting period and any travel anticipated during the next reporting period must be provided. A discussion of major problems encountered during the reporting period and actions taken to address these problems, including actions taken to prevent the problems from re-occurring, shall be included. The Annual Progress Report shall also include details regarding any breaches of the Organizational Conflict of Interest and Non-disclosure/Confidentiality Plan, how they were resolved, and any additional efforts the Contractor shall undertake to prevent any future occurrences. Annual Progress Reports shall not exceed 60 pages in length. An Annual Progress Report will not be required for the period when the Final Report is due. Monthly Progress Reports shall not be required when an Annual Progress Report is due.

(3) Final Report

The Final Report is to include a summation of the work performed and the results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. An Annual Progress Report will not be required for the period when the Final Report is due. There is no page limitation on the Final Report.

(4) Summary of Salient Results

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

b. Other Reports and Deliverables

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

(1) Draft and Final Initial Transition Plan (see Statement of Work (SOW), paragraph 6.A.)

(2) Training Program for Contractor Staff (see SOW, paragraph 5.C.)

(3) Draft and Final Standard Operating Procedures (see SOW, paragraph 5.D.)

(4) IT Systems Security Plan (see SOW, paragraph 5.F.)

(5) Communication Plan (see SOW, paragraph 5.E.)

(6) Draft and Final Standard Operating Procedures for new activities (see SOW, paragraph 5.D.)

(7) Draft and Final Option Plan (see SOW, paragraph 7.A.)

(8) Annual Report on Organizational Conflict of Interest and Non-disclosure/Confidentiality, to be included with Annual Progress Report (see Statement of Work, paragraph 4.B).

(9) Draft and Final - Final Transition Plan (see Statement of Work, paragraph 6.B.)

c. When requested, all reports shall be provided electronically to the Project Officer and Contracting Officer using the email addresses specified at the time of award and using current NIAID-supported file type (Microsoft Word at the time of release of this RFP). Reports shall not be bound nor in color unless necessary to understand any charts or graphics that are included. Reports should be printed on two-sided paper.

d. The address to which reports will be sent are:

Contracting Officer
Office of Acquisitions (OA)
Division of Extramural Activities (DEA)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

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 first annual utilization report shall be due on or before _____. Thereafter, reports shall be due on or before the ___ calendar day following the reporting period. 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 (OA)
Division of Extramural Activities (DEA)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)
6700-B 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 is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at the National Institute of Allergy and Infectious Diseases, NIH, Bethesda, Maryland.

   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 **52.246-5, Inspection of Services - Cost-Reimbursement** (April 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

a. The period of performance of this contract shall be from December 1, 2007 through November 30, 2009.

b. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased as listed below:

Option	Option Period
1	December 1, 2009 through November 30, 2010
2	December 1, 2010 through November 30, 2011
3	December 1, 2011 through November 30, 2012
4	December 1, 2012 through November 30, 2013
5	December 1, 2013 through November 30, 2014

ARTICLE F. 2. DELIVERIES

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

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

Item	Type of Report	Recipients	Delivery Schedule
1.	Monthly Progress Report	1 original hard copy to CO 1 elec. copy to PO and CO	The first report is due on/before January 10, 2008. Thereafter, each report is due on/before the 10th of each month following each reporting period.
2.	Annual Progress Report	1 original hard copy to CO 1 elec. copy to PO and CO	The first report is due on/before December 10, 2008. Thereafter, each report is due on/before the 30th of the month following each annual period. Monthly Progress Reports will not be submitted when the Annual Progress report is due.
3.	Final Report	1 original hard copy to CO 1 elec. copy to PO and CO	The Final Report is due on or before the expiration date of the contract. Monthly, and Annual Progress Reports will not be submitted the month the Final Report is due.
4.	Summary of Salient Results	1 original hard copy to CO 1 elec. copy to PO and CO	The Summary of Salient Results shall be submitted with the Final Report on or before the expiration date of the contract.

b. **Other Reports and Deliverables (b Delivery Schedule)**

Item	Type of Deliverable	SOW Reference	Recipients	Delivery Schedule
1.	Draft and Final Initial Transition Plan	*SOW, paragraph 6.A.*	1 hard copy to CO 1 elec. copy to PO and CO	Draft due within 15 calendar days of the contract effective date. Final due within 30 calendar days of the contract effective date.
2.	Training Program for Contractor Staff	*SOW, paragraph 5.D.*	1 hard copy to PO 1 elec. copy to PO and CO	Within 30 calendar days of the contract effective date.
3.	Draft and Final Standard Operating Procedures (SOPs)	*SOW, paragraph 5.C.*	1 hard copy to PO 1 elec. copy to PO and CO	Draft due within 60 calendar days of the contract effective date. Final due within 10 calendar days of receipt of Project Officer comments.
4.	IT Systems Security Plan	*SOW, paragraph 5.F.*	1 hard copy to CO 1 elec. copy to PO and CO	Within 60 calendar days of the contract effective date
5.	Communication Plan	*SOW, paragraph 5.E.*	1 hard copy to PO 1 elec. copy to PO and CO	Within first 90 calendar days after contract award.
6.	Draft and Final Standard Operating Procedures (SOPs) for new activities	*SOW, paragraph 5.C.*	1 hard copy to PO 1 elec. copy to PO and CO	Draft within 30 calendar days of the receipt of request for new activity. Final due within 10 calendar days of the receipt of comments from the Program Officer.
7.	Draft and Final Option Plan	*SOW, paragraph 7.A.*	To be specified upon notification of the Government's Intent to Exercise the Option	Draft due no later than 15 calendars of Government's notification and Final due no later than 45 days of notification.
8.	Annual Report on Organizational Conflict of Interest and Non-disclosure/Confidentiality	*SOW, paragraph 4.B.*	1 ohard copy to CO 1 elec. copy to PO and CO	This report is to be submitted with the Annual Progress Report (see paragraph a. above).
9.	Draft and Final Transition Plan	*SOW, paragraph 6.B.*	1 hard copy to CO 1 elec. copy to PO and CO	Draft due no later than 90 calendar days prior to contract expiration date and Final due no later than 60 calendar days prior to contract expiration date.

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

Addressee	Deliverable Item No.	Quantity
Contracting Officer Office of Acquisitions (OA) Division of Extramural Activities (DEA) National Institute of Allergy and Infectious Diseases (NIAID) National Institutes of Health (NIH) 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612	See above delivery schedules	See above delivery schedules

d. Unless otherwise specified, deliveries shall be made to the Delivery Point specified above Mondays through Fridays (excluding Federal Holidays) between the hours of 8:30 a.m. and 5:30 p.m. EST only. Supplies or services scheduled for delivery on a Federal holiday shall be made the following day.

ARTICLE F.3. LEVEL OF EFFORT *(See Section L.1., paragraph ---- of this solicitation).*

a. During the period of performance of this contract, the Contractor shall provide _____ direct labor [HOURS, MONTHS, YEARS]. The labor [HOURS, MONTHS, YEARS] [INCLUDE/EXCLUDE] vacation, holiday, and sick leave. These labor [HOURS, MONTHS, YEARS] [INCLUDE/EXCLUDE] subcontractor labor [HOURS, MONTHS, YEARS]. It is estimated that the labor [HOURS, MONTHS, YEARS] are constituted as specified below and will be expended approximately as follows:

	Labor [HOURS, MONTHS, YEARS]						
Labor Category	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**
Professional							
Other Professional							
Support							
Totals							

b. The Contractor shall have satisfied the requirement herein if not less than 90% nor more than110% of the total direct labor hours [months, years] specified herein are furnished.

c. In the event fewer [hours, months, years] than the minimum specified number of direct labor [hours, months, years] in the total categories are used by the Contractor in accomplishing the prescribed work and the Government has not invoked its rights under FAR Clause 52.249-6, TERMINATION (Cost-Reimbursement) incorporated in this contract, these parties agree that the fee will be adjusted based solely upon the quantity of [hours, months, years] by which the number of direct labor [hours, months, years] furnished is less than the number of direct labor [hours, months, years] specified in this ARTICLE. The resulting adjustment shall be evidenced by a contract modification.

ARTICLE F.4. 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.arnet.gov/far/

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with Alternate I (April 1984).
52.247-35, F.o.b. Destination Within Consignees Premises (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. 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 Section I of 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

a. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts NIH(RC)-1 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.

(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 (OA)
Division of Extramural Activities (DEA)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)
6700-B 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.

ARTICLE G.4. INDIRECT COST RATES

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

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

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

ARTICLE G.5. GOVERNMENT PROPERTY

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

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

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

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

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

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address: http://oamp.od.nih.gov/OD/CPS/cps.asp

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor will be

required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

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

ARTICLE H.2. 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.3. 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.4. 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.5. OMB CLEARANCE

In accordance with HHSAR 352.270-7, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Project Officer and the Contracting Officer has issued written approval to proceed.

ARTICLE H.6. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to clause 52.217-7 and 52.217-9 set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost plus fixed fee of the contract will be increased as set forth in the ESTIMATED COST PLUS FIXED FEE Article in SECTION B of this contract.

ARTICLE H.7. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

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

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

b. Subcontracting Reports

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

(1) Individual Subcontract Reports (ISR)

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

April 30th
October 30th

(2) Summary Subcontract Report (SSR)

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

October 30th

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

[e-mail address of Contracting Officer/Specialist will be provided upon award]

ARTICLE H.8. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to the P.L.(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown or the applicable Executive Level for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead and general and

administrative expenses (also referred to as “indirect costs” or “facilities and administrative (F&A) costs”). Direct salary has the same meaning as the term “institutional base salary.” An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The per year salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

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

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

[*Applicable information to be included at award]

ARTICLE H.9. INFORMATION SECURITY

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

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

a. Information Type

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

b. Security Categories and Levels

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

c. Position Sensitivity Designations

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

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

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

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

(2) The contractor shall submit a roster, by name, position 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/

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 the 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/nistpubs/ - 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* (). The details contained in the contractor's ISSP shall be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels of this Article.

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

ARTICLE H.10. ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS

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

ARTICLE H.11. ACCESS TO NATIONAL INSTITUTES OF HEALTH (NIH) ELECTRONIC MAIL

All Contractor staff that have access to and use of NIH electronic mail (e-mail) must identify themselves as contractors on all outgoing e-mail messages, including those that are sent in reply or are forwarded to another user. To best comply with this requirement, the contractor staff shall set up an e-mail signature ("AutoSignature") or an electronic business card ("V-card") on each contractor employee's computer system and/or Personal Digital Assistant (PDA) that will automatically display "Contractor" in the signature area of all e-mails sent.

ARTICLE H.12. PUBLICATION AND PUBLICITY

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

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

ARTICLE H.13. PRESS RELEASES

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

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

[applicable information to be included at award]

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

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS** (**1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

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

ARTICLE H.15. 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]

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

General Clauses for a Cost-Reimbursement Research and Development Contract

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

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

It is expected that the following substitution(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 (September 2006) is added.

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

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

(1) FAR Clause 52.204-9, Personal Identity Verification of Contractor Personnel (November 2006).

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

(3) FAR Clause 52.217-7, Option for Increased Quantity - Separately Priced Line Item (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] ...."

(4) FAR Clause 52.217-9, Option to Extend the Term of the Contract (March 2000).

"(a) The Government may extend the term of this contract by written notice to the Contractor within [INSERT THE PERIOD OF TIME WITHIN WHICH THE CONTRACTING OFFICER MAY EXERCISE THE OPTION]; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least __ days [60 days unless a different number of days is inserted] before the contract expires. The preliminary notice does not commit the Government to an extension."

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed __ [MONTHS/YEARS]."

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

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

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

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

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

(9) 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

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

(12) FAR Clause 52.227-17, Rights in Data--Special Works (June 1987).

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

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

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

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

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

(18) FAR Clause 52.247-63, Preference for U.S. Flag Air Carriers (June 2003).

(19) FAR Clause 52.251-1, Government Supply Sources (April 1984).

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

(1) HHSAR Clause 352.224-70, Confidentiality of Information (March 2005).

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

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

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

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

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

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

This contract incorporates the following clauses in full text.

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

a. FAR Clause 52.222-39, 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 provided as either attachments to this RFP or can be accessed through the weblinks provided below:

ATTACHMENTS TO THIS SOLICITATION: (The following documents are incorporated into this RFP)

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	See Attachment Section at the end of this RFP
Attachment 3:	Statement of Work	See Attachment Section at the end of this RFP
Attachment 4:	Division of AIDS – Enterprise System	See Attachment Section at the end of this RFP
Attachment 5:	Overview of Selected DAIDS Support Contracts	See Attachment Section at the end of this RFP
Attachment 6:	Division of AIDS Clinical Trial Portfolio – Information Summary	See Attachment Section at the end of this RFP
Attachment 7:	Additional Technical Proposal Instructions	See Attachment Section at the end of this RFP
Attachment 8:	Additional Business Proposal Instructions	See Attachment Section at the end of this RFP
Attachment 9:	Information Technology Systems Security - Prospective Offeror Non-Disclosure Agreement	http://rcb.cancer.gov/rcb-internet/forms/IT-security-nondisclosure.pdf

DOCUMENTS TO BE ATTACHED TO THE TECHNICAL PROPOSAL: (The following attachments must be completed, where applicable, and submitted with the Technical Proposal. They can be found at the electronic weblinks provided below and are, therefore not included as Attachments to this RFP.)

Title	Location
Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms.htm
Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf

DOCUMENTS TO BE ATTACHED TO THE BUSINESS PROPOSAL: (The following attachments must be completed, where applicable, and submitted with the Business Proposal. They can be found at the electronic weblinks provided below and are, therefore not included as Attachments to this RFP.)

Title	Location
Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm

Small Business Subcontracting Plan	http://rcb.cancer.gov/rcb-internet/forms/SBA_Plan.pdf
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
Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sf-lll.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. They can be found at the electronic weblinks provided below and are, therefore not included as Attachments to this RFP.)

Title	**Location**
Invoice/Financing Request Instructions--Cost-Reimbursement, NIH(RC)-1	http://rcb.cancer.gov/rcb-internet/forms/rc1.pdf
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
Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms.htm
Commitment To Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

1. Go to the Online Representations and Certifications Application (ORCA) at: http://ais.nci.nih.gov/forms/Suitability-roster.xls and complete the Representations and Certifications; and

2. Complete, and include as part of your BUSINESS PROPOSAL, SECTION K which can be accessed electronically from the INTERNET at the following address:
   http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

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

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

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

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

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

initial proposal should contain the offeror's best terms from a price and technical standpoint.

c. Cost/Pricing Information. The offeror's business proposal shall include the basic cost/pricing information specified in Section L.2.c.(1) of this RFP. In addition, the Government may require offerors included in the competitive range to submit additional information substantiating their proposed costs or prices. This additional cost/pricing information will be requested after establishment of the competitive range, and potentially includes payroll documentation, vendor quotes, invoice prices, and/or any other information deemed necessary by the contracting officer to evaluate the reasonableness of the price or to determine cost realism. [The information may also include submission and certification of cost or pricing data.]

d. **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 System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

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

It is anticipated that one award will be made from this solicitation and that the award will be made on/about December 1, 2007.

It is anticipated that the award from this solicitation will be a multiple-year cost reimbursement type, level of effort contract with a term of base period of 2 years and options to extend the contract for an additional 5 years for a total period of performance not to exceed 7 years. Incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

f. **LEVEL OF EFFORT**

The Government's requirement for the work set forth in the Statement of Work of this solicitation is 77 full time equivalents (FTE). It is estimated that the FTE are constituted as specified below and will be expended approximately as follows:

Labor Category	FTE/YEAR
Project Director	20%
Project Manager	100%
Other Professional Support	
Bio-ethicist	100%
Clinical Program Manager	100%
Clinical Study Manager	100%
Formulation Chemist	100%
Health Policy Specialist	180%
Health Specialist	400%
Lab Management Specialist	100%
Laboratory Oversight Manager	100%
Laboratory Program Specialist	100%
Medical Officer	300%

Nurse Consultant	200%
Pharmacist	200%
Policy Development Officer	200%
Program Analyst	700%
Program Manager	700%
Program Specialist	500%
Project Manager	100%
Program Support Specialist	200%
Regulatory Affairs Coordinator	200%
Regulatory Affairs Specialist	600%
Science Analyst	200%
Scientific Program Manager	100%
Scientific Program Support Spec.	200%
Scientific Writer	200%
Senior Administrative Program Spec.	100%
Senior Clinical Study Manager	100%
Senior Communications Specialist	100%
Senior Health Communications Spec.	200%
Senior Regulatory Affairs Specialist	200%
Senior Data Manager	100%
Senior Health Policy Expert	100%
Senior Laboratory Manager	100%
Senior Policy Analyst	100%
Senior Program Manager	100%
Task Leader	200%
Technical Projects Coordinator	100%
Technical Writer-Editor	200%

g. **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.

h. **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.

i. **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.

j. **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/approximately equal to cost or price/significantly less important than cost or price]. The relative importance of the evaluation factors is 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.

k. **CONCEPT REVIEW**

This project has not been reviewed by the Board of Scientific Counselors as required. Such review will occur prior to technical evaluation. Thus potential offerors are cautioned that cancellation of this RFP due to disapproval by the Board of Scientific Counselors is a possibility.

l. **PREPARATION COSTS**

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

m. **SERVICE OF PROTEST** (SEPTEMBER 2006) - FAR 52.233-2

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

Charles Grewe
Director, Office of Acquisitions
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases, NIH
6700B Rockledge Drive, Room 3412, 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.

