SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1. Purchase Authority: Public Law 92-218 as amended		
2. **Request for Proposal (RFP) Number:** RFP-NIAID-DAIT-NIHAI2008049	3. **Issue Date:** September 18, 2008	4. **Set Aside:** [ ] No [X] Yes See Part IV Section L
5. Title : Statistical and Clinical Coordinating Center for Autoimmune Disease Clinical Trials		
6. ISSUED BY: Office of Acquisitions National Institute of Allergy and Infectious Diseases National Institutes of Health 6700B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612		7. SUBMIT OFFERS TO: See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.
8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 3:00 p.m. local time on January 9, 2009. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.		
9. THE OFFICIAL POINT OF RECEIPT FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY IS THE ADDRESS PROVIDED FOR THE OFFICE OF ACQUISITIONS AS STATED IN ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH HHSAR CLAUSE 352.215-70, ENTITLED, "LATE PROPOSALS, AND REVISIONS" LOCATED IN SECTION L.1. OF THIS SOLICITATION.		
10. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. http://www.ccr.gov		
11. FOR INFORMATION CALL: Deborah Blyveis PHONE: 301-594-7211 e-MAIL: Blyveisd@NIAID.NIH.GOV COLLECT CALLS WILL NOT BE ACCEPTED.		
6700B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612		David T. Lisle Contracting Officer and Team Lead, AIT-RCB Office of Acquisitions National Institute of Allergy and Infectious Diseases, NIH, DHHS

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PART I - THE SCHEDULE

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

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

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The Statistical and Clinical Coordinating Center for Autoimmune Disease Clinical Trials (SACCC-ADCT) provides critical services for the design, implementation, oversight (including regulatory support and compliance, safety and clinical site monitoring and reporting, training, and distribution and quality control of study products), and analysis of DAIT-supported autoimmune disease clinical trials (ADCT) and associated mechanistic studies being conducted by two cooperative groups: The Autoimmunity Centers of Excellence (ACE) and The Stem Cell Therapy Consortium.

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

a. The estimated cost of this contract is $ TBD.

b. The fixed fee for this contract is $ TBD. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer, and 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, is $ TBD.

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

e. It is estimated that the amount currently allotted will cover performance of the contract through TBD.

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

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

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

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

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

a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated September 18, 2008, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

b. The applicable Privacy Act System of Records Number will be specified and shall be used in any design, development, or operation work to be performed under the resultant contract. Disposition of records shall be in accordance with SECTION C of the contract, and by direction of the Project Officer(s).

ARTICLE C.2. REPORTING REQUIREMENTS

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

a. **Technical Progress Reports**

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

   For proposal preparation purposes only, it is estimated that in addition to the required electronic version(s) 1 hard copies of these reports will be required as follows:

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

2. **Summary of Salient Results**

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

3. **Annual Technical Progress Report for Clinical Research Study Populations**

   The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. The Contractor shall submit this information in the format indicated in the attachment entitled, "Inclusion Enrollment Report," which is set forth in SECTION J of this contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report.

   The Contractor shall submit the report in accordance with the DELIVERIES Article in SECTION F of this contract. In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October, 2001 applies. If this contract is for Phase III clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website:

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

   Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol as approved by the IRB, and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

b. **Other Reports/Deliverables**

1. **Source Code and Object Code**

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

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

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

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

The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

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

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

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

SECTION D - PACKAGING, MARKING AND SHIPPING

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

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, the Project Officer is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Division of Allergy, Immunology and Transplantation
6610 Rockledge Drive
Bethesda, MD 20892

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

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

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

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this contract shall be from August 10, 2009 through August 9, 2016.

ARTICLE F.2. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the Items specified in the Delivery Schedule which are described in Attachment 4, "Reporting Requirements and Deliverables". The items specified in the Delivery Schedule 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 therein.

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

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

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

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

To be specified prior to award.

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

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

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.270-5 (January 2006)

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

(End of Clause)

The following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title
To be specified in contract.	

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

a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted as follows:

    a. One original to the following designated billing office:

    National Institutes of Health

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

E-Mail: NIAIDOAInvoices@niaid.nih.gov

The Contractor shall submit an electronic copy of the payment request to the approving official in lieu of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in a format compatible with the computer systems at NIH [e.g., MS Word, MS Excel, or Adobe Portable Document Format (PDF). ***Only one invoice should be submitted per e-mail. [Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]***

2. In addition to the requirements specified in FAR Subpart 32.9 for a proper invoice, the Contractor shall include the following information on all payment requests:

    a. Name of the Office of Acquisitions: Office of Acquisitions, National Institute of Allergy and Infectious Diseases.

    b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NIAIDOAInvoices.

    c. Vendor Identification Number. This is the 7 digit number that appears after the Contractor's name in Block 7 of Standard Form 26. *[Note: This only applies to new contracts awarded on/ after June 4, 2007, and any existing contract modified to include the number.]*

    d. DUNS number or DUNS+4 that identifies the Contractor's name and address exactly as stated on the face page of the contract.

    e. Identification of whether payment is to be made using a two-way or three-way match. This contract requires a Two-Way match.