(End of Provision)

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

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

(End of Provision)

2. INSTRUCTIONS TO OFFERORS

a. **GENERAL INSTRUCTIONS**

INTRODUCTION

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

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

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

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

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper 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 procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

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

Hard Metric - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).
Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.
Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

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

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

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

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

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

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

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

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

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.

- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(10) **Selection of Offerors**

a) The acceptability of the technical portion of each contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d) If the Government intends to conduct discussions prior to awarding a contract-

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

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

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

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

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

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

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

EACH INSTITUTION MUST:

(a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

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

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

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

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

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

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

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

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

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

4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the**

designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

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

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

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

(12) **Past Performance Information**

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

A list of the last five contracts completed during the past three years and the last three contracts awarded, currently being performed, that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as any subcontract over $650,000.

Include the following information for each contract or subcontract listed:

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

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

b) The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

(13) Electronic and Information Technology Accessibility

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

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

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

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

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

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).
b) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).
c) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
d) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).
e) Identification of Uncompensated Overtime, FAR Clause 52.237-10, (October 1997).

b. **TECHNICAL PROPOSAL INSTRUCTIONS**

NOTE: Offerors are also advised to also refer to the information included in Attachment 7, "Additional Technical Proposal Instructions" when preparing their Technical Proposal.

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 SECTION M - Evaluation Factors for Award of this solicitation.

(3) **Additional Technical Proposal Information**

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

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

(4) **Other Considerations**

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

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

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

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

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

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

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

Notice to Offerors of Requirements of: 42 CFR Part 73, Possession, Use, and Transfer of Select Agents and Toxins (relating to public health and safety):
(www.cdc.gov/od/sap/**42_cfr_73_**final_rule.pdf);
7 CFR Part 331, Possession, Use, and Transfer of Select Agents and Toxins (relating to plant health or plant products) (www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf); and,
9 CFR Part 121, Possession, Use, and Transfer of Select Agents and Toxins (relating to human and animal health, animal health or animal products)
(www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) - March 18, 2005.
These regulations implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and the Agricultural Bioterrorism Protection Act of 2002. They are designed to improve the ability of the United States Government to prevent, prepare for, and respond to bioterrorism and other public health emergencies. These regulations establish requirements regarding registration, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections, and notifications.

Listings of HHS select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at http://www.cdc.gov/od/sap/ and http://www.cdc.gov/od/sap/docs/salist.pdf . Listings of USDA select agents and toxins as well as information about the registration process for domestic institutions are available on the APHIS/USDA website at http://www.aphis.usda.gov/programs/ag_selectagent/index.html and http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_forms.html . For foreign institutions, see the NIAID Select Agent Award information (http://www.niaid.nih.gov/ncn/clinical/default_biodefense.htm).

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

Domestic Institutions

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

- include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.

- comply with 42 CFR part 73, 7 CFR part 331 and/or 9 CFR part 121 at:
  www.cdc.gov/od/sap/**42_cfr_73**_final_rule.pdf and
  www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf,
  as required, before using NIH funds for research involving Select Agents. No NIH funds can be used for research involving Select Agents if the final registration certificate is denied.

Foreign Institutions

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

- include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.

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

An NIAID-chaired committee of U.S. federal employees (including representatives of NIH grants/contracts and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will ultimately assess the results of the facility inspection, the regulations, policies, and procedures of the foreign institution for equivalence to the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at:
www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf
The committee will provide recommendations to the DEA Director, NIAID. The DEA Director will make the approval decision and notify the Contracting Officer. The Contracting Officer will inform the prime contractor of the approval status of the foreign institution. No NIH funds can be used for research involving Select Agents at a foreign institution until NIAID grants this approval.

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

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

The Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor (including subcontractor), or other source. The National Institute of Standards and

Technology (NIST) has issued a number of publications that provide guidance in the establishment of minimum security controls for management, operational and technical safeguards needed to protect the confidentiality, integrity and availability of a Federal information system and its information.

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

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

(a) Information Type

[X] Administrative, Management and Support Information:

[ ] Mission Based Information:

(b) Security Categories and Levels

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

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

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

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

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

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

(d) Information Security Training

HHS policy requires contractors/subcontractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements. The successful offeror will be responsible for assuring that each contractor/subcontractor employee has completed the NIH Computer Security Awareness Training course at: [insert link for course] prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract. The successful offeror shall maintain a listing of all individuals who have completed this training and shall submit this listing to the Project Officer.

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

(e) Offeror's Official Responsible for Information Security

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

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

The offeror must include in the "Information Security" part of its Technical Proposal, a completed Self-Assessment Questionnaire required by NIST Draft SP 800-26, Revision 1, Guide for Information Security Program Assessments and System Reporting Form at: (http://csrc.nist.gov/publications/nistpubs/800-26/sp800-26.pdf, See Appendix B for submission format.) NIST 800-26 assesses information security assurance of the offeror's internal systems security. This assessment is based on the Federal IT Security Assessment Framework and Draft NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems, at: (http://csrc.nist.gov/publications/nistpubs/800-53/SP800-53.pdf).

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

(g) Draft Information System Security Plan

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

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

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

(h) References

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

The following NIST publications may be found at the following site: http://csrc.nist.gov/publications/
[Note: The search tool on the left side of this page provides easy access to the documents.]

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

c. **BUSINESS PROPOSAL INSTRUCTIONS**

NOTE: Offerors are also advised to also refer to the information included in Attachment 8, "Additional Business Proposal Instructions and Uniform Budget Assumptions" when preparing their Business Proposal.

1) **Basic Cost/Price Information**

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

2) **Proposal Cover Sheet**

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

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

This cover sheet information is for use by offerors to submit information to the Government when cost or pricing data are not required but information to help establish price reasonableness or cost realism is

necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

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

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

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

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

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

1. **Direct Labor**

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

2. **Materials**

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

3. **Subcontracted Items**

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

4. **Raw Materials**

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

5. **Purchased Parts**

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

6. **Fringe Benefits**

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

7. **Indirect Costs**

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

8. **Special Equipment**

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

9. **Travel**

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

10. **Other Costs**

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

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

(a) Exceptions from cost or pricing data.

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

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

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

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

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

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

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

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

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

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

(End of provision)

5) **Salary Rate Limitation in Fiscal Year 2007**

Offerors are advised that pursuant to P.L. ******, no NIH Fiscal Year 2006 (October 1, 2006 - September 30, 2007) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. ****** applies only to Fiscal Year 2007 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. ****** states in pertinent part:

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

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

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

**********Pending Passage of Legislation.*

6) **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $550,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the

clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

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

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

c) The offeror understands that:

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

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

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

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

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

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

d) Each plan must contain the following:

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

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

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

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

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

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

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

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

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $550,000 adopt a plan similar to the plan agreed upon by the offeror.

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

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

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

7) **HUBZone Small Business Concerns**

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

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

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $550,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

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

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

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

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

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

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

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

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

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

9) **Total Compensation Plan**

a) **Instructions**

1) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors will submit, as a part of their business proposal, a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

2) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

3) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

b) **Evaluation**

1) **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

2) **Cost (Professional Compensation)**

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

3) **Other (Labor Relations)**

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

4) **Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

(10) Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a) **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b) **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c) **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

(11) 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, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

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

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

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

c) **Financial Capacity**

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

d) **Incremental Funding**

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

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.

(End of provision)

e) **Facilities Capital Cost of Money**, FAR 52.215-16, (June 2003)
(This is applicable if you are a commercial organization.)

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

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

(End of Provision)

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

[ ] The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(12) 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

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

(14) Representations and Certifications - SECTION K

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

(15) Travel Costs/Travel Policy

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

b) **Travel Policy**
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.

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

SECTION M - EVALUATION FACTORS FOR AWARD

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. In any case, the Government intends to make an award to that offeror whose proposal provides the best overall value to the Government.

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

B. EVALUATION OF OPTIONS

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

C. 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. The information under each evaluation criteria is of equal importance.

OFFERORS AND REVIEWERS ARE ADVISED TO REFER TO - Additional Technical Proposal Instructions – Attachment 7 - OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATION RELATED TO THE PREPARATION OF TECHNICAL PROPOSALS.

TECHNICAL EVALUATION CRITERIA:	WEIGHT
1. TECHNICAL APPROACH AND PROJECT MANAGEMENT	30 Points

a) Adequacy of the offeror’s understanding of the statement of work and the purpose of the contract to perform Clinical Research Support, Program Operations Support, and Communications Support.

b) Suitability, adequacy and feasibility of the methods and approaches to accomplish the elements for the statement of work with respect to Clinical Research Support, Program Operations Support, and Communications Support, including plans for tracking and monitoring of projects; quality control; budget control; compliance with deadlines; managing concurrent activities and staffing adjustments required to meet changing needs over the course of the award.

c) Suitability, adequacy and feasibility of the staffing strategy proposed for Clinical Research Support, Program Operations Support, and Communications Support.

d) Suitability, adequacy and feasibility of the proposed staffing matrix including assignment of tasks to various positions. Adequacy, suitability, and feasibility of plans to maintain a stable, experienced staff that will provide continuity of personnel who are experienced and knowledgeable about NIAID extramural programs, clinical trials requirements and international HIV/AIDS research efforts.

e) Adequacy, suitability, and feasibility of plans to identify, recruit and hire well qualified staff to work in diverse under-resourced countries. Adequacy, suitability, and feasibility of recruitment plan to ensure quick "ramp up" of staff upon initiation of the contract and at the time options are exercised.

f) Suitability, adequacy, clarity and feasibility of organizational roles and responsibilities including consultants and subcontractors. This includes lines of authority, reporting, and processes for making and monitoring work assignments.

g) Suitability, adequacy and flexibility of the plan to address the unique and complimentary needs of the various components within NIAID and to manage staff whose duties may cross NIAID organizational lines. Demonstrated ability to establish and manage an organizational structure necessary to carry out the support functions to be performed under this contract, including standard operating procedures, staff training, and communications.

h) Demonstrated ability relevant to the statement of work to implement Initial and Final Transitions of the contract as specified by the statement of work.

2. QUALIFCATIONS AND AVAILABLILITY OF PERSONNEL 30 Points

Suitability and adequacy of the qualifications, experience, training and availability of staff to accomplish tasks of similar scope and complexity.

a) Scientific and Technical Leadership. Suitability, adequacy, and ability of the staff proposed to: a)provide oversight/supervision to staff in scientific, clinical, and regulatory areas; b) effectively communicate the work requirements to staff assigned to the contract as well as to corporate headquarters; c) provide professional, technical and managerial skill to oversee and manage a project of comparable size and complexity; and d) understand and follow applicable regulations (e.g., international clinical trials, Food and Drug Administration requirements, conflict of interest, confidentiality and non-disclosure, etc.).

b) Administrative and Management Leadership. Suitability, adequacy, and ability of the staff proposed to provide operational management of the project and to serve as the lead administrative point of contact. Suitability, adequacy, and ability of the offeror to effectively implement, coordinate and maintain the proposed staffing strategy to meet the requirements of the contract. Suitability, adequacy, and ability to effectively implement, coordinate and maintain resources to meet the requirements of the contract.

c) Other Scientific and Technical Personnel. Suitability, appropriateness and adequacy of all other proposed scientific and technical personnel from the prime contractor and all proposed subcontractors, including the suitability, adequacy, and appropriateness of the proposed mix of staff, expertise, experience, and training, to carry out all of the requirements of the contract.

3. CORPORATE RESOURCES 15 Points

a) Adequacy and suitability of the demonstrated relevant corporate experience in providing support covering the full range of activities requested in the statement of work, including experience working with federal agencies and knowledge of extramural grant and contract programs.

b) Suitability, availability and adequacy of physical space and equipment needed to support the contract to allow for sufficient communication with contractor and federal staff domestically, while on travel or at remote sites. Suitability and adequacy of plans to ensure effective communication during non-standard work hours, during emergencies, and between staff on this contract and the corporate offices. Suitability and feasibility of plans to accommodate NIAID's need for easy and rapid access to staff with short notice for urgent situations. Suitability and adequacy of the plan for establishment of close physical proximity of the Contractor's main or satellite office. Ability to execute this plan in an efficient and timely manner.

4. ORGANIZATIONAL CONFLICT OF INTEREST MITIGATION and NONDISCLOSURE PLAN — 15 Points

   a) Suitability, adequacy, and feasibility of the plans to anticipate, identify, analyze and mitigate potential conflicts of interest at the individual and institutional level, including the involvement of third party organizations since this contract supports the management of extramural programs.

   b) Suitability, adequacy, and feasibility of the plans to anticipate, identify, analyze and mitigate or prevent inappropriate disclosure of proprietary, privileged, or confidential information, to include consideration of clinical settings as well as other situations relevant to the scope of work.

5. OPTIONS — 10 Points

   a) Suitability, adequacy, and feasibility of the plans to rapidly expand the staff in increments of ten (10) additional FTEs, if requested.

   b) Suitability, adequacy, and feasibility of the plans to increase the performance period if requested.

   c) Demonstrated capabilities to provide project management, facilities, equipment and other resources to implement any options.

TOTAL POSSIBLE SCORE: 100 Points

D. PAST PERFORMANCE FACTOR

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

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

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

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

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

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

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

E. 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

ATTACHMENT 1
PACKAGING AND DELIVERY OF THE PROPOSAL

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

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

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:
"RFP NO. NIH-NIAID-DAIDS-08-33
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**
Anita Hughes Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20817	Anita Hughes Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612

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

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

C. NUMBER OF COPIES:

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

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

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

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

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

CREATING AND NAMING ELECTRONIC FILES:

1. A separate CD should be submitted for the Technical Proposal and Business Proposal information.

Offerors who submit both Technical and Business Proposals on the same CD will be required to resubmit them on separate CDs.

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

Note: We would prefer that multiple files not be submitted. However, if multiple files are submitted for either proposal, please include the name of the section in the file name.

EXAMPLE: XYX Company-08-33-Technical-Approach-6-16-07

3. CDs should be named using the following format:

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

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

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

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

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

ATTACHMENT 2
PROPOSAL INTENT RESPONSE SHEET
RFP No.: NIH-NIAID-DAIDS-08-33
RFP Title: NIAID HIV/AIDS Scientific and Operations Support

Please review the attached Request for Proposal. Furnish the information requested below and return this Proposal Intent Response Sheet by mail, FAX or email to Anita Hughes by **May 15, 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 FOR NOT SUBMITTING:

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

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

Names of Other Key Personnel:
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:
Anita Hughes, Contract Specialist
OA, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612
RFP-NIH-NIAID-DAIDS-08-33
FAX# (301) 402-0972
Email: hughesan@niaid.nih.gov

ATTACHMENT 3
STATEMENT OF WORK
NIAID HIV/AIDS Scientific and Operations Support
RFP NIH-NIAID-DAIDS-08-33

BACKGROUND and INTRODUCTION

The AIDS pandemic is growing worldwide at an alarming rate and has disproportionately affected the health, economic development, and political stability of many of the world's poorest and most vulnerable populations. To combat this global threat and to prevent the spread of HIV infection, the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Department of Health and Human Services (DHHS), supports biomedical research to increase basic knowledge of the pathogenesis, natural history, and transmission of HIV disease and to evaluate new and improved approaches for the detection, treatment, and prevention of HIV infection and its complications. NIAID 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. The significant majority of these activities are housed in the NIAID Division of AIDS (DAIDS) with limited support provided to other organizational components of NIAID. The NIAID HIV/AIDS programs must be built with flexibility and must coordinate across the Institute and with other organizations in order to permit rapid, efficient and scalable response to emerging scientific and clinical opportunities. The recent competition of the Leadership for HIV/AIDS Clinical Trials Networks (RFA-AI-05-001, http://grants.nih.gov/grants/guide/rfa-files/**RFA-AI-05-001**.html) and the Units for HIV/AIDS Clinical Trials Networks (RFA AI-05-002, http://grants.nih.gov/grants/guide/rfa-files/RFA-AI-05-002.html) exhibits the goal of supporting a flexible and dynamic infrastructure for HIV/AIDS research that is continued in this contract.

There is currently an Interagency Agreement between the NIAID/DAIDS and the U.S. Army Medical Research and Material Command (USAMRMC) that allows for cooperation and sharing of resources to accomplish their respective missions with regard to HIV AIDS. In turn, the USAMRMC oversees a cooperative agreement with the Henry M. Jackson Foundation for Military Medicine (HJF), a Congressionally chartered non-profit foundation that includes activities associated with providing scientific and operations support to DAIDS. Some of these activities will be supported through this contract.