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

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

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

ARTICLE G.4. INDIRECT COST RATES

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

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6100 Building, Room 6B05

6100 EXECUTIVE BLVD MSC-7540
BETHESDA MD 20892-7540

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

ARTICLE G.5. GOVERNMENT PROPERTY

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

http://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 evaluation(s) shall be submitted.

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

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

b. Electronic Access to Contractor Performance Evaluations

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

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

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

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

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

ARTICLE H.2. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

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

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

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

ARTICLE H.3. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

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

ARTICLE H.4. NEEDLE EXCHANGE

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

ARTICLE H.5. PRESS RELEASES

Pursuant to the current HHS annual appropriations act, the Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the

percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

ARTICLE H.6. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING SCIENTIFIC INFORMATION

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

ARTICLE H.7. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

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

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

ARTICLE H.8. SALARY RATE LIMITATION LEGISLATION PROVISIONS

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

b. Payment of direct salaries is limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred. See the following Web site for Executive Schedule rates of pay: http://www.opm.gov/oca/. *(For current year rates, click on Salaries and Wages / Executive Schedule / Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages / cursor to bottom of page and select year / Executive Schedule / Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)*

ARTICLE H.9. PRIVACY ACT, HHSAR 352.270-11 (January 2006)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as HHS employees. These provisions also apply to all subcontracts awarded under this contract which require the design, development or operation of the designated system(s) of records (5 U.S.C. 552a(m)(1)).

The contract work statement: (a) Identifies the system(s) of records and the design, development, or operation work to be performed by the Contractor; and (b) specifies the disposition to be made of such records upon completion of contract performance.

(End of clause)

45 CFR Part 5b contains additional information which includes the rules of conduct and other Privacy Act requirements and can be found at: http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr5b_06.html.

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. This document is also available at: http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm.

ARTICLE H.10. INFORMATION SECURITY

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

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

a. Information Type

[ ] Administrative, Management and Support Information

[X] 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

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)

   [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).

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

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

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

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

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

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

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

d. Information Security Training

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

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

e. Rules of Behavior

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

f. Personnel Security Responsibilities

Contractor Notification of New and Departing Employees Requiring Background Investigations

1. The Contractor shall notify the Contracting Officer, the Project Officer, and the Security Investigation Reviewer **within five working days** before a new employee assumes a position that requires a suitability determination or when an employee with a security clearance stops working under the contract. The Government will initiate a background investigation on new employees requiring security clearances and will stop pending background investigations for employees that no longer work under the contract.

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

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

1. Contractor Agreement

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

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

2. Contractor-Employee Non-Disclosure Agreements

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

h. NIST SP 800-53 Self-Assessment

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

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

The annual update shall be submitted to the Project Officer, with a copy to the Contracting Officer.

i. Information System Security Plan

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

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

requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels of this Article.

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

j. Common Security Configurations

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

ARTICLE H.11. STORAGE FACILITY REQUIREMENTS AND CERTIFICATION

The Contractor shall ensure that all materials generated under this contract for which commercial records storage is required, shall be stored in a facility that meets National Archives and Records Administration (NARA) requirements for safe, secure and certified storage as required by 36 CFR 1228, subpart K.

The Contractor shall provide the Contracting Officer with the name(s) and location(s) of the commercial records storage facility used to store materials under this contract. In addition, the Contractor shall provide a copy of the "Facility Standards for Records Storage Facilities Inspection Checklist," self-certifying that the facility being used to store federal records meets established NARA standards. NARA Standards are available at: http://www.archives.gov/about/regulations/part-1228/k.html

Sixty (60) days prior to contract end date, the Contractor shall submit to the Project Officer and Contracting Officer, an inventory of all materials stored. The disposition of these materials shall be determined no later than the expiration date of the contract.

ARTICLE H.12. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY (January 2008)

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, and/or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 provisions is available at http://www.section508.gov/. The complete text of Section 508 Final provisions can be accessed at http://www.access-board.gov/sec508/provisions.htm.

The Section 508 standards applicable to this contract/order are identified in the Statement of Work. The contractor must provide a written Section 508 conformance certification due at the end of each order/contract exceeding $100,000 when the order/contract duration is one year or less. If it is determined by the Government that EIT products and services provided by the Contractor do not conform to the described accessibility in the Product Assessment Template, remediation of the products and/or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor at its own expense.

In the event of a modification(s) to the contract/order, which adds new EIT products and services or revised the type of, or specifications for, products and services the Contractor is to provide, including EIT deliverables such as electronic documents and reports, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products and services support Section 508 accessibility requirements. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at http://508.hhs.gov.

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

Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding increment funding for a subsequent performance period under this contract, as applicable, the Contractor must

provide a Section 508 Annual Report to the Contracting Officer and Contracting Officer's Technical Representative (also known as Project Officer or Contracting Officer's Representative). Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available at: http://508.hhs.gov/ under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding incremental funding, as applicable.

Schedule for Contractor Submission of Section 508 Annual Report:

The anniversary date of the contract.

[End of HHSAR 352.270-19(c)]

ARTICLE H.13. CONFIDENTIALITY OF INFORMATION

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

ARTICLE H.14. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.270-6, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

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

ARTICLE H.15. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

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

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

ARTICLE H.16. YEAR 2000 COMPLIANCE

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

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

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

(End of Clause)

2. **Noncommercial Supply Items Warranty**
YEAR 2000 WARRANTY--NONCOMMERCIAL SUPPLY ITEMS

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

YEAR 2000 COMPLIANT ITEMS
TBD

(End of Clause)

3. **Commercial Supply Products Warranty**
YEAR 2000 WARRANTY--COMMERCIAL SUPPLY ITEMS

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

YEAR 2000 COMPLIANT ITEMS
TBD

(End of Clause)

ARTICLE H.17. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

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

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

ARTICLE H.18. SHARING RESEARCH DATA

A data sharing plan must be submitted with the proposal and must be approved by the Office of Acquisitions. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

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

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

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

ARTICLE H.19. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at: http://www.usfa.fema.gov/hotel/index.htm.

ARTICLE H.20. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

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

ARTICLE H.21. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

Beginning April 7, 2008, NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html.

ARTICLE H.22. GUIDELINES FOR INCLUSION OF WOMEN, MINORITIES, AND PERSONS WITH DISABILITIES IN NIH-SUPPORTED CONFERENCES

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

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

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

See the policy announcement for additional details and definitions at:
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-066.html

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

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

General Clauses for a Cost-Reimbursement Research and Development Contract

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

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

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

c. FAR Clauses **52.219-9, Small Business Subcontracting Plan** (April 2008), and **52.219-16, Liquidated Damages--Subcontracting Plan** (January 1999) are deleted in their entirety.

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

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (December 2007).

2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (December 2007).

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

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

3. FAR Clause **52.219-6, Notice of Total Small Business Set-Aside** (June 2003).

4. FAR Clause **52.219-14, Limitations on Subcontracting** (December 1996).

5. FAR Clause **52.222-29, Notification of Visa Denial** (June 2003).

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

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** (December 2007).

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

    Additional purposes for which the limited rights data may be used are:

    TBD.

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

    Additions to, or limitations on, the restricted rights set forth in the Restricted Rights Notice of subparagraph (g)(4) of the clause are expressly stated as follows: TBD.

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

    Specific data items that are not subject to paragraph (j) include: TBD.

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

14. FAR Clause **52.227-17, Rights in Data--Special Works** (December 2007).

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

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

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

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

1. *HHSAR Clause **352.224-70, Confidentiality of Information** (January 2006).*

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

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

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

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

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

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

This contract incorporates the following clauses in full text.

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

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

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

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

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

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

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

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

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and
(ii) Within 60 to 120 days prior to the exercise date specified in the contract for any option thereafter.

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

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

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

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

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

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

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

(End of clause)

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

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

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

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

Notice to Employees

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

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

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

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

To locate the nearest NLRB office, see NLRB's website at http://www.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 2021, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

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

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

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c).
For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint

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

(End of Clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal (R & D)	See Attachment Section at the end of this RFP.
Attachment 2:	Proposal Intent Response Sheet	See Attachment Section at the end of this RFP.
Attachment 3:	Statement of Work	See Attachment Section at the end of this RFP.
Attachment 4:	Reporting Requirements and Deliverables	See Attachment Section at the end of this RFP.
Attachment 5:	Additional Technical Proposal Instructions and Format for Technical Proposal; and Table of Contents	See Attachment Section at the end of this RFP.
Attachment 6:	Additional Business Proposal Instructions and Uniform Cost Assumptions	See Attachment Section at the end of this RFP.
Attachment 7:	Advanced Understandings	See Attachment Section at the end of this RFP.
Attachment 8:	Additional RFP Materials	See Attachment Section at the end of this RFP.

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 9:	Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Attachment 10:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Attachment 11:	Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 12:	Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Attachment 13:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	http://oamp.od.nih.gov/contracts/BUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls
Attachment 14:	Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Attachment 15:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 16:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 17:	Privacy Act System of Records Number 09-25-0200	http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm
Attachment 18:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Attachment 19:	Government Property Schedule	To be determined during negotiations.
Attachment 20:	Commitment to Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Attachment 21:	Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Attachment 22:	Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST:

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

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

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. **GENERAL INFORMATION**

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

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

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

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

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

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

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

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

(c) Submission, modification, revision, and withdrawal of proposals.