SCOPE

The purpose of this contract is to provide scientific, technical and operational expertise for NIAID HIV and AIDS research and particularly clinical research activities that are conducted as part of grant and contract awards. This contract is intended to augment the capacity of services provided by existing research support contracts and provide needed flexibility and scalability. This contract will also involve daily interaction between Contractor and NIAID federal staff for time sensitive activities that require continuity, a high degree of collaborative problem solving and time sensitive decision making. The Contractor shall provide support for NIAID clinical research activities, program operations, communications, conflict of interest mitigation, non-disclosure and confidentiality issues, project management, and initial and final contract transitions. Options are included to increase the performance period and/or the level of effort.

In carrying out this contract, Contractor staff shall not make decisions on behalf of the Federal Government, and shall not exercise any federal approval authority with respect to the research activities and responsibilities of NIAID grantees and contractors. All written and oral communications intended to convey official decisions or to provide direction and oversight to NIAID grantees and contractors are solely the responsibility of NIAID staff.

In addition, all Contractor staff shall be required to sign a non-disclosure agreement to meet NIH standards for protecting confidentiality of information and conflict of interest regarding: 1) Government information that NIAID provides to the Contractor, 2) all proprietary information that NIAID receives from third parties and provides to the Contractor in order to perform under the contract, and 3) all proprietary information that the Contractor receives from third parties in order to perform under the contract. Contractor staff shall be required to handle proprietary information in the strictest confidence and shall be bound by the terms of an Organizational Conflict of Interest and Non-disclosure/Confidentiality Plan.

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.

Contractor staff shall be available to attend meetings with Government staff at NIAID facilities within short notice. Close proximity is needed because DAIDS operates in an ever-changing, high paced, highly regulated environment which often requires immediate consultation with key individuals on issues such as human subject protection, safety reports, pharmaceutical issues, and site assessment issues. The portfolio of regulatory and clinical activities at DAIDS necessitates physical access to critical files by both Government and Contractor employees and requires that these files be available for auditing by other Federal agencies.

The Contractor shall be required to provide information through the Division of AIDS Enterprise System (DAIDS-ES) system, a comprehensive system that supports the business functions and management and oversight responsibilities of the Division of AIDS. Additional information regarding the DAIDS-ES is included in the Attachment 2 entitled "DIVISION OF AIDS – ENTERPRISE SYSTEM (DAIDS-ES)."

Specifically, the Contractor shall provide**:**

1. CLINICAL RESEARCH SUPPORT

Assist NIAID staff in carrying out their responsibilities for participating in and overseeing the design, implementation, conduct and oversight of clinical trials and clinical studies supported through grants, contracts and interagency agreements. This includes NIAID-sponsored Phase I, II, III, IV and post-marketing trials of HIV therapeutic, vaccine and prevention clinical research. NIAID currently supports clinical research efforts through large clinical networks, individual single or multi-site grants, and partnerships with other Federal and non-Federal agencies. NIAID is currently supporting approximately 400 trials related to HIV and AIDS in various stages. These trials range from 10 to 6,000 participants and are conducted in 46 countries. Approximately 22 of the 46 countries are resource poor. Assistance and support shall be provided in the following areas:

A. Development and Review of Clinical Study Concepts and Protocols. In the context of clinical studies, the term "concept" means the initial written description of a particular clinical scientific study by the grantee. Such concepts are evaluated and considered for further development into a "protocol" by grantee organizations. Protocols finalized by grantees are then submitted to the NIAID for regulatory assessment. The tasks described below are limited to providing technical or scientific expertise during the development of concepts and protocols prior to submission to NIAID for regulatory assessment.

1) Assistance for *Clinical Study Concept Development*. Provide support and assistance to NIAID staff in carrying out their responsibilities for activities associated with the development of concepts for clinical studies to be considered for implementation. Support shall include collecting information or data relevant for: (a) concept development, such as literature surveys of the current scope of HIV infection or the co-infections or co-morbidities; (b) data on the success of current regimens or strategies; (c) data to support the rationale for the conduct of the study (e.g., for a study of directly observed therapy); and (d) information about different models used in prior studies such as peer-supported, clinic-based trials. For a "when to start" treatment study, such efforts could include: (a) collecting references about starting a study early or late; (b) providing expertise or advice to Clinical Concept Development Team members with respect to study design, study population and other aspects of the proposed concept as referenced in DAIDS-approved network bylaws and/or Standard Operating Procedures; (c) preparing, for review by NIAID staff, drafts of limited components of the concept document; (d) preparing materials for NIAID staff that relate to organizing and conducting meetings for concept review; (e) participating in conference calls and meetings to provide expert advice.

2) Assistance in *Clinical Study Concept Review*. Provide support and assistance to NIAID staff in carrying out their responsibilities for activities associated with the review of concepts for clinical studies to be considered for development and implementation. Support services, with the review

and approval by NIAID staff, shall include: (a) preparation of drafts of limited components of the concept document; (b) preparation of materials related to the organization and conduct of meetings for concept review; (c) participation in concept review conference calls and meetings; (d) preparation of summaries of the evaluation of concepts, including strengths and weaknesses, issues and concerns raised and to be resolved or pursued further, and interim and final decisions regarding concept approval, disapproval or need for revision and resubmission; (e) assistance in communicating the outcomes of concept reviews; and (f) tracking of documents pertaining to concept development and review.

3) Assistance for *Clinical Protocol Development*. Assist NIAID staff in carrying out their responsibilities with respect to the activities of Clinical Protocol Development Teams established to design clinical protocols for approved clinical concepts. Support shall include: (a) collecting data needed for study design and making recommendations pertaining to study design and statistical analysis plans in the areas listed under 1.A.1) above, and/or conducting research on the probabilities of certain events required to make sample size calculation,(e.g., failure or toxicity rates of therapies); and (b) participating, in an advisory capacity, in Clinical Protocol Development Team meetings and conference calls to provide specific expertise on various aspects of the protocols in development.

4) Assistance in *Clinical Protocol Review*. Assist NIAID staff in carrying out their responsibilities with respect to clinical protocol review. Support shall include: (a) assistance in obtaining the required review of protocols by NIAID protocol review committees, the NIAID Regulatory Affairs Branch and/or the NIAID Regulatory Compliance Center (RCC) contractor; (b) reviewing and providing recommendations to NIAID staff on the quality and completeness of protocol-related materials such as Investigator Brochures (IBs) and Manuals of Operations (MOPs); and (c) assistance in the management and tracking of protocols and protocol-related documents. This also includes providing medical expertise for protocol review and providing recommendations to NIAID staff with respect to Study Data Monitoring Plans (SDMPs) and safety monitoring plans and requirements.

B. Clinical Protocol Implementation

Assist NIAID staff in carrying out their responsibilities related to various aspects of implementing approved protocols. This shall include but is not limited to the following:

1) Clinical Research Site Identification, Assessment, Preparation and Training

a) Review data and other information provided by NIAID clinical research support contractors and provide recommendations to assist NIAID staff in determining the capacity of individual sites to participate in the conduct of specific protocols. This includes, for example, serving as an advisor to NIAID staff in the interpretation and evaluation of clinical site information, including pharmacy facilities and services, laboratory facilities and services, data management systems and quality control procedures, site ability to meet performance standards, site infrastructure, and site staffing level and qualifications to carry out specific protocols.

b) When the need for site identification, assessment, preparation and training services exceed those provided for under extant NIAID clinical research support contracts, this Contractor shall be asked to assist NIAID staff in the collection and evaluation of clinical site information, including, for example, pharmacy facilities and services, laboratory facilities and services, data management systems and quality control procedures, site ability to meet performance standards, site infrastructure, and site staffing level(s) and qualifications to carry out specific protocols.

c) Participate in an advisory capacity on teams for site preparation and follow-up visits intended to prepare sites for conducting clinical trials in accordance with protocol-specific requirements. Review written reports on site preparation issues and problems prepared by NIAID clinical research support contractors and provide recommendations to NIAID staff for the resolution of identified problems and other required corrective actions. When the capacity to conduct team site preparation and follow-up visits exceeds that provided for under extant NIAID clinical research support contracts, the Contractor shall be asked to assist NIAID staff in carrying out

their responsibilities to conduct site preparation team visits and/or to ensure that problems and required corrective actions have been appropriately implemented and documented.

d) Assist NIAID staff in the scheduling of site visits and tracking and managing of site visit reports and other materials necessary to document that appropriate clinical, laboratory, pharmacy and data management facilities and services, staff and operating procedures are in place to carry out specific protocols at individual clinical research sites to carry out specific protocols.

e) Review and provide advice to NIAID staff on the adequacy and appropriateness of materials prepared for clinical research site training with respect to protocol implementation and protocol-specific requirements. Assist NIAID staff in the scheduling of study-specific training and attend training sessions in an advisory capacity, when necessary and appropriate.

f) Assist NIAID staff and NIAID clinical research support contractors in the design and implementation of site and protocol-specific training conducted at individual sites and/or at clinical research group meetings. For example, training topics shall include: NIAID procedures for submission of data to the Regulatory Compliance Center (RCC) contractor; NIAID Expedited Adverse Event (EAE) reporting; NIAID pharmacy procedures; clinical site monitoring procedures and processes; and protocol-specific requirements.

2) *Investigational New Drug (IND) Applications*: (a) Assist NIAID staff in carrying out their responsibilities for the preparation and filing of INDs for clinical trials in which the NIAID serves as the IND sponsor; (b) provide assistance in preparing for pre-IND meetings and teleconferences with the U.S. Food and Drug Administration (FDA); and (c) provide recommendations for responding to questions and inquiries from the FDA regarding IND review and approval.

3) *Human Subjects Requirements*: Assist NIAID staff in carrying out their responsibilities to ensure that the appropriate documentation of local Institutional Review Board (IRB) approvals of protocols for all participating sites, including protocol amendments are present and up to date. Assist NIAID staff in maintaining a tracking system for all such documents.

4) *Essential Documentation*: Assist NIAID staff in carrying out their responsibilities to approve Essential Documentation, as defined by the International Conference on Harmonization ICH-E6-GCP (http://www.fda.gov/cder/guidance/959fnl.pdf)

5) *Study Product Requirements*: Assist NIAID staff in carrying out their responsibilities for: (a) ensuring that all participating sites have received the appropriate supply of study products; (b) maintaining required documentation of study product receipt and appropriate storage, packaging and labeling; and (c) appropriate return and/or disposal of study products.

C. Protocol Oversight

Assist NIAID staff in carrying out their responsibilities for the oversight of DAIDS-sponsored clinical trials and studies, including adherence to all state, local, Federal and international regulations and DAIDS, NIAID, NIH and DHHS policies and guidelines. This includes the following:

1) *Site Compliance with Regulatory and Protocol-Specific Requirements*: Participate in an advisory capacity in clinical site monitoring visits conducted by NIAID clinical research support contractors and provide recommendations to NIAID staff to assist in fulfilling their responsibilities for evaluating clinical site compliance with U.S., international, and institutional regulatory requirements. This includes: (a) reviewing data and reports prepared by NIAID clinical research support contractors on compliance with Federal regulations and protocol-specific requirements; (b) providing advice to NIAID staff on the findings and recommendations for the effective resolution of compliance problems and deviations; and (c) tracking and documenting the implementation of NIAID-approved actions for correcting study compliance problems and deviations.

2) *Site Compliance with Data Collection and Data Management Requirements*: Assist NIAID staff in carrying out their responsibilities for assessing and ensuring site compliance with the NIAID policy; Data Management Requirements for Data Collection Sites

(http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/PDF/Stats/DataMgt_StatPolicy.pdf) This includes staff qualifications and training for data collection; standard operating procedures for data acquisition, entry, and processing; data queries and error correction; quality management, quality assurance and quality control; physical data management systems (hardware, software) and physical and data security; disaster contingency plans, data audits, and database closure and archiving.

3) *Site Compliance with Pharmacy Requirements*: Assist NIAID staff in carrying out their responsibilities for assessing and ensuring site compliance with NIAID requirements for pharmacy facilities and services (http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/PDF/Pharmacy/PharmFacilities.pdf and http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/PDF/Pharmacy/PharmActivities.pdf) This includes: (a) reviewing data and reports prepared by NIAID staff or DAIDS clinical research support contractors on site pharmacy facilities and services and compliance with NIAID and other regulatory requirements; (b) providing advice to NIAID staff on the findings and recommendations for the effective resolution of compliance problems and deviations; and (c) tracking and documenting the implementation of NIAID-approved actions for correcting compliance problems and deviations.

4) *Site Laboratory and Specialized Laboratory Compliance*: Assist NIAID staff in carrying out their responsibilities for ensuring individual site laboratory and specialized laboratory compliance with protocol-specific laboratory requirements. This includes: (a) reviewing and providing advice to NIAID staff for evaluating both routine and specialized laboratory monitoring and audit reports that are prepared by NIAID laboratory quality assurance/quality control contractors and include laboratory assessments to monitor study participant safety, specimen processing and storage, clinical research laboratory testing for study endpoints, and shipping of clinical specimens from participating sites for evaluation by selected specialized laboratories; (b) participating in an advisory capacity in site visits and audits to assess laboratory capabilities and compliance with current Good Laboratory Practices (cGLP) 21 CRF (58), FDA regulatory requirements, and NIAID policies; (c) reviewing and providing recommendations to NIAID staff for decisions regarding the implementation of improvements and corrective actions based on NIAID evaluation of site and specialized laboratory compliance; and (d) participating in an advisory capacity in training and quality assurance activities conducted by NIAID clinical research support contractors for site and specialized laboratories.

5) *Safety Oversight and Monitoring*: Provide assistance to NIAID staff to ensure and document that NIAID requirements for study progress and safety monitoring have been met (http://www3.niaid.nih.gov/research/resources/DAIDSClinRsrch/PDF/Safety/StudyProgSafetyMonitor.pdf). This includes:

   a) providing medical expertise to assist and advise NIAID staff in safety monitoring and in the identification and resolution of safety issues, including the review of Serious Adverse Event (SAE) reports and safety monitoring tables;

   b) reviewing Investigator Brochures (IBs) and package inserts, providing recommendations to NIAID staff for modification of NIAID risks lists, and assisting NIAID staff in coordinating the NIAID-wide and external review of risks lists;

   c) tracking Protocol Development Team responses to address safety concerns and safety reports and correspondence through the review and approval process; and

   d) assisting in the identification of protocols with potential safety concerns and providing recommendations on safety-related policies and procedures. This also shall include providing advice and assistance to NIAID staff in the design, development, and implementation of an integrated NIAID pharmacovigilance system, and in the collection and evaluation of safety data on study products and study interventions relevant to NIAID-sponsored clinical trials across studies, across networks and/or across research programs.

6) *Data and Safety Monitoring Board (DSMB) Activities*: Assist NIAID staff in supporting Data Safety and Monitoring Board activities including:

a) Assist NIAID staff with the planning, preparation for and documentation of DSMB meetings held at domestic and international sites. This shall include support needed to develop agendas, coordinate protocol reviews, and distribute necessary materials to all relevant parties. Draft DSMB meeting summaries and Institutional Review Board (IRB) reports for review by NIAID staff within the period specified by the Project Officer. Within 5-10 calendar days of a DSMB recommendation to change an ongoing study (e.g., stop a trial or one arm), the Contractor shall prepare summary documentation of DSMB recommendations and assist in coordinating communication with NIAID staff, investigators, and site personnel.

b) Assist NIAID staff in the collection and analysis of blinded safety data and preparation of presentations for scheduled DSMB meetings or conference calls. Assist staff in the compilation and analysis of information on emerging safety or operational issues for presentation to the DSMB when requested.

c) When requested by the Project Officer, coordinate travel and logistical arrangements for DSMB meetings and conference calls held in domestic or international settings. This shall include international travel arrangements for non-federal DSMB members. The Contractor shall also provide a mechanism for the payment of honoraria and reimbursement of DSMB members and ad hoc medical/scientific experts for travel expenses in accordance with Government Travel Regulations (GTR).

d) Update SOPs, DSMB Charters and other data and safety monitoring policies as appropriate.

7) *Biostatistical Support*: On approval of the Project Officer, the Contractor shall, whenrequested, assist NIAID staff in the development or assessment of any of the following:

a) Statistical Analysis Plans (SAP). When requested, write or compile and analyze information needed for Statistical Analysis Plans (SAPs). SAPs shall include: an overview of the study; a description of demographic and baseline characteristics; a description of endpoint analyses; a description of safety analyses; a description of any interim analyses; and a description of summary formats and layout. The Contractor shall ensure that SAPs correspond to the statistical section of the protocol.

b) Statistical Design. Provide input to the Protocol Development Team regarding study design to ensure that the study will be properly conducted, yield statistically valid answers to the scientific question(s) posed in the protocol including design configuration, type of comparison, sample size calculation, interim analyses, primary, secondary, and other endpoints, and techniques to avoid bias.

c) Statistical Monitoring. Provide recommendations to NIAID staff for statistical adjustments needed due to protocol changes and assist in developing study data monitoring plans in collaboration with the Data Manager and Protocol Chair.

d) Interim Analyses. Conduct and report to NIAID staff interim analyses per the process described in the protocol, and maintain confidentiality of data and results.

e) Statistical Analyses. Under direction of the Project Officer, perform the statistical analysis according to the process outlined in the statistical section of the protocol and in the Statistical Analysis Plan and report the analysis results to the study team.

D. Modification and Closure of Ongoing Clinical Trials

Assist NIAID staff in implementing changes needed following DSMB recommendations to modify (i.e., discontinue an arm) or close ongoing clinical trials. Assist NIAID statistical and research program staff in preparing summaries of the findings supporting study modification or closure and instructions on

implementing study modification/closure for participating clinical investigators, other clinical site staff, and NIAID clinical research support contractors.

E. Laboratory Projects

1) Advise NIAID staff working with DAIDS-supported laboratories in converting research and development assays associated with Phase I/II clinical trials into validated assays that meet the requirements for FDA licensure. Provide a variety of consultative services to assist in the transitioning of clinical end-point assays into high through-put assays needed for Phase III field testing and large scale studies.

2) Assist NIAID staff in planning and coordinating scientific and administrative laboratory projects resulting from NIAID participation in the Global Enterprise and related partnerships, including ensuring appropriate implementation of action items or tasks related to those partnerships. Examples of technical advice that may be requested include: expertise needed to expand the capacity of the ongoing proficiency panel testing program for immunogenicity assays such as ELISpot and intracellular cytokine staining; technical support to advance new assays and novel reagents into standardization and validation phase; technical expertise to establish on-line data input and reporting systems, and pass-fail criteria for laboratories involved in immune monitoring.

F. Clinical Research Document Tracking

Assist NIAID staff in designing, implementing and managing an efficient system for tracking clinical research documents and recording appropriate quality control of all documents needed for the life cycle of NIAID-sponsored clinical trials (IND and non-IND). This includes the following documents:

1) Clinical development plans
2) Protocols, protocol amendments and protocol clarifications
3) Investigator Brochures and updates
4) Manuals of Operations
5) Source documentation guidelines
6) Study-specific procedures
7) Case Report Forms (CRFs) with data management review and instructions
8) Informed consent
9) Clinical Study Reports (CSR) that integrate statistical and clinical data
10) Study reports prepared for scientific and lay audiences
11) Final study analyses and reports
12) Abstracts, manuscripts and journal articles

G. Support for Pharmaceutical Collaborations

Assist NIAID staff in developing and maintaining liaison with pharmaceutical collaborators with respect to study product supply and other issues pertaining to the evaluation of investigational products developed by industry. This includes reviewing and commenting on options for blinding, randomization and stability testing, and reviewing batch records for specific projects involving pharmaceutical company investigational products. This also includes providing advice and assistance to NIAID staff in the development of Clinical Trial Agreements (CTAs) with pharmaceutical and biotechnology companies providing investigational products/devices for evaluation in DAIDS-supported clinical research programs/projects.

H. Specialized Support

Provide scientific and technical expertise to NIAID in highly specialized areas related to the development or conduct of clinical trials in domestic and international settings. Support may occur in various settings, including attendance at committee meetings within DAIDS or with groups outside DAIDS, on-site visits, at Institutional Review Boards (IRBs) and at clinical research review groups.

Examples of areas in which the diverse specialized expertise may be required include:

1) Pre-formulation studies
2) Development of clinical dosage form
3) Development and manufacture of clinical research materials
4) Providing summaries of regulatory and license requirements for drug safety testing and shipping for multiple countries, on ethical issues relating to the conduct of clinical trials in resource limited countries, and on good clinical practices
5) Human subject protection issues

I. Other Clinical Research Support

1) *Clinical Research Training Programs*: Assist NIAID staff with respect to clinical research training programs, policies, needs and requirements. This includes:

a) assisting NIAID staff in developing training policies and standards to facilitate adherence to regulatory requirements and responsibilities, International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines and other relevant clinical research standards and guidelines, and NIH, NIAID and DAIDS policies and standard operating procedures;

b) assisting NIAID staff, NIAID clinical research support contractors and Network leaders in the design and development of a strategic training plan that encompasses: (i) an extensive inventory of existing training materials and programs; (ii) needs assessment and identification of necessary training curricula and priorities; (iii) detailed development plans with milestones and timelines; and (iv) plans for implementation, including schedules, required resources, and selection of appropriate modalities and trainers;

c) assisting NIAID staff in coordinating the development of training programs and materials across DAIDS-sponsored clinical research programs in coordination with other clinical research support contractors, in tracking development and implementation of training programs, and in coordinating scheduling of training to eliminate redundancies and maximize efficiency and effectiveness;

d) assisting NIAID staff and NIAID clinical research support contractors in identifying and addressing ongoing training requirements, needs and requests;

e) assisting NIAID staff to harmonize training curricula and materials for DAIDS-wide and NIAID-wide use, and providing advice and assistance to other NIAID and NIH components, other Federal clinical research sponsors, and regulatory agencies; and

f) arranging or facilitating travel (e.g. transportation, lodging, per diem, local transportation, reimbursement) for Contractor staff to participate in site visits, attend meetings, conferences, and workshops, and other activities involving travel as necessary to perform their job duties. Develop SOPs for contract employees for domestic and international travel including mechanisms for efficient handling of travel documents (passports, visas, tickets). All travel by contract employees will require approval of the Project Officer or his/her designee. International travel by contract employees requires approval by the Contracting Officer at least six weeks prior to commencement of travel. Assist NIAID and Division of Extramural Activities Support (DEAS) staff in the coordination and scheduling of site visits and other activities requiring travel for staff of the NIAID, DAIDS-supported contractors and DAIDS-supported investigators to ensure minimal disruption to clinical sites and the most efficient and cost-effective use of resources.

2) *Clinical Research Regulations, Policies and Guidelines*: Provide advice to NIAID staff on a broad range of regulations, policies and guidelines governing the conduct of research involving human subjects in domestic and international settings. This includes: (i) compiling and preparing an inventory of existing DAIDS, NIAID, NIH and Department of Health and Human Services (DHHS) policy documents and sources; (ii) establishing and maintaining an electronic reference source for such policies, including renewal/revision dates; (iii) assisting in identifying gaps in NIAID research policies, recommending policy changes, coordinating the gathering of input on proposed policy

changes from DAIDS staff and, based on such input, preparing drafts of policy changes for NIAID staff review and approval; and (iv) assisting NIAID staff in ensuring that program actions and advice are consistent with DAIDS, NIAID, NIH and DHHS goals, policies, national and international statutes, regulations, rules and directives.

2. PROGRAM OPERATIONS SUPPORT

A. Portfolio Tracking, Analysis and Monitoring

1) Assist NIAID staff in designing and implementing an efficient system for tracking DAIDS-supported grants, contracts and interagency agreements, including associated documents, according to multiple parameters, e.g.: scientific area, location of award, funded investigators, level of support, funding mechanism and expiration date, and reporting requirements. Assist NIAID staff in preparing reports and analyses to array data on DAIDS-funded grants, contracts and interagency agreements by various parameters, including trends in funding.

2) Review progress reports and other required documents for NIAID-funded grants, contracts and interagency agreements to assist NIAID staff in carrying out their responsibilities for ensuring adherence to project aims, milestones and timelines, and deliverables. Based on review of these grant, contract and interagency agreement materials, provide recommendations to NIAID staff regarding: adherence to project requirements, including terms and conditions of award and the implementation of funding mechanism-specific tasks; progress and potential operational, compliance and other issues that may affect the accomplishment of project goals and objectives; and the potential need for and value of modifications to funded research projects to ensure successful completion.

3) Assist in developing and implementing systems to alert NIAID staff of required programmatic actions on grants, contracts and interagency agreements and to track actions taken, including time-sensitive activities such as milestone achievement, preparation of product development schedules and clinical trial implementation.

4) Review scientific advances and emerging technical/scientific opportunities and resources and provide recommendations to NIAID staff on the implications of such advances, opportunities and resources for current and potential NIAID-supported research programs.

5) Serve as the lead for data entry and tracking of NIAID employee time and attendance records using the established NIAID processes and electronic systems.

B. Data Management Systems and Data Quality Assurance: Assist NIAID staff with data management systems and data quality assurance for DAIDS-supported clinical and non-clinical research programs. This includes the following:

1) assessing the adequacy of current and proposed data management systems in meeting the Division's clinical and non-clinical support needs;
2) providing advice to NIAID staff on data quality assurance policies and procedures, including adherence to FDA and other regulatory requirements, and on the quality of data submitted to or accessed by NIAID staff;
3) participating in an advisory capacity on in-house and outside data management working groups to develop standard operating procedures and beta testing of the DAIDS Enterprise System; and
4) providing advice to NIAID staff on changes in FDA and other regulatory requirements that impact database design and data collection tools and procedures.

C. Provide advice to NIAID staff on activities conducted through cross-organization technical/scientific working groups, meetings, conferences, product reviews or project reviews. Responsibilities include use of scientific and technical judgment to recommend and coordinate resources needed, document meeting actions and outcomes, and make recommendations for follow-up by NIAID staff. Contractor staff may be required to perform these activities where groups, meetings, conferences, product reviews or project review meetings are scheduled. Generally they will occur at NIAID offices.

D. Program Inquiries and Requests for Information: Assist NIAID staff in preparing responses to inquiries and requests for information concerning NIAID-funded research programs and policies from a broad range of audiences, including advocacy groups, health care professionals, health care research organizations, industry, investigators, Congress, other components of the Department of Health and Human Services, and other Federal agencies. Provide assistance in gathering data and programmatic information necessary to respond to inquiries/requests and prepare draft responses for review and approval by NIAID staff. Assist NIAID staff in developing and managing a document control system for all programmatic inquiries and requests for information, including version control, filing, and retrieval of documents and responses.

E. Public Health Policy Development: Assist NIAID staff in carrying out their responsibilities with respect to the development of public health policies for HIV/AIDS research in domestic and international settings. Examples of policies considered in the past include: the purchase of investigational products for evaluation in DAIDS-supported clinical trials; policies governing study-related injuries; use of generic drugs in clinical trials at domestic and international sites; provision of antiretroviral therapy (ART) after clinical trials; and harmonization of documents such as Confidential Disclosure Agreements (CDA), Material Transfer Agreements (MTAs), and Material Evaluation Agreement (MEAs). Support to be provided shall include the following: (i) participating in an advisory capacity in NIAID meetings with advocacy groups, health care service organizations, foundations and other non-governmental organizations involved in HIV/AIDS clinical trials, and international private and public institutions to identify important policy issues, and to make recommendations to NIAID staff on approaches for addressing such issues within the context of DAIDS-sponsored research programs; (ii) participating in an advisory capacity on working groups and committees both within and outside of the Federal government to provide advice on public health policy issues (e.g., NIAID, NIH, CDC, DHHS, and FDA working groups and committees); and (iii) providing advice and assistance to NIAID staff in responding to requests for information and advisory opinions on public health policy issues.

F. Development of Collaborations: Assist NIAID staff in developing collaborations with a broad range of organizations and groups to ensure appropriate involvement and input into DAIDS-sponsored research programs. This shall include the following:

1) identifying both scientific and non-scientific, domestic and international partners/collaborators to assist in carrying out the mission of the NIAID, including private foundations, patient advocacy groups, health care delivery organizations, etc.;

2) developing strategies for effective communication with such groups and organizations, including strategies designed to obtain advice on research areas of mutual interest; and

3) participating in an advisory capacity in NIAID meetings and other modes of communication with partners/collaborators to promote the scientific agenda of the NIAID, identify opportunities for collaboration and sharing of information, and develop and implement action plans for collaborative activities.

G. Research Support for Document Development: Provide expert support to NIAID staff relevant to the issues that impact HIV and AIDS clinical programs, collaborations, and product development efforts. This may involve clinical trial agreements, confidentiality or disclosure agreements, or strategies to facilitate private sector participation in DAIDS programs. This support will be used by DAIDS staff to triage projects involving legal matters to the NIAID Office of Technology Development (OTD), track the flow and completion of programmatic work, and facilitate uniform and consistent application of relevant policies within DAIDS and DAIDS-sponsored activities. The Contractor shall not be authorized to provide legal advice to NIAID and shall work through a Division point of contact to coordinate with all appropriate NIAID offices, including the NIAID OTD.

H. Evaluation of NIAID-sponsored Research: Provide specialized expertise to assist NIAID staff in the design and implementation of systematic evaluation of NIAID-sponsored research funded through grants, cooperative agreements and contracts. Findings will be used by DAIDS staff to improve effectiveness of awards toward meeting DAIDS scientific goals and/or to inform decisions for future grant and/or contract activities. Areas that may be covered by evaluation activities include: Effectiveness (Are NIAID research efforts achieving the goals and objectives intended ?); Efficiency (Are awards supported through effective

use of resources such as budget and staff time?); Cost-Effectiveness (Does the value or benefit and objectives of a particular award or group of awards exceed the cost of support?); and Attribution (Can it be demonstrated that progress towards goals and objectives is a result of NIAID-sponsored or NIAID-funded activities, as opposed to other concurrent events or interventions?). This shall include the following:

1) assist NIAID staff to design and plan individual evaluations that are practical and feasible and conducted within available resources, time, and political context;

2) assist NIAID staff with the implementation of evaluations through the collection of information on the activities, characteristics, and outcomes of individual awards and/or groups of awards; and

3) comply with the provisions of the 1995 Paperwork Reduction Act if such evaluations require collection of data from more than nine individuals. See http://www.whitehouse.gov/omb/inforeg/infocoll.html for further information

3. COMMUNICATIONS SUPPORT

Assist NIAID staff in carrying out their responsibilities for ensuring and/or overseeing the development and implementation of appropriate activities and materials designed to educate, raise awareness and document the results of DAIDS-sponsored clinical research programs for relevant scientific and non-scientific constituencies. This includes the following:

A. reviewing and assessing the appropriateness and adequacy of plans for community education, outreach and the recruitment and retention of study participants for Network and non-Network clinical trials, including the provision of recommendations on approaches to improve outreach, education, and recruitment/retention plans and activities.

B. identifying opportunities to enhance understanding of the purpose, processes and results of DAIDS-sponsored HIV-related research by various constituency groups, including: the HIV/AIDS scientific research community; national, regional and local HIV/AIDS prevention and health care organizations; research advocacy organizations; national minority and minority-health organizations; and the general public.

C. preparation and review of various materials pertaining to ongoing research programs and the results of DAIDS-sponsored research projects for scientific and lay audiences. This shall include: reviewing and providing advice on materials for publication in scientific journals prepared by NIAID grantees and contractors; providing analyses and summaries of major findings prepared by NIAID staff; and preparing, for NIAID staff review and approval, draft summaries of the results of DAIDS-funded grantees and contractors for both domestic and international lay communities.

D. developing oral and written presentations for use at both internal and external programmatic and scientific meetings. Examples include Clinical Trial Network-related meetings, domestic and international site visits, annual AIDS Vaccine meetings, the bi-annual International AIDS Conference, the annual microbicides meeting, meetings with other components of the Department of Health and Human Services, and meetings with constituency groups.

E. preparation of materials for the press, including press releases and statements, question and answer documents, and background documents, and in the preparation of original news and feature articles for internal and public websites using Federal and NIH standards for web content.

F. obtaining user or reader feedback and adapting written materials, manuals, SOPs, or presentations to improve communication effectiveness without compromising technical content or accuracy.

G. maintaining and archiving information provided to audiences outside NIAID such as website content or presentations developed or made by NIAID staff and NIAID contractors.

H. staffing exhibition booths at domestic and international conferences and meetings to distribute and discuss approved materials on NIAID research programs.

I. assistance with general communication-related activities and protocol-specific communication activities to NIAID staff, DAIDS-funded Networks, non-Network grantees and contractors, and other groups/organizations collaborating with the NIAID.

4. CONFLICT OF INTEREST MITIGATION, NON-DISCLOSURE AND CONFIDENTIALITY PLAN

A. Implement and monitor on an ongoing basis the Organizational Conflict of Interest and Non-disclosure/Confidentiality Plan as negotiated prior to contract award and incorporated by reference in the contract.

B. Conduct an annual review and include in the Annual Progress Report details regarding any breaches of the plan, how they were resolved, and any additional efforts the Contractor shall undertake to prevent any future occurrences. The report on Conflict of Interest Mitigation, Non-Disclosure/Confidentiality shall include:

a. Contract Number;
b. summary of training provided to employees including hire date and training dates;
c. summary of receipt of signed non-disclosure and confidentiality agreements for all contract employees including consultants and subcontractors;
d. summary of identified as real or apparent conflicts of interest and actions taken to mitigate the conflict in the previous 12 months;
e. summary of steps taken to ensure non-disclosure and confidentiality of information in the previous 12 months; and
f. recommended modifications to the extant Organizational Conflict of Interest and Non-disclosure/Confidentiality Plan.