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

(2) The first page of the proposal must show--

(i) The solicitation number;

(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);

(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) Submission, modification, revision, and withdrawal of proposals.

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

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

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

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

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

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

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

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

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

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

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

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

(e) Restriction on disclosure and use of data.

(1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:

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

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

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

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

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

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

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

(f) Contract award.

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

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

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

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

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

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

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

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

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

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

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

> *(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.*
>
> *(ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.*
>
> *(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;*
>
> *(iv) A summary of the rationale for award.*

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

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

(End of Provision)

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

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

b. **NOTICE OF SMALL BUSINESS SET-ASIDE**

1. **General.** Bids or proposals under this procurement are solicited only from small business concerns. The procurement is to be awarded only to one or more such concerns, organizations, or individuals. This action is based on a determination by the Contracting Officer, alone or in conjunction with a representative of the Small Business Administration, that it is in the interest of maintaining or mobilizing the Nation's full productive capacity, or in the interest of war or national defense programs, or in the interest of assuring that a fair proportion of Government procurement is placed with small business concerns. Bids or proposals received from others will be considered non-responsive.
2. **Definitions.** The term "small business concern" means a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts, and can further qualify under the criteria set forth in the regulations of the Small Business Administration (13 CFR 121.3-8). In addition to meeting these criteria, a manufacturer or a regular dealer submitting bids or proposals in his own name must agree to furnish in the performance of the contract end items manufactured or produced in the United States, its territories and possessions, Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia, by small business concerns, provided that this additional requirement does not apply in connection with construction or service contracts.

c. **NAICS CODE AND SIZE STANDARD**

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

1. The North American Industry Classification System (NAICS) code for this acquisition is 541711.
2. The small business size standard is 500.

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

It is anticipated that one will be made from this solicitation and that the award will be made on/about August 10, 2009.

It is anticipated that the award from this solicitation will be a multiple-year Cost-Reimbursement type Completion contract with a Term of 7 Years, and that incremental funding will be used (See Section L.2.c. Business Proposal Instructions).

e. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 16 FTEs per year. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

f. **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.

g. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

h. **RELEASE OF INFORMATION**

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

i. **PREPARATION COSTS**

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

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

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

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

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

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

(End of provision)

2. **INSTRUCTIONS TO OFFERORS**

a. **GENERAL INSTRUCTIONS**

INTRODUCTION

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

1. **Contract Type and General Clauses**

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

2. **Authorized Official and Submission of Proposal**

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

   I. COVER PAGE

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

   II. TECHNICAL PROPOSAL

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

   III. BUSINESS PROPOSAL

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

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

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

4. **Separation of Technical and Business Proposals**

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

5. **Alternate Proposals**

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

6. **Evaluation of Proposals**

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

7. **Potential Award Without Discussions**

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

8. **Use of the Metric System of Measurement**

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

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

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

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

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

9. **Standards for Privacy of Individually Identifiable Health Information**

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

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

10. **Privacy Act - Treatment of Proposal Information**

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

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

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

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

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

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

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

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

11. **Selection of Offerors**

    a. The acceptability of the scientific 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.

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

12. **Institutional Responsibility Regarding Conflicting Interests of Investigators**

    45 CFR Part 94 promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research to be performed under NIH contracts will be biased by any conflicting financial interest of an Investigator. The Institution shall comply with all requirements of 45 CFR Part 94 at http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=cc7504e541bc62939c52389e9afc27d5&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45.

13. **Past Performance Information**

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

    A list of the last 5 contracts completed during the past three years and ALL CONTRACTS currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as $550,000.

    Include the following information for each contract or subcontract listed:

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

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

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

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

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794D), as amended by the Workforce Investment Act of 1998, and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Provisions (36 CFR part 1194), require that, unless an exception applies, all EIT products and services developed, acquired, maintained, or used by any Federal department or agency permit:

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

Accordingly, any vendor submitting a proposal/quotations/bid in response to this solicitation must demonstrate compliance with the established EIT accessibility provisions. Information about Section 508 provisions is available at http://www.section508.gov/. The complete text of Section 508 Final Provisions can be accessed at http://www.access-board.gov/sec508/provisions.htm.

The Section 508 standards applicable to this solicitation are identified in the Statement of Work/ Specification/Performance Work Statement. In order to facilitate the Government's evaluation to determine whether EIT products and services proposed meet applicable Section 508 accessibility standards, offerors must prepare an HHS Section 508 Product Assessment Template, in accordance with its completion instructions, and provide a binding statement of conformance. The purpose of the template is to assist HHS acquisition and program officials in determining that EIT products and services proposed support applicable Section 508 accessibility standards. The template allows vendors or developers to self-evaluate their products or services and document in detail how they do or do not conform to a specific Section 508 standard. Instructions for preparing the HHS Section 508 Product Assessment Template may be found at http://508.hhs.gov.

Respondents to this solicitation must also provide any additional detailed information necessary for determining applicable Section 508 standards conformance, as well as for documenting EIT products and/or services that are incidental to the project, which would constitute an exception to Section 508 requirements. If a vendor claims its products and/or services, including EIT deliverables such as electronic documents and reports, meet applicable Section 508 standards in its completed HHS Section 508 Product Assessment Template, and it is later determined by the Government - i.e., after award of a contract/order, that products and/or services delivered do not conform to the described accessibility in the Product Assessment Template, remediation of the products and/or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor at its expenses.

(End of provision)

15. **Prohibition on Contractor Involvement with Terrorist Activities**

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

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a. *Data Universal Numbering System (DUNS) Number, FAR Provision 52.204-6 (April 2008).*

b. *Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).*

c. *Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).*

d. *Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).*

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

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

b. **TECHNICAL PROPOSAL INSTRUCTIONS**

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

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

1. **Technical Discussions**

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

a. **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

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

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

3. Methods

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

4. Schedule

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

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. Single Principal Investigator/Project Director

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

2. Other Investigators

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

3. Additional Personnel

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

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

4. Resumes

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

2. **Other Considerations**

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

   a. Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
   b. Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
   c. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
   d. Other factors you feel are important and support your proposed research.
   e. Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

3. **Technical Evaluation**

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

4. **Obtaining and Disseminating Biomedical Research Resources**

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

the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

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

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

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

a. **Sharing Research Data**

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

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan in its technical proposal for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:

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

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

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

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

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

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

a. Information Type

[ ] Administrative, Management and Support Information:

[X] Mission Based Information:

b. Security Categories and Levels

Confidentiality Level:	[ ] 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)

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

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

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

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

d. Information Security Training

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

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

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

e. Offeror's Official Responsible for Information Security

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

f. NIST SP 800 53 Self Assessment

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

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

g. Draft Information System Security Plan

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

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

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

h. Common Security Configurations

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

i. References

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

   The following NIST publications may be found at the following site: http://csrc.nist.gov/publications/
   [Note: The search tool on the left side of this page provides easy access to the documents.]
4. NIST Special Publication 800-16, Information Technology Security Training Requirements; and
   Appendix A-D
5. NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems
6. NIST SP 800-26, Revision 1, Computer Security
7. NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems
8. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I; and
   Volume II, Appendices to Guide For Mapping Types of Information and Information Systems To Security Categories, Appendix C, and Appendix D
9. NIST SP 800-64, Security Considerations in the Information System Development Life Cycle
10. FIPS PUB 199, Standards for Security Categorization of Federal Information and Information Systems
11. FIPS PUB 200, Minimum Security Requirements for Federal Information and Information Systems

c. **BUSINESS PROPOSAL INSTRUCTIONS**

1. **Basic Cost/Price Information**

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

2. **Proposal Cover Sheet**

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

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

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

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

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

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

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

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

   1. **Direct Labor**

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

   2. **Materials**

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

   3. **Subcontracted Items**

      Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $550,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source

and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. **Raw Materials**

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

5. **Purchased Parts**

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

6. **Fringe Benefits**

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

7. **Indirect Costs**

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

8. **Special Equipment**

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

9. **Travel**

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

10. **Other Costs**

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

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

(a) Exceptions from cost or pricing data.

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

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.
(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;
(B) For market priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;
(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

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

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

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

(End of provision)

Alternate I** (October 1997) of FAR Clause **52.215-20, Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data** (October 1997). As prescribed in 15.408(l), **substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:
(b)(1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

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

5. **Salary Rate Limitation in Fiscal Year 2008**

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

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

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

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

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

6. **Other Administrative Data**

   a. **Property**

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

         a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.

         b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

      2. Government Property

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

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

         b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;

c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and

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

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

3. Government-Furnished Property

   No Government Furnished Property is offered for this acquisition.

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

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

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

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

(End of Provision)

c. **Financial Capacity**

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

d. **Incremental Funding**

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

Incremental Funding, HHSAR 352.232-75 (January 2006)

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

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

(End of provision)

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

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

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

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

(End of Provision)

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

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

*[ ] Fac Cap Cost of Money (Has Not) **has not** specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.*

7. **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.

8. **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

9. **Proposer's Annual Financial Report**

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

10. **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

11. **Travel Costs/Travel Policy**

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

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

12. **Certification of Visas for Non-U.S. Citizens**

    Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its outlying areas, then the offeror must indicate in the proposal that these individuals have the required visas.

SECTION M - EVALUATION FACTORS FOR AWARD

1. **GENERAL**

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost, and past performance. Although technical factors are of paramount consideration in the award of the contract, past performance, and cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost. The Government intends to make an award to that offeror whose proposal provides the best overall value to the Government.