C. Conduct training on the Organizational Conflict of Interest and Non-Disclosure/Confidentiality Plan for all new Contractor staff within the time limits negotiated in the plan; and conduct "refresher" training for all Contractor staff on an annual basis.

5. PROJECT MANAGEMENT

Establish and manage an organizational structure necessary to carry out the support functions to be performed under this contract, including Contractor staffing, office space, and standard operating procedures. Specifically, the Contractor shall meet the following requirements and specifications:

A. Ensure that Contractor staff are available to meet with the Project Officer or his/her designees at the offices of NIAID in Bethesda, Maryland with short notice. For any staff on official travel, his/her "acting" shall be available.

B. Provide adequate office space to house all staff assigned to the contract, as well as associated office equipment, furnishings and facilities.

C. <u>Contractor Staff Training</u>:

1) Within 30 calendar days of the contract effective date, develop and conduct a standard training program for all Contractor staff covering, at minimum, the following topics:

a) Contract purpose and scope;
b) NIAID and DAIDS organizational structure and existing DAIDS-supported research programs and research support contracts;
c) Contractor organizational and management structure;
d) SOPs to be utilized by the Contractor for implementing support functions, including the internal assignment and monitoring of tasks/projects;

e) SOPS to be utilized by the Contractor to mitigate conflicts of interest, disclosure and

confidentiality of information; and

f) Limitations on the type of support that can be provided to NIAID within the scope of the contract.

2) Conduct standard training programs for new employees within 30 calendar days of the employee start date.

3) Maintain training records for all contract employees.

D. Standard Operating Procedures: Within 60 calendar days of the contract effective date develop, for Project Officer review and approval, draft Standard Operating Procedures (SOPs) for major activities conducted under this contract, including the assignment, planning, initiation, monitoring and completion of tasks/projects; travel procedures and reporting; and equipment purchase/management.

1) This includes the requirement for Project Officer approval of all Contractor staff travel no later than 6 weeks in advance of the departure date.
2) For activities initiated after the first 60 calendar days of the contract effective date, draft SOPS shall be developed and forwarded for Project Officer review and approval within 30 calendar days of the request for the new activity.
3) All SOPs shall be revised in accordance with Project Officer comments and final SOPs submitted within 10 calendar days of receipt of Project Officer comments.
4) Implement and monitor Contractor staff compliance with all approved SOPs.

E. Communication Plan:

Develop within the first 90 days of the contract effective date, a Communication Plan to ensure that Contractor staff performing similar functions are aware of their related activities on a scheduled basis to achieve efficient dissemination of knowledge and sharing of best practices across organizational boundaries within NIAID. The Communication Plan shall address establishment and implementation of equivalent communication plans and procedures between Contractor and NIAID staff who support similar functions. The Contractor shall implement the Communication Plan after receiving review and approval of the Plan by the Project Officer.

F. Information Security

The Contractor shall follow best practices in the area of information security. The National Institute of Standards and Technology's (NIST) Computer Security Resource Center (CSRC) has developed many publications on information security and has established a "best practices" web site. The CSRC web site can be found at http://www.csrc.nist.gov/index.html. One best practice is the development of an IT System Security Plan (SSP). The IT System Security Plan (SSP) details the overall security infrastructure for the systems. It includes details of the system, the various controls of the system, the information security policies of the organization, and any connections that the system has to other systems internal and external to the organization. NIST has developed a Special Publication NIST SP-800-18 Revision 1 Guide for Developing Security Plans for Federal Information Systems, (http://www.csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf). The Contractor can use this document as a guideline for developing the SSP. The SSP should be provided to the Project Officer in electronic and paper format within 60 days of contract award.

6. INITIAL AND FINAL TRANSITIONS

A. Initial Transition

Develop and implement a plan to ensure the orderly and efficient transition of data, materials, and other resources from the incumbent provider. This shall include the following:

1) *Draft Initial Transition Plan*: Within 15 calendar days of the contract effective date, develop and submit, for Project Officer review and approval, a Draft Initial Transition Plan. The Draft Initial

Transition Plan shall not exceed 50 pages. The Project Officer shall have 5 working days in which to provide written comments to the Contractor. The Draft Initial Transition Plan shall include:

a. Contract Number;
b. overview of Transition Plan;
c. description of how ongoing activities will be assumed by the Contractor, if applicable; and
d. description of orderly and efficient acquisition of data, materials, and other resources.

2) *Final Initial Transition Plan*: Within 30 calendar days of the contract effective date, prepare and submit, for Project Officer review and approval, the Final Initial Transition Plan that addresses all comments and modifications provided by the Project Officer.

3) *Initial Transition Plan Implementaiton*: Within 30 calendar days of the contract effective date, prepare and submit, for Project Officer review and approval, the Final Initial Transition Plan that addresses all comments and modifications provided by the Project Officer.

4) *Initial Transition Plan Implementation*: Implement the NIAID-approved Initial Transition Plan to ensure full assumption of responsibilities no later than 45 calendar days after the effective date of the contract. The Contractor shall make every attempt to fully staff the base contract period within 90 days of award.

B. Final Transition: Develop and implement a plan to ensure the orderly and efficient transition of data, materials and other resources to a successor contractor or to the Government. This shall including the following:

1) *Draft Final Transition Plan*: No later than 90 calendar days prior to the contract expiration date, prepare and submit, for Project Officer review and approval, a Draft Final Transition Plan. The Draft Final Transition Plan shall not exceed 50 pages. The Project Officer shall have 30 calendar days in which to provide written comments to the Contractor. The Draft Final Transition Plan shall include:

a) Contract Number;
b) overview of Transition Plan;
c) detailed description of how ongoing activities will be transferred to a new Contractor, if applicable;
d) listing of all deliverables listed under the DELIVERABLES AND REPORTING SECTION;
e) listing of all unused materials;
f) listing of all equipment purchased under this contract including computers, laptops, desks, chairs, tables, Blackberries, and other property of the U.S. Government purchased under this contract;
g) copies of all electronic and hard copies files, Contractor developed databases, entries and related files; and
h) all other files requested by the Project Officer necessary to ensure the orderly transition to a new Contractor or to the Government.

2) *Final Transition Plan*: No later than 60 calendar days prior to the contract expiration date, prepare and submit, for Project Officer review and approval, the Final Transition Plan that addresses all comments and modifications provided by the Project Officer.
3) *Final Transition Plan Implementation*: Implement the NIAID-approved Final Transition Plan to ensure full assumption of responsibilities by a successor contract by the expiration date of the contract. The Contractor shall maintain full operations of the functions of the contract during the final transition period.

7. OPTIONS

A. Option to Extend Period of Performance

The Government expects to award a contract with a base period of performance of 2 years and may exercise the option to extend the period of performance on an annual basis for up to 5 additional years.

B. Option to Increase Level of Effort

In addition, options may be exercised to increase the level of effort to be provided under the contract in increments of 10 full time equivalents (FTEs). Increases will be added to the base level of effort for a period of one year and may be renewed for future years 2 through 7 of the contract period of performance. The maximum level of effort to be supported under this contract is 157 FTEs.

C. Draft Option Plan: Develop and submit, for Contracting Officer and Project Officer review, a Draft Option Plan to increase the level of effort to be provided under the contract in increments of 10 full time equivalents (FTEs). Increases will be added to the base level of effort for a period of one year and may be renewed annually for up to 5 years beyond the base period of performance. The maximum level of effort to be supported under this contract is 157. The Draft Option Plan shall be submitted for planning and coordinating purposes and shall address the following activities associated with such annual increases:

1) additional office space and office equipment needs;
2) plans for advertising additional positions and for evaluating the qualifications of job applicants; and
3) plans for standard training of additional Contractor staff and specialized training with respect to conflict of interest mitigation, non-disclosure and confidentiality requirements.

D. Final Option Plan: Based on Project Officer and Contracting Officer comments on the Draft Option Plan, prepare and submit a Final Option Plan.

E. Final Option Plan Implementation: Implement the approved Final Option Plan and provide a report to the Project Officer and the Contracting Officer when implementation has been completed.

Attachment 4 - DIVISION OF AIDS – ENTERPRISE SYSTEM (DAIDS-ES)
NIAID/HIV AIDS Scientific and Operations Support
NIH-NIAID-DAIDS-08-33

The Contractor may be required to provide some information through the DAIDS-ES. While some of this may be accomplished through a link from DAIDS-ES to the Contractor's web site, some data may need to be shared with DAIDS-ES, in which case data sharing agreements, standards, etc., will be required. The DAIDS-ES is a comprehensive system that supports the business functions, management and oversight responsibilities of the Division of AIDS. The current components of the DAIDS-ES include:

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

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

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

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, cooperative agreement holders, grantees, etc.) will implement applications or data exchange mechanisms using platform technology standards such as: Web Services, eXtensible Markup Language (XML), XML Schema Definitions (XSD), RDBMS, .NET Framework, UDDI, IIS, Internet Explorer, Service Oriented Architecture (SOA), Design Patterns, Frameworks and Templates as defined by the DAIDS-ES. Collaborators shall adhere to these guidelines and standards on a continual basis. This requirement will include the need to utilize DAIDS-ES-specified software Application Programming Interfaces (APIs) or XML and XSD, where appropriate, in all relevant applications that affect specific types of transactions, Graphical User Interfaces (GUI) and other software-based tasks that interact with or become part of the DAIDS-ES. Depending upon the architecture and implementation of 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. Collaborator's data system(s) may have to be adapted or modified to accommodate the DAIDS standard(s).

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

Attachment 5
NIAID HIV/AIDS Scientific and Operations Support
RFP NIH-NIAID-DAIDS-08-33

Overview of Selected NIAID Division of AIDS Research Support Contracts

Overview of DAIDS Research Support Contracts

The DAIDS currently holds several contracts that provide a variety of clinical trials support and other services to the expansive DAIDS clinical trials portfolio. Currently, these contractors are providing services to DAIDS-funded vaccine, prevention and therapeutic studies at over 700 sites and in more than 40 countries, and are working closely with DAIDS-funded Networks, non-Network clinical research projects, programs and investigators, central laboratories, operations centers and statistical and data management centers.

Several of these contracts with which this new contractor may interface with are summarized below. The successful contractor will be expected to interface with these contractors in order to perform functions specified within the Statement of Work. The DAIDS also has pending contracts and as these contracts are awarded, the contractor will be notified of any required interface.

DAIDS-Enterprise System (DAIDS-ES) Information Technology Contractor

This contract, N01-AI-30060, is held by Capital Technology Information Services (CTIS), Inc., located in Rockville, MD. In June of 2002 the DAIDS-ES Team performed an analysis and initiated a reengineering of DAIDS business processes with the goal of overcoming information access barriers, and to begin the architectural development of a DAIDS enterprise system. The DAIDS-ES will ultimately integrate the modules involving key business areas that support the DAIDS agenda in HIV/AIDS vaccine, prevention and therapeutics research. The DAIDS-ES will also create a foundation for new applications and provide a common user experience for the Division with the benefit of lower infrastructure and development costs. As networks and contractors initiate work within the DAIDS system, each entity will be expected to interface with the DAIDS-ES. Additional information on the DAIDS-Enterprise System can be found at: **http://www.niaid.nih.gov/daids/rfa/network06/pdf/DAIDS%20Enterprise%20System%2011-10.pdf.**

DAIDS Clinical Research Products Management Center

This contract, N01-AI-85352, is held by McKesson BioServices, Inc. located in Rockville, MD. Staffed by registered pharmacists, the contract provides support to the DAIDS Clinical Trials Networks through the receipt, storage. shipment and management of clinical research products for Network trials. Each Network and all Network clinical research sites interface with this contractor before receiving study products. Specific responsibilities of this contractor include:

- Receipt and storage of study products
- Security and safety
- Inventory management
- Packaging and labeling
- Shipping and distribution

- Processing and disposal of returns
- Database inventory and distribution
- Coordination with domestic international shippers

DAIDS Regulatory Compliance Center (RCC) Contractor

This contract, N01-AI-30032, is held by Technical Resources International, Inc. located in Bethesda, MD. The RCC provides regulatory support for all DAIDS-funded clinical trials and coordinates regulatory support functions with DAIDS, all DAIDS-supported clinical research sites, and the Network data management centers. Responsibilities of the RCC contractor including:

- Preparation and management of IND submissions
- Distribution of original and subsequent IND submissions to the FDA, the participating pharmaceutical company, and parties within DAIDS
- Review and processing of Serious Adverse Event reports
- Review of protocols and informed consents for compliance with regulations
- Working with DAIDS Medical Officers during the protocol generation process and during safety monitoring of all DAIDS IND trials
- Processing of site/protocol registration and ensuring that each site has appropriate protocol registration documents prior to protocol initiation.

"Good Clinical Practices" Monitoring Contractors

DAIDS currently utilizes two contractors to evaluate Good Clinical Practice (GCP), regulatory compliance, accurate protocol implementation, international quality assurance, and test agent accountability during periodic on-site visits to all DAIDS-funded sites. These two contractors (PPD Development Inc., Wilmington, NC, contract number N01-AI-05405, and Westat, Inc., Rockville, MD, contract number N01-AI-15445) perform the following:

- Examination of source documents to assess accuracy and completeness of trial data
- Identification of issues with protocol implementation, adherence to GCP and all applicable regulatory requirements
- Verification of proper storage, dispensing and accountability of investigational study products
- Provision of training on general protocol conduct, clinical practices, quality management, and DAIDS procedures
- Review of internal quality assurance/quality control plans
- Review of ongoing QA/QC processes
- Review of site operations management
- Verification of proper collection, handling, and storage of lab specimens
- Site initiation

HIV Clinical Research Management Support Contractor

This contract, N01-AI-50022, is held by PPD Development, Inc., located in Wilmington, NC. The primary objective of the contract is to provide over-arching research program management resources (personnel, administrative, contractual, logistical, and operational) for DAIDS in order to augment the capabilities of DAIDS-supported clinical trials, primarily for the DAIDS Clinical Trial Networks. Contractor support services are closely integrated and closely coordinated with existing DAIDS clinical trial Networks and DAIDS operational systems for planned and ongoing trials. The Contractor assumes varying degrees of responsibility for activities related to study oversight, management, and/or conduct of a large portfolio of trials located throughout the world. The Contractor assumes differing roles support of clinical trials, while coordinating these efforts from an overall oversight/research program management perspective through detailed trial and site support services. Support is also provided for standardization of "common" operational research procedures for the contract. The primary areas in which clinical research support services are provided include:

1. Centralized Clinical Research Program Management
2. Site Identification/Preparation/Management/Evaluation
3. Clinical Trials Management Services
4. Clinical Trial Compliance Services

Attachment 6
NIAID HIV/AIDS Scientific and Operations Support
RFP NIH-NIAID-DAIDS-08-33

NIAID Division of AIDS Clinical Trial Portfolio -- Information Summary

The following information describes the clinical trial networks and major clinical trial programs that comprise the current DAIDS portfolio. A table listing ongoing clinical trials currently being supported through DAIDS-funded networks and other collaborations is also provided. This information is subject to change dependent on a variety of factors. The DAIDS is providing this information to give offerors a brief overview of current DAIDS efforts so that each offeror can more fully understand potential areas of support for this contract. The Contractor will not be expected to support all of the efforts described below.

Clinical trial networks and major collaborations are profiled in the following order:

1. **AIDS Clinical Trials Group (ACTG)**
2. **International Network for Strategic Initiatives in Global HIV Trials (INSIGHT)**
3. **Microbicide Trials Network (MTN)**
4. **International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT)**
5. **HIV Vaccine Trials Network (HVTN)**
6. **HIV Prevention Trials Network (HPTN)**
7. **Department of Defense/NIAID HIV Research Collaboration**
8. **Additional Collaborations for HIV/AIDS Vaccine Research**

1. Adult AIDS Clinical Trials Group

Principal Investigator: Constance A. Benson, M.D.

Summary: The AIDS Clinical Trials Group (ACTG) is a worldwide collaborative clinical trials network that conducts translational and therapeutics research.

Background: The ACTG was first established in 1987 to pursue therapeutics research for both adults and children, and to evaluate strategies to prevent mother-to-child transmission of HIV.

Research Agenda: The ACTG's mission focuses on five scientific areas of research: translational research and drug development; optimization of clinical management, including co-infections and co-morbidities; vaccine research and development; prevention of mother to child transmission of HIV; and prevention of HIV infection. In addition, the ACTG plans to collaborate with a number of other NIH Institutes and Centers, including the National Institute of Dental and Cranial Research, the National Institute of Nursing Research and the National Institute of Mental Health to explore mutually beneficial research opportunities. Research will be pursued both domestically and internationally.

The ACTG's two highest priorities are highlighted below. Translational research and drug development efforts in the ACTG are aimed at the evaluation of 1) anti-HIV compounds with novel mechanisms of action/new targets, including small molecule entry inhibitors, uncoating inhibitors, integrase inhibitors, and maturation inhibitors; 2) new classes of drugs with unique and improved features, such as different resistance profiles or better pharmacologic or toxicologic properties; and 3) new therapies for individuals with co-infections, focusing on tuberculosis, hepatitis C, and human papillomavirus. In addition, the ACTG will focus on the integration of immune-based therapies into treatment regimens, emphasizing mechanisms of antiviral effect and immune reconstitution, and the evaluation of new hypotheses

generated by pathogenesis studies, initially focusing on defining the virulence and pathogenic potential of X4 viruses in the context of CCR5 and CXCR4 inhibitor treatment.

In the area optimization research, the ACTG will evaluate: 1) the effectiveness of new regimens or new treatment strategies, particularly those that incorporate agents with a novel mechanism(s) of action; and 2) therapies and therapeutic strategies for treating co-infections and complications, including prophylaxis, acute and maintenance treatment, and treatment with ARV agents. In addition, the ACTG will strive to optimize therapies on the basis of safety, adherence, resistance, durability of response, and prevention of transmission.

For more information, please visit the AACTG website at: www.aactg.org.

2. International Network for Strategic Initiatives in Global HIV Trials (INSIGHT)

Principal Investigator: James D. Neaton, Ph.D.

Summary: The International Network for Strategic Initiatives in Global HIV Trials (INSIGHT) is a worldwide collaborative clinical trials network that conducts research in the area of optimization of HIV management and co-morbidities.

Background: INSIGHT is a merger of two existing clinical trials research groups, ESPRIT (Evaluation of Subcutaneous Proleukin® in a Randomized Clinical Trial) established in 1999 and the CPCRA (Terry Beirn Community Programs for Clinical Research on AIDS) established in 1989 which initiated the Strategies for Management of Antiretroviral Therapy (SMART) study in 2002. The network is currently conducting research in 36 countries.

Research Agenda: INSIGHT's mission is to conduct studies in the area of optimization of clinical management of HIV, including co-morbidities. INSIGHT will evaluate strategies for using antiretroviral therapies (ART) and immunomodulatory therapies and study interventions to prevent and treat complications of HIV and ART in order to prolong disease-free survival in a demographically, geographically, and socio-economically diverse population of individuals infected with HIV. INSIGHT will conduct large randomized trials with morbidity and mortality outcomes, preceded, where appropriate, by vanguard (smaller pilot) studies to refine design parameters. INSIGHT studies will be designed to be relevant to both resource-abundant and resource-constrained countries. Studies will be directed at understanding how to minimize the adverse effects of long-term treatment, while maximizing treatment benefits. Sub-studies will be conducted as part of larger trials. The large trials conducted by INSIGHT also provide a significant body of data for epidemiological analyses using the combined database of several trials. In addition, nested case-control studies that take advantage of the large cross-study database with clinical outcomes and the associated specimen repositories will be carried out.

INSIGHT plans to foster relationships with other the networks, other institutes at NIH, and international groups in order to maximize efficiency and research productivity. Trials carried out by INSIGHT will help inform clinical practice.

For more information, visit the INSIGHT website at: www.insight-trials.org/index.php.

3. Microbicide Trials Network (MTN)

Principal Investigator: Sharon Hillier, Ph.D.

Summary: The Microbicide Trials Network (MTN) is a worldwide collaborative clinical trials network seeking to reduce the sexual transmission of HIV through the development and evaluation of microbicide products.

Background: The MTN is a new clinical trial research group established in 2006, building on the microbicide work previously established in the HIV Prevention Trials Network (HPTN).

Research Agenda: The MTN's mission is to conduct scientifically rigorous and ethically sound clinical trials that will support licensure of topical microbicide products. The current generation of microbicide candidates may only provide partial protection from HIV infection; however, given the dynamics of HIV in the developing world, it is likely that even partial protection may translate to significant community benefits for prevention. Some of the scientific questions that will be addressed through MTN studies include a comparison of tenofovir gel and placebo; the relative safety and effectiveness of tenovofir gel or oral tenofovir disoproxil fumarate; evaluation of new formulation technologies as they become available, such as the vaginal ring; the safety of vaginal microbicides for rectal use; and the long-term virological sequelae of exposure to reverse transcriptase inhibitor microbicides in subjects who have chronic HIV infection or who seroconvert during an MTN study. Studies currently underway will

provide critical infrastructure, expertise and data to evaluate 2nd generation products. The depth and breadth of the preclinical pipeline and promising animal model efficacy data provide reason to be optimistic that identification of a safe and effective microbicide is realistic. The MTN plans to partner with both the National Institute of Child Health and Human Development and the National Institute of Mental Health to explore mutually beneficial research opportunities.

For more information, visit the MTN website at: http://www.mtnstopshiv.org.

4. International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT)

Principal Investigator: Jay Brooks Jackson, M.D., M.B.A.

Summary: The International Maternal Pediatric Adolescent AIDS Clinical Trials Group (IMPAACT) is a worldwide collaborative clinical trials network devoted to significantly decreasing the mortality and morbidity associated with HIV disease in pregnant women, children and adolescents.

Background: IMPAACT is a merger of the Pediatric AIDS Clinical Trials Group and the Perinatal Scientific Working Group of the HIV Prevention Trials Network (HPTN). The PACTG has been a joint effort between the National Institute of Allergy and Infectious Diseases (NIAID) and the National Institute of Child Health and Human Development (NICHD) since 1993, and NICHD will continue to work collaboratively with IMPAACT.

Research Agenda: IMPAACT's mission is to significantly decrease the mortality and morbidity associated with HIV disease in children, adolescents, and pregnant women. Toward this end, IMPAACT will develop and evaluate safe and cost effective approaches for the interruption of mother-to-infant transmission; evaluate treatments for HIV-infected children, adolescents, and pregnant women, including treatment and prevention of co-infections and co-morbidities; and evaluate vaccines for the prevention of HIV sexual transmission among adolescents. On both a domestic and international scale, IMPAACT's research plan encompasses four of NIAID's six designated areas of highest scientific priority including the prevention of mother to child transmission (PMTCT), translational research and drug development, optimization of clinical management, including co-morbidities, and vaccine. IMPAACT plans to collaborate with NICHD and the National Institute of Mental Health to explore mutually beneficial research opportunities.

For more information, visit the IMPAACT website at: http://pactg.s-3.com.

5. HIV Vaccine Trials Network

Principal Investigator: Lawrence Corey, M.D.

Summary: The HIV Vaccine Trials Network (HVTN) is a worldwide collaborative clinical trials network searching for an effective and safe HIV vaccine.

Background: The AIDS Vaccine Evaluation Group (AVEG), which carried out early-stage testing of vaccine candidates, was reorganized in 1999 and no longer exists as named. The HVTN built upon AVEG's previous work and expanded its scope of activities.

Research Agenda: The HVTN's mission is to facilitate the process of testing preventive vaccines against HIV/AIDS, conducting all phases of clinical trials, from evaluating experimental vaccines for safety and the ability to stimulate immune responses, to testing vaccine efficacy. The HTVN's top ten priorities are to: 1) develop and maintain a clinical trials network that will provide an objective and transparent platform to evaluate the safety, immunogenicity and efficacy of candidate HIV vaccine for the prevention of HIV infection in adult and adolescent populations globally; 2) conduct head-to head comparisons of candidate vaccines to determine whether there are competitive advantages in safety and/or immunogenicity between the candidates, especially products that fall into a class of agents such as pox virus vectors, replication defective adenovirus vectors or DNA plasmids; 3) perform a series of phase II trials in populations throughout the world to determine if a vaccine candidate or vaccine regimen "qualifies" for further efficacy evaluation; 4) develop standardized risk reduction counseling methods that are applicable across HVTN sites and standard approaches to measurement monitoring of HIV risk behaviors during vaccine trials; 5) design and conduct HIV vaccine efficacy trials in men and women at risk of sexual and/or parenteral acquisition of HIV throughout the world that provides rigorous tests of critical scientific concepts for the development of HIV vaccines and ultimately delivers sufficient characterization of the safety and efficacy of a

candidate vaccine to enable its licensure; 6) to optimize the design of clinical trials that will define potential correlates of protection within HIV vaccine efficacy trials; 7) define potential correlates of protection within HIV vaccine efficacy trials; 8) evaluate the safety, immunogenicity and effectiveness of HIV preventive vaccines in adolescents; 9) develop and implement an integrated strategy within the HVTN efficacy trials program for the assessment of indirect and overall effects of CTL-mediated HIV vaccine candidates on HIV transmission at the individual and population levels; and 10) continue to develop and support mutually beneficial coordination and collaboration between the HVTN and relevant NIH networks, federal agencies, and non-governmental research organizations to advance the highest quality HIV vaccine research, with optimal efficiency and cost-effectiveness.

For more information, please visit the HVTN website at: www.hvtn.org.

6. HIV Prevention Trials Network

Principal Investigator: Sten Vermund, M.D., Ph.D.

Summary: The HIV Prevention Trials Network (HPTN) is a worldwide collaborative clinical trials network that develops and tests the safety and efficacy of a variety of interventions designed to prevent the transmission of HIV.

Background: The HPTN was first established in 2000, building on the work of the HIV Network for Prevention Trials (HIVNET).

Research Agenda: The HPTN's mission is to test new prevention strategies to reduce the rate of HIV transmission from HIV-infected, and acquisition rate in HIV-uninfected persons. Research is conducted in HIV at-risk persons, recently infected persons, and individuals with established HIV infection. The HPTN concentrates on the following four strategies: 1) use of antiretroviral drugs to reduce HIV transmission (in partnership with the ACTG); 2) control and prevention of sexually transmitted infections to reduce HIV transmission; 3) treatment of substance abuse, particularly injection drug use and stimulant use like cocaine and methamphetamines, to reduce HIV transmission; and 4) application of behavioral change modalities to reduce HIV transmission. The HPTN engages many of NIAID's network partners, the National Institute of Mental Health, the National Institute on Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism in development of HIV prevention research.

HPTN studies focus on strategic testing of interventions and modalities based on available agents and tools in populations and geographical regions that are bearing a disproportionate burden of infection. This is intended to facilitate rapid scale-up and more immediate impact on the pandemic. In addition, the HPTN will refine and expand its expertise in the development and validation of tools for the early detection of HIV infection, a collaboration with the Center for HIV/AIDS Vaccine Immunology.

Four active Phase III clinical trials are ongoing:

- HPTN 039 seeks to assess whether suppression of HSV-2 with acyclovir can reduce HIV transmission (Connie Celum).
- HPTN 043 introduces community-level education and advocacy to increase voluntary counseling and testing for HIV, to reduce HIV transmission at the community level (Thomas Coates).
- HPTN 052 studies discordant couples (one HIV+ and one HIV-) randomized to earlier (350-550 CD4+ cells/μL) vs. later antiretroviral therapy to assess impact of therapy on transmission to the uninfected partner. In partnership with ACTG, HPTN 052 also studies the clinical outcomes of the two groups of HIV+ persons, i.e., earlier vs. later therapy (Myron Cohen).
- HPTN 058 uses buprenorphine-naloxone to help treat opiate addiction in countries with high seroconversion rates among injection drug users, with the goal of reducing HIV seroincidence (David Metzger).

For additional information, please visit the HPTN website at: www.hptn.org.

7. Department of Defense/NIAID HIV Research Collaboration

The National Institute of Allergy and Infectious Diseases (NIAID) has an Interagency Agreement (IAA) with U.S. Army Medical Research and Materiel Command (USAMRMC) of the Department of Defense (DOD) to put in place a collaboration arrangement for oversight and management of the U.S. Military HIV Research Program (USMHRP) to NIAID. Both NIAID and USAMRMC are committed to a common goal: to prevent the further spread of HIV/AIDS by developing safe and effective vaccines, other prevention strategies and innovative HIV treatment.

The intent of the IAA is to:

1. leverage NIH core competencies and expertise in supporting, overseeing and conducting HIV/AIDS research
2. utilize and retain DOD's scientific capabilities and experience in preventing HIV infection in the military and conducting research internationally, and to coordinate NIAID and DOD research capabilities, infrastructure, and clinical trials
3. consolidate and coordinate NIAID and DoD efforts regarding HIV/AIDS research and development.

The IAA establishes a formal relationship between NIAID and USAMRMC for planning and implementing various facets of HIV vaccine research. NIAID will continue to support HIV research and development that is relevant to and supportive of the military mission. The Henry M. Jackson Foundation for the Advancement of Military Medicine (HJF), a private, non-profit organization works, closely with the USAMRMC as a resource for the program.

Currently, USMHRP partners with DAIDS to evaluate vaccine candidates developed by the VRC and other vaccine manufacturers. The USMHRP is engaged in activities in Thailand, Kenya, Uganda, and Tanzania, with the goal of including these sites in Phase III vaccine trials.

For more information, please visit the USMHRP website at: http://www.hivresearch.org/.

8. Additional Collaborations for HIV/AIDS Vaccine Research

The Dale and Betty Bumpers Vaccine Research Center (VRC)

The VRC at the National Institutes of Health was established to facilitate research in vaccine development. The VRC is dedicated to improving global human health through the rigorous pursuit of effective vaccines for human diseases. The Center's activities include basic research to establish mechanisms of inducing long-lasting protective immunity against HIV and other pathogens that present special challenges to vaccine development; the conception, design, and preparation of vaccine candidates for HIV and related viruses; laboratory analysis and animal testing of vaccine candidates; and clinical trials of vaccine candidates. Many of DAIDS recent clinical trials are testing vaccine candidates developed by the VRC. For more information, please visit the VRC website at: www.niaid.nih.gov/vrc.

Center for HIV/AIDS Vaccine Immunology (CHAVI)

CHAVI was established by DAIDS as part of the Global HIV/AIDS Vaccine Enterprise. It aims to elucidate basic sciences questions and conduct early phase clinical trials of HIV vaccine candidate at clinical sites around the world. Dr. Barton Haynes of Duke University serves as the Principal Investigator of CHAVI's scientific leadership group. Working with DAIDS, CHAVI's leadership team has begun establishing international clinical trial sites, developing clinical trial protocols, collecting samples, forming a EuroCHAVI Genetics Consortium, and establishing the HIV Transmitted Virus Sequence Database. For more information, please visit the CHAVI website at: http://chavi.org.

Partnership for AIDS Vaccine Evaluation (PAVE)

PAVE is a voluntary consortium of U.S. government agencies and U.S. government funded organizations involved in HIV vaccine research. Members of PAVE include NIH, the DAIDS-supported HIV Vaccine Trials Network, the Dale and Betty Bumpers Vaccine Research Center, the U.S. Military HIV Research Program, the Centers of Disease Control and Prevention, the U.S. Agency for International Development, and the International AIDS Vaccine Initiative. Currently, DAIDS is working with PAVE to develop its first collaborative clinical trial. For more

information, please visit the PAVE website at: www.hivpave.org.

International AIDS Vaccine Initiative (IAVI)

IAVI was founded in 1996 to speed discovery of an HIV vaccine. It partners with private companies, academic institutions and government agencies, such as NIH, worldwide. Currently, DAIDS, the HVTN, the USMHRP, and IAVI are conducting three independent clinical trials to evaluate a vaccine candidate developed by the NIH VRC. These trials have been harmonized in study design with the goal of designing and conducting a future efficacy trial. For more information, please visit the IAVI website: http://iavi.org.

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Attachment 6
NIAID Division of AIDS Ongoing Clinical Trial Portfolio -- Information Summary

Number	Name of Study	PI/ Collaborator	Countries	Phase/Type	Category	Study Status	Duration or Start/Stop*
RV 144	A Phase III Trial of Aventis Pasteur Live Recombinant ALVAC-HVI (vCP1521) Priming with VaxGen gp120 B/E (AIDSVAX B/E) Boosting in HIV-Uninfected Thai Adults	USMHRP	Thailand	III	Vaccine	Follow-up	Oct 03 to June 09
RV 172	A Phase I/II Clinical Trial to Evaluate the Safety and Immunogenicity of a Multiclade HIV-1 DNA Plasmid Vaccine, VRC-HIVDNA016-00-VP, Boosted by a Multiclade HIV-1 Recombinant Adenovirus-5 Vector Vaccine, VRC-HIVADV014-00-VP in HIV Uninfected Adult Volunteers in East Africa	USMHRP, VRC	Kericho, Kenya; Kampala, Uganda; and Mbeya, Tanzania	I/II	Vaccine	Enrolling	August 06 to Oct 08
IAVI V-001	A Phase I, Randomized, Placebo-Controlled, Double-Blind Trial to Evaluate the Safety and Immunogenicity of a Multiclade HIV-1 DNA Plasmid Vaccine Followed by Recombinant, Multiclade HIV-1 Adenoviral Vector Vaccine or the Multiclade HIV-1 Adenoviral Vector Vaccine Alone in Healthy Adult Volunteers not Infected with HIV	IAVI	Nairobi, Kenya and Kigali, Rwanda	I	Vaccine	Enrolling	Nov 05 to Nov 06 (estimate)*
HVTN 050	A Study of the Safety, Tolerability and Immunogenicity of a Three-Dose Regimen of the MRKAd5 HIV-1 gag Vaccine in Healthy Adults from Various Regions in the World	HVTN	U.S. and at international sites: South Africa, Malawi, Thailand, Peru, Brazil, Haiti, Puerto Rico, and the Dominican Republic	II	Vaccine	Follow-up	June 03 to March 09

*Estimated duration. The actual duration of trials may vary from the duration listed. These estimates are intended to provide an overall picture of the types and number of clinical trial activities underway rather than to serve as a resource list for individual trials.