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

2. **EVALUATION OF DATA SHARING PLAN**

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy.

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

3. **EVALUATION CRITERIA**

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

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

CRITERIA	**WEIGHT**
CRITERION 1: TECHNICAL PLAN/APPROACH	**120**

The ability to perform the scientific, clinical and technical functions specified in the Statement of Work as evidenced by the soundness, appropriateness, adequacy, and feasibility of the following:

1) Statistical Design and Analysis, and Protocol Development (45)

A. Statistical Design
Organizational experience and proposed plans and procedures to:

1. perform the statistical design and feasibility assessment functions specified in the Statement of Work for clinical trial Concept Proposals and Full Proposals, clinical protocols, mechanistic and non-interventional studies, and preclinical safety study evaluations; and
2. identify major problems and/or deficiencies encountered in statistical design functions, and recommending and implementing corrective actions.

B. Statistical Analysis
Organizational experience and proposed plans and procedures to perform the statistical analysis functions for clinical trials and for mechanistic and non-interventional studies specified in the Statement of Work.

C. Protocol Development
Organizational experience and proposed plans and procedures to:

1. assist with the clinical, medical, pharmacological/pharmacokinetic, toxicologic, chemistry and manufacturing aspects of clinical protocol development;
2. identify common problems and difficulties encountered in developing clinical protocols, and recommend and implement corrective actions; and
3. prepare and/or assist in preparing protocol-related documents required for the implementation of clinical trials.

2) Clinical Trial Implementation Activities (50)

A. Regulatory Activities
Organizational experience and proposed plans and procedures to support regulatory activities, including:

1. assisting with preparation of statistical design and analysis components, documents, and materials for pre- and post-IND/CTA or IDE/CTA submissions;
2. annual IND/CTA or IDE/CTA reporting;
3. written communications and oral presentations to regulatory health authorities;
4. systems of records for regulatory submissions and communications and Sponsor Essential Clinical Documents;
5. electronic tracking of safety reports;
6. compliance with GCP, GLP and GMP guidelines and requirements;
7. audits; and
8. regulatory affairs administrative and management support.

B. Clinical Site Monitoring

1. Organizational experience and proposed plans and procedures for performing all clinical site monitoring and reporting functions specified in the Statement of Work, including proposed processes, SOPs, forms, templates and work instructions.
2. Description of clinical site performance problems and deficiencies, and remedial actions recommended and implemented.

C. Data Management, Safety Oversight, and Reporting

1. Data Management and Reporting

    a. The proposed computer-based systems, system capabilities, and plans and procedures for system implementation, operation, and maintenance of a relational database management system including back-up and disaster recovery procedures and query abilities.

    b. The plans for quality control and reporting for all clinical and laboratory data and Adverse Event (AE) and Serious Adverse Event (SAE) information, including compliance with current Federal regulations and globally-accepted standards.

2. Safety Oversight and Reporting

    a. Organizational experience and proposed plans and procedures for carrying out the safety oversight and reporting functions specified in the Statement of Work, including:

        i. developing DSMPs;

        ii. presenting final draft protocols and interim analyses to, addressing questions from, and summarizing results of deliberations of safety oversight structures; and

        iii. establishing and managing the Safety Reporting Center, including proposed computer-based system, SOPs, forms and evaluation, quality control and notification procedures.

    b. Discussion of problems and deficiencies in study site AE and SAE reporting and improvements recommended and implemented.

D. Study Product Preparation, Receipt, Distribution and Quality Control

1. *Preparation of Study Products*
Organizational experience and proposed plans and procedures for over-encapsulation, relabelling and repackaging of study materials, performance of associated release and stability testing, identify testing, and SOPs for these activities.

2. *Receipt, Distribution and Quality Control of Study Products*
Organizational experience and proposed plans and procedures for:

    a. receipt, storage, repackaging, distribution, quarantine, quality control, inventory and disposal of study products, including safety and security procedures;

    b. evaluating protocols for pharmaceutical needs and practice;

    c. assisting site pharmacists in establishing research pharmacies, SOPs and QA programs; and

    d. establishing websites for clinical site pharmacists.

E. Repository of Biological Specimens
Organizational experience and proposed plans and procedures for operating and managing a repository of biological specimens, including:

1. procedures and processes from specimen receipt and verification to storage and final distribution;

2. the proposed computerized specimen tracking and inventory database management system; and

3. operational and risk reduction capabilities, quality assurance systems, and plans for back-up/disaster recovery contingencies.

3) Other activities (25)

A. Clinical Study Collaboration Portals and Training

1. *Clinical Study Internet-based Collaboration Portals*
Organizational experience and proposed plans and procedures to establish, maintain, and update clinical study-specific collaboration portals.