Number	Name of Study	PI/ Collaborator	Countries	Phase/Type	Category	Study Status	Duration or Start/Stop*
HVTN 063	A phase I clinical trial to evaluate the safety and immunogenicity of HIV CTL Mulit-epitope (MEP) vaccine or gag+IL-12 plasmid vaccine in healthy HIV-1 uninfected adults.	HVTN	US, Brazil: Rio, Sao Paulo	I	Vaccine	Follow-up	Sept 05 to Aug 07
HVTN 064	A phase I clinical trial to evaluate the safety and immunogenicity of the recombinant protein vaccine EP-1043 and the DNA vaccine EP HIV-1090 given alone and in combination in healthy, HIV-1 uninfected adult participants.	HVTN	US, Peru: Lima, Iquitos	I	Vaccine	Follow-up	Jan 06 to Oct 07
HVTN 204	A Phase II Clinical Trial to Evaluate the Safety and Immunogenicity of a Multiclade HIV-1 DNA Plasmid Vaccine, Followed by a Multi-clade Recombinant Adenoviral Vector HIV-1 Vaccine Boost, VRC-HIVADV014-00-VP in Uninfected Adult Participants	HVTN, VRC	US, Jamaica, Haiti, Brazil, and South Africa	II	Vaccine	Enrolling	Sept 05 to Dec 07
HVTN 502	A Multicenter, Double-Blind, Randomized, Placebo-Controlled Phase II Proof-of-Concept Study to Evaluate the Safety and Efficacy of Three-Dose Regimen of the Merck Adenovirus Serotype 5 HIV-1 Vaccine gag/pol/nef (MRKAd5 HIV-1 gag/pol/nef) in Adults at High Risk of HIV Infection	HVTN	US, Puerto Rico, Peru, Haiti, Dominican Republic, and Jamaica, Brazil, Toronto, Montreal and Vancouver, Canada, and Sydney, Australia	IIb	Vaccine	Enrolling	Dec 04 to June 09
HPTN 027	A Phase I Study to Evaluate the Safety and Immunogenicity of ALVAC-HIV vCP1521 in Infants Born to HIV-1 Infected Women in Uganda.	HPTN	Uganda	I	Prevention	Enrolling	Oct 06 to Oct 07 (estimate)*

* Estimated duration. The actual duration of trials may vary from the duration listed. These estimates are intended to provide an overall picture of the types and number of clinical trial activities underway rather than to serve as a resource list for individual trials.

Number	Name of Study	PI/ Collaborator	Countries	Phase/Type	Category	Study Status	Duration or Start/Stop*
HPTN 035	A Phase II/IIb safety and effectiveness study of the vaginal microbicides BufferGel and 0.5% PRO2000/5 Gel (P) for the prevention of HIV infection in women (Malawi, South Africa, USA, Zambia, Zimbabwe)	HPTN	Malawi, South Africa, USA, Zambia, Zimbabwe	II/IIb	Prevention	Enrolling	Feb 05 to Q3 2008
HPTN 040/P1043	Trial of Three Neonatal Antiretroviral Regimens for Prevention of Intrapartum HIV Transmission	HPTN/PACTG	Brazil, India, Malawi, Thailand, USA, Zimbabwe	III	Prevention	Enrolling	Estimate 5 years *
Investigator-initiated	Evaluate a six-week regimen of nevirapine administered to HIV-uninfected infants born to HIV-infected breastfeeding mothers	Andrea Ruff	Ethiopia	III	Prevention	Follow-up	February 2001 to 2007 (estimate)*
Investigator-initiated	Evaluate a six-week regimen of nevirapine administered to HIV-uninfected infants born to HIV-infected breastfeeding mothers	Robert Bollinger	India	III	Prevention	Follow-up	August 2002 to May 2007
Investigator-initiated	Evaluate a six-week regimen of nevirapine administered to HIV-uninfected infants born to HIV-infected breastfeeding mothers	Brooks Jackson	Uganda	TBD	Prevention	Follow-up	TBD
Investigator-initiated	A randomized trial of Lopinavir/Ritonavir/Combivir vs Abacavir/Zidovudine/ Lamividine for virologic efficacy and the prevention of mother to child HIV transmission among breastfeeding women with CD4 counts > 200 cells/mm3 in Botswana	Roger Shapiro	Botswana	II	Prevention	Enrolling	July 2006 to 2008 (estimate)*
Investigator-initiated	Male Circumcision Trial for HIV Prevention	Ronald Gray	Uganda	III	Prevention	Follow-up	August 2003 to Sept 2007 07 (last study visit)
Investigator-initiated	Trial of Male Circumcision to Reduce HIV Incidence	Robert Bailey	Kenya	III	Prevention	Follow-up	February 2002 to Sept 2009
* Estimated duration. The actual duration of trials may vary from the duration listed. These estimates are intended to provide an overall picture of the types and number of clinical trial activities underway rather than to serve as a resource list for individual trials.							

Number	Name of Study	PI/ Collaborator	Countries	Phase/Type	Category	Study Status	Duration or Start/Stop*
A5214	A Phase I, Randomized, Placebo - Controlled, Double-Blind Study Evaluating the Safety of Subcutaneous Single Dose Interleukin-7 in HIV-1-Infected Subjects who are Receiving Antiretroviral Treatment	ACTG	US	I	Treatment	Enrolling	July 06 to Dec 2007 (estimate)*
A5175	A Phase IV, Prospective, Randomized, Open-Label Evaluation of the Efficacy of Once-Daily PI & Once-Daily Non-NRTI - Containing Therapy Combinations for Initial Treatment of HIV-1 Infected individuals from Resource - Limited Settings (PEARLS) Trial	ACTG	US, Brazil, Haiti, India, Malawi, Puerto Rico, South Africa, Zimbabwe	IV	Treatment	Enrolling	May 05 to May 09 (estimate)*
A5176	A Phase I/II, Randomized, Double-Blind Study to Evaluate Safety, Tolerability, & Immunogenicity of LC002, a DermaVir Vaccine, in HIV-1-Infected Subjects Under Tx w/HAART	ACTG	US	I/II	Treatment	Enrolling	Feb 06 to Feb 08 (estimate)*
A5207	A Phase II Randomized Comparison of Three Antiretroviral Strategies Administered for Seven or Twenty-One Days to Reduce the Emergence of Nevirapine Resistant HIV-1 Following a Single Intrapartum Dose of Nevirapine	ACTG	Haiti, India, Malawi	II	Treatment	Enrolling	March 06 to March 2008 (estimate)*
A5178	Suppressive Long-term Antiviral Management of Hepatitis C Virus (HCV) and HIV-1 Coinfected Subjects (SLAM-C)	ACTG	US, Puerto Rico	II	Treatment	Enrolling	Aug 04 to Aug 07 (estimate*)
A5221	A Strategy Study of Immediate Versus Deferred Initiation of Antiretroviral Therapy for HIV-Infected Persons Treated for Tuberculosis with CD4 <200 Cells/mm 3	ACTG	US	IV	Treatment	Enrolling	Sept 06 to Sept 2010 (estimate)*

*Estimated duration. The actual duration of trials may vary from the duration listed. These estimates are intended to provide an overall picture of the types and number of clinical trial activities underway rather than to serve as a resource list for individual trials.

Number	Name of Study	PI/ Collaborator	Countries	Phase/Type	Category	Study Status	Duration or Start/Stop*
A5128	A Randomized Phase II Study of Therapeutic Immunization and Treatment Interruption Among Subjects Who Began Potent Antiretroviral Therapy Within 16 Days of Diagnosis of Acute or Recent HIV Infection	ACTG	US	II	Treatment	Enrolling	Oct 06 to Oct 08 (estimate)*
A5208	Optimal Combined Therapy After Nevirapine Exposure	ACTG	Botswana, Kenya, Malawi, South Africa, Uganda, Zambia	III	Treatment	Enrolling	Nov 05 to Nov 2010 (estimate)*
P1030	A Phase I/II Study of Lopinavir/Ritonavir in HIV-1 Infected Infants <6 Months of Age.	PACTG	US, Brazil, Puerto Rico	I/II	Treatment	Enrolling	Sept 06 to Sept 08 (estimate)*
P394	A Phase I Study of the Safety and Pharmacokinetics of Tenofovir Disoproxil Fumarate in HIV-I Infected Pregnant Women and Their Infants	PACTG	US, Puerto Rico	I	Treatment	Enrolling	March 04 to Mar 08 (estimate)*
P1047	Phase II Safety and Immunogenicity Study of Quadrivalent Human Papillomavirus [Types 6, 11, 16, 18] L1 Virus-Like Particle [VLP] Vaccine (Gardasil®) In HIV-Infected Children > 7 to < 12 Years of Age	PACTG	US, Puerto Rico	II	Treatment	Enrolling	Nov 06 to Nov 08 (estimate)*
P1060	Parallel Randomized Clinical Trials Comparing the Responses to Initiation of NNRTI-Based vs. PI-Based Antiretroviral Therapy in HIV-Infected Infants who have and have not received single dose NVP for PMTCT.	PACTG	US, Puerto Rico	II	Treatment	Enrolling	Sept 06 to Sept 08 (estimate)*

* Estimated duration. The actual duration of trials may vary from the duration listed. These estimates are intended to provide an overall picture of the types and number of clinical trial activities underway rather than to serve as a resource list for individual trials.

ATTACHMENT 7
ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS,
FORMAT FOR TECHNICAL PROPOSAL, and TABLE OF CONTENTS
NIAID HIV/AIDS Scientific and Operations Support
NIH-NIAID-DAIDS-08-33

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

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

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

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

Offerors are reminded that the total page limitation for the entire Technical Proposal is **200** pages including all appendices and attachments (including biographical sketches). Any pages in excess of this limit will be expunged from the proposal and will not be considered in the technical review.

Proposals shall NOT include links to Internet Web site addresses (URLs) or otherwise direct readers to alternate sources of information.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1

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

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

Provide a brief overview of the Technical Proposal, including: (i) a summary of the activities to be performed by the offeror and those that shall be performed by proposed subcontractors; (ii) identification of the proposed subcontractors and a list of key personnel of the offeror and the proposed subcontractors with degrees and titles; and (iii) a brief description of the facilities, equipment, and other resources to be made available by the offeror and all proposed subcontractors.

SECTION 3: TECHNICAL APPROACH AND PROJECT MANAGEMENT

I. PROJECT MANAGEMENT

A. Project Organization and Staffing: Provide a plan for project organization, staffing, coordination and management to ensure the effective and efficient planning, initiation, implementation, conduct, monitoring and completion of tasks identified in the Statement of Work. Describe in detail the responsibilities and level of effort for all proposed personnel who will be assigned to the contract, including proposed subcontractors and consultants, and provide an administrative and technical framework indicating clear lines of authority and responsibility for all proposed personnel and addressing flexibility to change staffing based on the needs of the contract. Include a proposed staffing plan to address requirements for the provision of support services from multiple staff with different areas of expertise at different times over the course of the contract period of performance, proposed approaches for establishing project priorities, and methods for resolving workload issues and redistributing workload when necessary.

B. Staff Recruitment and Retention: Describe organizational experience in and provide proposed strategies to identify, recruit and retain employees over the duration of the contract period of performance. This should include a discussion which demonstrates the offeror's understanding of the education, training, knowledge, experience and expertise required to carry out contract support functions. Provide a list of the titles of positions advertised and filled by the offeror over the past 5 years that are relevant to the support functions to be carried out under this contract. In addition, provide a discussion of common problems encountered in both the recruitment and retention of scientific, technical and administrative personnel and approaches used by the offeror to resolve problems encountered.

C. Staff Assignment and Monitoring: Describe organizational experience in and proposed strategies for assigning, tracking and monitoring the performance of all personnel, including staff of the offeror and all proposed subcontractors and consultants, with particular attention to requirements for staff to work on multiple assignments that may cross organizational boundaries within DAIDS, within NIAID, and with other government agencies and private organizations/institutions.

D. Standard Operating Procedures (SOPs): Describe organizational experience in the development, implementation and monitoring of adherence to SOPs for the provision of scientific and technical support. Provide a SOP template and a list of SOPs, by topic, to be developed for major scientific, technical and activities to be conducted under this contract

E. Staff Training: Describe organizational experience in designing and conducting staff training. Provide proposed plans and procedures to be used to develop and conduct training programs, including initial training shortly after contract award and training for new staff hired during the contract period of performance.

F. Communications: (i) Describe organizational experience in and provide proposed plans for keeping Contractor staff, subcontractor staff and all proposed consultants informed of the range of tasks underway to maximize the sharing of information and "lessons learned". Also describe proposed mechanisms to ensure effective communications among staff during travel. (ii) Outline how the PI will communicate with the Project Officer and Contracting Officer and how the PI will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities). For the purposes of the technical proposal anticipate that Contractor staff should propose a communication approach that will accommodate international travel each year in support of seven (7) site visits, two (2) site initiation visits, five (5) training workshops in GCLP, and two (2) laboratory audits and a similar number of domestic activities.

II. CLINICAL RESEARCH SUPPORT

A. *Development and Review of Clinical Study Concepts and Protocols, Clinical Protocol Implementation and Protocol Oversight* (SOW 1.A., 1.B. and 1.C.)

Describe organizational experience in the provision of scientific and technical support services for a wide variety of clinical trials conducted in both the U.S. and in resource limited locales in Africa, Southeast Asia, Latin America, the Caribbean and Eastern Europe. This description should include the following:

1. Examples of scientific and technical support services provided over the past 5 years for clinical trials conducted in domestic and resource limited countries, including: (i) types of investigational products

evaluated (e.g., therapeutics, vaccines, etc.); (ii) phase of clinical trials supported; (iii) clinical trial sponsors; (iv) number of study participants, number of clinical trial sites, and location of clinical trial sites; (v) scope of support services provided for each project; and (vi) the number and type of personnel employed.

2. Discuss proposed plans and procedures for the provision of these clinical research support services, including the types of expertise required, and provide a list of recent Standard Operating Procedures (SOPs) used to manage and coordinate such services. Include a discussion of any proposed changes in SOPs to accommodate the size, scope and complexity of the support services to be provided under this contract.

3. A discussion of problems and obstacles encountered in the provision of clinical research support services over the past 5 years, approaches used to resolve problems and overcome obstacles, and how these approaches were implemented within the organization and with project sponsors.

B. *Laboratory Projects* (SOW 1.E.): Describe recent organizational experience in the provision of scientific and technical support services for clinical laboratory projects; discuss problems and obstacles encountered in the provision of such services and approaches implemented to resolve problems and overcome obstacles. Provide a focused example of how you staffed a similar service in the last five years.

C. *Pharmaceutical Collaborations* (SOW 1.G.): Describe recent organizational experience in working with pharmaceutical and biotechnology companies with respect to the clinical evaluation of investigational products/devices developed by industry. Include experience pertaining to study product supply and other study product issues, as well as experience in assisting with the development of formal agreements with industry collaborators for the sponsorship/conduct of clinical trials. Provide a focused example of how you staffed a similar service in the last five years.

D. Specialized Support (SOW 1.H.): Describe recent organizational experience in the provision of scientific and technical expertise in highly specialized areas, including pre-formulation studies, manufacture of clinical research materials, development of clinical dosage forms, and drug safety testing. Provide a focused example of how you staffed a similar service in the last five years.

E. Other Clinical Research Support (SOW 1.I.)

1) Clinical Research Training: Describe recent organizational experience with clinical research training activities, including: identification and assessment of training needs, design of training programs, development of training materials, and harmonization of policies, practices and standards across multiple clinical research programs. Give examples of assistance provided with respect to: (i) assessing training needs and the results of those assessments; and (ii) designing and conducting training programs, including audience, content, agendas and format (e.g., webcasts, training workshops, etc.). Also, provide a focused example of how you staffed a similar service in the last five years. Include a discussion of the most common problems and/or deficiencies encountered in the conduct of clinical research for which training is critical.

2) Clinical Research Regulations, Policies and Guidelines: Describe recent organizational experience in the provision of clinical research support services with respect to a broad range of regulations, policies and guidelines governing the conduct of research involving human subjects in domestic and international settings. Include proposed plans to assist in the inventory, assessment and updating of regulations, policies and guidelines.