2. *Training*

    a. Organizational experience and proposed plans and procedures for developing and conducting training programs for clinical site personnel for both regulatory requirements/guidelines and protocol-specific procedures and requirements.

    b. Proposed plan for initial and ongoing training of site monitors, identification of training problems/ deficiencies, and improvements recommended and implemented.

B. Other Technical and Administrative Support
Organizational experience and proposed plans and procedures for coordinating and supporting the administrative aspects of NIAID safety oversight structures, the ACE Steering Committee, the Consortium Operations Committee and SMTs, including preparation of SOPs and summaries of meetings/ teleconferences.

C. Initial Transition
Proposed plan for the secure, orderly and efficient transfer and/or receipt of clinical and laboratory data, study-related materials, and other contract-generated resources, including

1. timelines and detailed plans to ensure a seamless transition of currently enrolling studies;
2. detailed plans for database transition; and
3. plan to provide final study reports and other required regulatory reports for all studies in transition.

D. Quality Assurance/Quality Control
Organizational experience and proposed QA/QC Plan and procedures for:

1. standardizing contract processes;
2. ensuring the quality and validity of all SACCC activities, including compliance with regulatory requirements and other guidelines;
3. metrics/measures to assess performance, quality and timeliness;
4. methods to document and address problems/deficiencies; and
5. plans for training Contractor staff on internal QA/QC procedures.

CRITERION 2: SCIENTIFIC AND TECHNICAL PERSONNEL 50

Appropriateness and adequacy of the education, training, experience, expertise, qualifications and effort of proposed scientific and technical personnel of the offeror and all proposed subcontractors.

1) Principal Investigator: Includes expertise, experience, and training to carry out contract requirements with respect to the following:

A. statistical design, development and analysis of all phases of clinical trials;
B. management, coordination and oversight of statistical design and analysis components of pre-IND and IND submissions;
C. design and management of data collection and quality control systems;
D. management and coordination of safety oversight and reporting functions;
E. the provision of statistical design and data coordination functions in support of clinical trial networks and other regulatory, monitoring and support service organizations; and
F. interactions and collaborations with government sponsors, government-supported clinical investigators and clinical trial networks, and industry collaborators in protocol design, development, execution, oversight, analysis and reporting.

2) Other Scientific and Technical Personnel: Includes the adequacy of the proposed mix of staff expertise, experience, and training to carry out contract requirements with respect to the following:

A. statistical design and analysis;
B. specialized services for the development of clinical protocols;
C. preparation of protocol-related documents and regulatory submissions;

D. preparation and/or evaluation of manufacturing procedures and methods for generating investigational products;

E. safety oversight support, including DSMP development and evaluations of AE and SAE Reports;

F. information technology support, including database management and website design and maintenance;

G. operation and management of repository functions; and

H. receipt and distribution of study products.

CRITERION 3: FACILITIES, EQUIPMENT AND OTHER RESOURCES **15**

The availability and suitability of the facilities, equipment and other resources of the offeror and all proposed subcontractors for conducting the SACCC functions specified in the Statement of Work, including:
1) central data management facility and off-site back-up facility;
2) central facility to serve as the Safety Reporting Center, including telephone help line;
3) facilities and equipment for repository of biological specimens;
4) facilities and equipment for study product preparation and for receipt, storage, inventory, distribution, quarantine and disposal of study products;
5) clinical study internet-based collaboration portals;
6) computers, hardware, software, and security systems in place;
7) controlled access areas for secure storage of study data and confidential study information; and
8) webcast and video capabilities for training purposes that can be uploaded to the internet.

CRITERION 4: PROJECT MANAGEMENT **15**

1) Adequacy of the plan for project management in terms of staffing, organization, responsibilities, leadership and lines of authority for the offeror and all proposed subcontractors.
2) Suitability of systems proposed for tracking project activities and monitoring progress, timelines, and budgets.
3) Suitability of the plan for how the PI will communicate with the Project Officer and the Contracting Officer, as well as establish, monitor and manage the lines of communication between all performance sites and activities.
4) Suitability of the plan for soliciting, evaluating, negotiating, awarding and managing any proposed subcontracts in accordance with Federal regulations.
5) Adequacy of the experience and education of contract management staff in the acquisition and management of subcontracts under Federal contracts.
6) Adequacy of experience in identifying and remediating subcontractor performance problems or noncompliance with subcontract terms and conditions.

TOTAL POSSIBLE WEIGHT: **200**

Other Factors:

1. HUMAN SUBJECT EVALUATION
   Protection of Human Subjects from Research Risks, Data and Safety Monitoring, Women and Minorities, Children
2. EVALUATION OF DATA SHARING PLAN
3. PAST PERFORMANCE FACTOR

4. **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.