III. PROGRAM OPERATIONS SUPPORT

Describe organizational experience in and discuss proposed plans and procedures for the provision of program operations support services in the areas specified below, including plans for the management and coordination of program operations support functions.

A. *Portfolio Tracking, Analysis and Monitoring* (SOW 2.A.):

1) Designing and implementing an efficient system for tracking DAIDS-supported grants, contracts and interagency agreements according to multiple parameters.
2) Reviewing progress reports and other required documents for adherence to project aims, milestones, timelines, and deliverables; and providing recommendations on adherence to project requirements, progress and potential operational, compliance and other issues, and the potential need for and value of modifications to funded research projects to ensure successful completion.
3) Developing and implementing alert systems for actions required and for tracking actions taken, and preparing product development and clinical trial implementation schedules.
4) Reviewing scientific advances and emerging technical/scientific opportunities and resources and providing recommendations on their implications for current and potential NIAID-support research programs.

B. *Data Management Systems and Data Quality Assurance* (SOW 2.B.):

1) Assessing the adequacy of data management systems.
2) Providing expert advice on data quality assurance policies and procedures and on the quality of data submitted to or accessed by system users.
3) Identifying changes in FDA and other regulatory requirements and assessing their impact on database design and data collection tools and procedures.
4) Include a description of data management systems supported over the past 5 years, their sponsors, purpose/function, size and key features, as well as quality control/quality assurance procedures used, and identify working groups/committees to which advice and assistance has been provided. Also include a discussion of common problems and obstacles encountered in the design, management and quality control of data systems, particularly for large clinical trial programs/networks, and approaches used to resolve problems and overcome obstacles.

C. *Program Inquiries and Requests for Information* (SOW 2.D.):

1) Preparing responses to inquiries and requests for information on biomedical research programs from a broad range of sources both public and private.
2) Gathering data and programmatic information necessary for preparing responses.
3) Developing and managing document control systems for filing, retrieval and version tracking.

Include examples of responses and accompanying materials prepared over the past 5 years in response to inquiries from multiple sources – both public and private.

D. *Public Health Policy Development* (SOW 2.E.):

1) Developing policies for the conduct of biomedical research, particularly clinical trials, in domestic and international settings.
2) Working with Federal agencies, health care service organizations, and patient advocacy groups and other organizations to identify and recommend approaches for addressing important public health policy issues.
3) Identify working groups/committees to which advice and assistance has been provided over the past 5 years and provide examples of the types of policy issues within the purview of such working groups/committees.

E. *Development of Collaborations* (SOW 2.F.):

1) Identifying both scientific and non-scientific, domestic and international partners/collaborators to assist in carrying out the missions of government agencies and/or private organizations supporting biomedical research, particularly to clinical research.
2) Developing strategies and action plans for effective communication with such partners/collaborators in areas of mutual interest.
3) Identify working groups/committees and events in which the offeror has participated to provide expert advice and assistance with respect to the development of collaborations relevant to the scope of

research to be supported under this contract, and provide examples of recommendations and other materials developed for such events, working groups and/or committees.

F. *Research Support for Document Development* (SOW 2.G.):

Developing various documents to codify key features and arrangements for clinical research activities, e.g., collaborations with industry, other DHHS and Federal agencies, private foundations, etc. Such documents include Clinical Trial Agreements, Material Transfer Agreements, confidentiality agreements, and disclosure agreements.

G. Evaluation of NIAID-sponsored Research (SOW 2.H.):

1) Designing and implementing systematic evaluations of biomedical research programs with respect to effectiveness, efficiency, cost-effectiveness, and attribution.
2) Complying with the provisions of the 1995 Paperwork Reduction Act where necessary for the implementation of program evaluations.
3) Collecting information on research program activities, characteristics and outcomes for the implementation of evaluations.
4) Identify sponsors and research programs for which expert advice and assistance has been provided over the past 5 years. If publicly available, provide copies of final program evaluations for which assistance has been provided. Include a discussion of key principles, features and effective approaches for the assessment of biomedical research programs, including approaches to ensure that such evaluations are practical and feasible.

IV. COMMUNICATIONS SUPPORT (SOW 3.)

Describe organizational experience in and discuss proposed plans and procedures for the provision of communications support services in the areas specified below, including plans for the management and coordination of program operations support functions.

A. Reviewing and assessing the appropriateness and adequacy of plans for community education, outreach and the recruitment and retention of study participants, and providing recommendations on approaches to improve outreach, education, and recruitment/retention plans and activities.
B. Identifying opportunities to enhance understanding of the purpose, processes and results of biomedical research, particularly clinical research, by various constituency groups and the general public.
C. Preparing and reviewing of various materials pertaining to ongoing biomedical research programs, particularly clinical research programs, and the results of sponsored biomedical research projects for scientific and lay audiences, including scientific publications and summaries of major findings.
D. Developing oral and written presentations for use at both internal and external programmatic and scientific meetings.
E. Preparing materials for the press, including press releases and statements, question and answer documents, and background documents, and original news and feature articles.
F. Obtaining user or reader feedback and adapting written materials, manuals, SOPs, or presentations to improve communication effectiveness.
G. Maintaining and archiving information provided to scientific and lay audiences.

Identify recent projects for which communications services have been provided and give examples of written materials for scientific and lay audiences resulting from those projects.

V. INITIAL AND FINAL CONTRACT TRANSITION (SOW 6.)

Discuss your understanding and experience with the typical risk management practices implemented during the transition of a major, large-scale support contract in support of a complex biomedical research program. Describe proposed plans for executing an effective and efficient transition, including transition staffing plans,

within 90 calendar days of the contract effective date for the initial transition and within 60 calendar days of the contract expiration date for the final transition.

SECTION 4: QUALIFCATIONS AND AVAILABLILITY OF PERSONNEL

Provide documentation of the education, training, expertise, experience, qualifications and availability of the proposed personnel of the offeror and all proposed consultants and subcontractors. Limit CVs to 2-3 pages, include experience with projects of similar scope, size and complexity over the past 10 years, and provide citations for relevant publications and letters documenting availability for the proposed work. In cases where specific individuals are not identified and proposed, provide a description of the education, training, qualifications, experience and expertise required for all such positions for the offeror and all proposed subcontractors and consultants. A detailed listing of the required number of FTEs and the estimated labor mix is included in SECTION L, INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS, General Information, Level of Effort.

A. KEY PERSONNEL

1. Oversight, management and coordination of biomedical research support projects, particularly for clinical research programs, involving a broad range of scientific, technical and administrative services, multiple ongoing and overlapping tasks, and time-sensitive performance requirements;
2. Working with Government officials, grantees, contractors, and industry collaborators to provide scientific and technical support for biomedical research programs, particularly clinical research programs;
3. Identifying and mitigating real and potential conflicts of interest on the part of the organization and its employees, consultants and subcontractors;
4. Developing, implementing and monitoring adherence to standard operating procedures governing the provision of research support services.

B. SCIENTIFIC AND TECHNICAL PERSONNEL

Provide documentation for the proposed scientific and technical personnel to perform the following functions:

1. *Clinical Research Support for:*

a) development and review of clinical study concepts and protocols, clinical protocol implementation and protocol oversight
b) laboratory projects
c) pharmaceutical collaborations
d) specialized support
e) other clinical research support

2. *Program Operations Support for:*

a) portfolio tracking, analysis and monitoring
b) data management systems and data quality assurance
c) program inquiries and requests for information
d) pubic health policy development
e) development of collaborations
f) research support for document development
g) evaluation of NIAID-sponsored research
h) travel coordination

C. *Communications Support for:*

1) assessing the adequacy of existing community education and outreach plans and identifying approach for enhancing understanding
2) reviewing and preparing various communications materials for scientific and lay audiences, including: press releases, background documents, original news and feature articles, and scientific publications and presentations

3) obtaining user feedback
4) maintaining and archiving communications materials

SECTION 5: CORPORATE RESOURCES

Document the availability and adequacy of facilities, equipment, space and other resources necessary to carry out the Statement of Work, including:

I. The location and features of facilities dedicated to the project for the offeror and any proposed subcontractors (lease or ownership information should be provided).

II. A description of plans and procedures to be utilized to ensure compliance with all safety guidelines and regulations, including training and monitoring of personnel. This includes safety procedure and training during travel in domestic and international settings.

III. Identification and description of support resources (including Information Technology systems) which will be required to effectively complete the SOW. This should include proposed plans to accommodate NIAID's need for easy and rapid access to staff and documents housed at the Contractor's facility with short notice for urgent situations. Close physical proximity of the Contractor's main or satellite office and/or plans to ensure that this interaction can be successfully accomplished in a cost-effective and timely manner are essential.

SECTION 6: CONFLICT OF INTEREST MITIGATION, NON-DISCLOSURE AND CONFIDENTIALITY

I. Provide a detailed description of the individual and institutional conflicts of interest that may arise during the performance of the contract on the part of the offeror and all proposed subcontractors, and proposed strategies, plans, policies and procedures to manage and mitigate individual and institutional conflicts of interest. Describe organizational experience with mitigating/resolving conflict of interest issues for similar projects. ***Please address conflicts of interest that may arise as a result of the type of work the offeror and all proposed subcontractors carry out for NIAID at the present time. For example, this contract includes requirements to monitor existing NIAID-sponsored clinical studies. A conflict of interest may arise if the offeror or any proposed subcontractors were to carry out the required monitoring activities under this contract because your organization would be monitoring/evaluating its own work.*** **For additional examples of Organization Conflicts of Interest, please refer to the Federal Acquisition Regulations, Part 9.5.**

II. Provide a proposed plan to identify and manage the risk of disclosure of confidential information from grantees, contractors, private collaborators/partners (including industrial collaborators), participants in clinical trials and government agencies at the individual and organizational level.

III. Provide an organizational Conflict of Interest and Non-disclosure/Confidentiality plan that addresses the following:

A. Information on how the organizational structure of the Contractor will assist with preventing confidential information from being shared with individuals in the company who do not need access to that information (including financial information).
B. A clear discussion of how the Contractor would propose to mitigate any perception that it will have access to confidential information, including information about planned or pending solicitation or financial information about any of its competitors.
C. A clear discussion of how the Contractor would preclude a perception of impaired objectivity by prohibiting transfer of personnel performing under this contract to work on or develop proposal(s) for funding for activities in which they had access to privileged information.
D. A clear discussion of how the Contractor would counter an assertion that there would be unfair access to information by prohibiting transfer of personnel performing the existing contract to the division planned to support the new proposed effort (precluding transfer of information).
E. A clear explanation of how management reporting chains will be restructured so that work is isolated in different elements of the company (precluding transfer of information).

F. A clear explanation of how the Contractor intends to organize itself such that all new work under the proposed new contract effort will be performed by a division that has no contract responsibilities or management of the existing contract that is causing the COI (to assure objectivity).
G. A clear explanation of steps it will take to ensure any personnel hired under this contract, including sub-Contractors and consultants adhere to the approved conflict of interest mitigation and non-disclosure plans.
H. The plan shall contain an annual review and reporting requirement to the Project Officer which details any breaches of the plan, how they were resolved, and any additional efforts the Contractor will undertake to prevent any additional occurrences."

SECTION 7: OPTIONS

The Government expects to award a contract with a base period of performance of 2 years and may exercise the option to extend the period of performance on an annual basis for up to 5 additional years.

In addition, options may be exercised to increase the level of effort to be provided under the contract in increments of 10 full time equivalents (FTEs). Increases will be added to the base level of effort for a period of one year and may be renewed for future years 2 through 7 of the contract period of performance. The maximum level of effort to be supported under this contract is 157 FTEs.

Describe proposed strategies to rapidly expand the staff in increments of ten (10) additional FTEs. In addition, describe proposed plans for and demonstrate capabilities to provide project management, facilities, equipment and other resources to implement this option.

Describe proposed strategies to rapidly expand the staff in increments of ten (10) additional FTEs. This should include a discussion which demonstrates the offeror's understanding of the knowledge, experience and expertise required to carry out the functions specified in the Statement of Work. In addition, describe proposed plans for and demonstrate capabilities to provide project management, facilities, equipment and other resources to implement this option.

SECTION 8: OTHER CONSIDERATIONS

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

a) Information Technology (IT) Systems Security

The IT System Security Plan (SSP) details the overall security infrastructure for the systems. It includes details of the system, the various controls of the system, the information security policies of the organization, and any connections that the system has to other systems internal and external to the organization. The National Institute for Standards and Technology (NIST) has developed a Special Publication NIST SP-800-18 Revision 1 Guide for Developing Security Plans for Federal Information Systems, (http://www.csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf). The Contractor can use this document as a guideline for developing the SSP. The SSP should be provided to the Project Officer in electronic and paper format within 60 days of contract award.

Section L of the RFP specifies the minimum documentation requirements for IT Systems security. All related documentation should be included in the Technical Proposal in this clearly marked section. The Technical Proposal should include a plan for IT Systems security as required by this RFP.

ATTACHMENT 8
ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS
NIAID HIV/AIDS Scientific and Operations Support
NIH-NIAID-DAIDS-08-33

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

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

BUSINESS PROPOSAL – TABLE OF CONTENTS

SECTION 1 – PROPOSAL COVERSHEET (use form NIH 2043 identified in Section J).

SECTION 2 – COST OR PRICE SUPPORT
Section L of the RFP specifies the minimum documentation requirements for cost data and all cost related support. All related documentation should be included in the proposal in a clearly marked section.

SECTION 3 – UNIFORM COST ASSUMPTIONS
Uniform Budget Assumptions:

a. Domestic and International Travel Costs (excluding Data Safety Monitoring Board Costs): All offerors are to include a uniform assumption of $104,000/year for domestic travel and $336,000/year for international travel for staff and meeting travel. This amount should be inflated in accordance with the offeror's proposed rate of inflation.

The estimate for international travel costs are based on the following:

International Location	Attend conference assume 3 days/site	Site visit, laboratory audit, training assume 2 days
United Kingdom	1	0
Europe (Netherlands, Belgium, Portugal)	14	0
Central Africa (Uganda or Kenya)	0	11
West Africa (Cameroon, Senegal)	1	5
South Africa	2	6
China	0	2
Cambodia	0	2
India	0	2
Thailand	0	3
South America (Brazil, Peru)	0	2
Puerto Rico	1	0
Canada	7	0

b. Data Safety Monitoring Board Support (DSMB). Offerors should propose honoraria, travel and meeting costs for this activity. The NIAID anticipates there will be three meetings per year for each of four (4) DSMBs; for a total of 12 meetings. Each DSMB will generally have eight members. Honorarium will not exceed the Government rate of $250/day. It is expected that 50% of the time, the meetings will be held in Bethesda, Maryland and the remaining meetings will be held in Durbin, South Africa. The members of the DSMB will be 50% U.S. residents and 50% international.

SECTION 4 – OPTIONS

Option to Extend the Period of Performance
A separate business proposal must be submitted for each Option. The Government expects to award a contract with a base period of performance of 2 years (12/1/07 – 11/30/09). The Government anticipates exercising options to extend the period of performance on an annual basis from 12/1/09 through 11/30/14.

Option to Increase the Level of Effort
A total of 77 Full Time Equivalents (FTE) is required for the base contract period. A level of effort/term type contract is anticipated. This level of effort will remain stable throughout the period of the contract. If additional effort is required, we will exercise options to address this need.

Options may be exercised to increase the level of effort to be provided under the contract in increments of 10 FTE. Increases will be added to the base level of effort for a period of one year and maybe renewed for future years 2 through 7 of the contract period of performance. For example, if an option is exercised to increase the level of effort by 10 FTE in Year 2, the additional 10 FTE will be needed through Year 7 when the contract expires. The maximum level of effort to be supported under this contract is 157 FTE. Offerors should assume (for proposal purposes only) the following schedule for exercising options to increase the level of effort:

Base Year 1	No options will be exercised for additional level of effort
Base Year 2	1 option will be exercised for additional level of effort (10 FTE)
Option Year 3	2 options will be exercised for additional level of effort (10 FTE each)
Option Year 4	2 options will be exercised for additional level of effort (10 FTE each)
Option Year 5	2 options will be exercised for additional level of effort (10 FTE each)
Option Year 6	1 option will be exercised for additional level of effort (10 FTE)
Option Year 7	No options will be exercised for additional level of effort

The following breakdown of the anticipated labor mix for the 10 FTE is provided for estimating and purposes only. The labor mix will depend on the activities surrounding the need for increased level of effort and will be determined at the time the option is to be exercised:

Clinical Program Manager	100%
Clinical Study Manager	50%
Lab Management Specialist	50%
Laboratory Program Specialist	50%
Medical Officer	50%
Nurse Consultant	50%
Pharmacist	50%
Program Analyst	100%
* Program Manager	100%
Program Specialist	50%
Project Manager	100%
Senior Administrative Program Spec.	100%
Senior Data Manager	50%
Task Leader	50%
Technical Writer-Editor	50%

SECTION 5 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

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

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

3) Past Performance Data, including references
Section L of the RFP specifies the minimum documentation requirements for providing past performance information. This information should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.