PACKAGING AND DELIVERY OF THE PROPOSAL

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

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

A. EXTERNAL PACKAGE MARKING:

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

"**RFP-NIAID-DAIT-NIHAI2008049**
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
Deborah Blyveis Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214 Bethesda, Maryland 20817	Deborah Blyveis Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612

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

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

C. NUMBER OF COPIES:

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

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

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

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

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

CREATING AND NAMING ELECTRONIC FILES:

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

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

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

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

3. CDs should be named using the following format:

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

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

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

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

Document	Number of Copies	Page Limits
Technical Proposal and all Appendices	**PAPER** One (1) unbound SIGNED ORIGINAL. Six (6) unbound COPIES **ELECTRONIC FILES ON CD** Three (3) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices)	**Not to Exceed 300 pages (inclusive of all Attachments and Appendices)**
Business Proposal	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** Three (3) Compact Disks containing an electronic copy of the Business Proposal	N/A
Breakdown of Proposed Estimated Cost using Electronic Cost Proposal EXCEL Workbook	This Attachment to the Business Proposal should be submitted as a separate EXCEL file on the Business Proposal Compact Disk. **See Section J, Attachment entitled Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet to access the Excel Workbook.**	N/A

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DAIT-NIHAI2008049
RFP Title: Statistical and Clinical Coordinating Center for Autoimmune Disease Clinical Trials (SACCC-ADCT).

Please review the attached Request for Proposal. Furnish the information requested below and return this page by November 1, 2008. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

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

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

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

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

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

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

RETURN VIA FAX OR E-MAIL TO:
OA, NIAID, NIH
Room 3214
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Debbie Blyveis
RFP-NIH-NIAID-DAIT-NIHAI2008049
FAX# (301) 480-4675
Email : blyveisd@NIAID.NIH.GOV

ATTACHMENT 3: STATEMENT OF WORK

STATISTICAL AND CLINICAL COORDINATING CENTER FOR AUTOIMMUNE DISEASE CLINICAL TRIALS (SACCC-ADCT) RFP-NIAID-DAIT-NIHAI2008049

1) BACKGROUND and INTRODUCTION:

Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Department of Health and Human Services (DHHS), strives to better understand, treat, and ultimately prevent immunologic, infectious, and allergic diseases. The NIAID Division of Allergy, Immunology, and Transplantation (DAIT) supports extramural basic, pre-clinical and clinical research focusing on immune-mediated diseases through a variety of research grants and contracts. This includes support for clinical research to evaluate the safety and efficacy of therapeutic and preventive approaches and agents and to elucidate the underlying mechanisms of such approaches and agents.

The Statistical and Clinical Coordinating Center for Autoimmune Disease Clinical Trials (SACCC-ADCT) provides critical services for the design, implementation, oversight (including regulatory support and compliance, safety and clinical site monitoring and reporting, training, and distribution and quality control of study products), and analysis of DAIT-supported autoimmune disease clinical trials (ADCT) and associated mechanistic studies being conducted by two cooperative groups:

- **The Autoimmunity Centers of Excellence** (ACE) program is designed to accelerate the discovery, development, and testing of new immunological therapies for autoimmune diseases. This program fosters collaborations between basic and clinical scientists and supports cooperative single- and multiple-site Phase 1 and 2 clinical trials, as well as associated mechanistic studies. It was established in 1999 and expanded in 2004 to the current 9 sites with a total annual budget of $11.6 million. Since 2004, 13 protocols have been developed or are in development; of these 6 protocols have initiated enrollment and 3 are in follow-up or have been completed. The program will be renewed in FY 2009 (RFA-AI-08-010; http://grants.nih.gov/grants/guide/rfa-files/RFA-AI-08-010.html) under the co-sponsorship of NIAID, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), the National Institute of Arthritis, Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Neurological Disorders and Stroke (NINDS), and the NIH Office of Research on Women's Health. This recompetition is expected to be comparable in size to the current program.

- **The Stem Cell Therapy Consortium** (hereinafter referred to as "Consortium") was created in 1999 through the award of several contracts to study hematopoietic stem cell transplantation (HSCT) for the treatment of autoimmune diseases (http://www.niaid.nih.gov/contract/archive/9931rfp.htm). The contracts resulted in the opening and active enrollment of clinical protocols using high dose immunosuppressive therapy (HDIT),

followed by HSCT for the treatment of Severe Systemic Sclerosis (SSC) and Multiple Sclerosis (MS). In addition to clinical outcomes, mechanisms of disease, remission and relapse are evaluated as part of these studies. The SSC trial is a Phase II/III pivotal trial evaluating safety and clinical efficacy in subjects with severe, rapidly progressive systemic sclerosis. (See http://clinicaltrials.gov/ct2/show/NCT00114530.) The Phase II single arm MS trial focuses on safety and the assessment of biological activity using MRI measures and clinical outcomes. (See http://clinicaltrials.gov/ct2/show/NCT00288626.)

The initial SACCC-ADCT contract was awarded to Rho Federal Systems, Inc. in 2002 (Contract Number N01-AI-25481) and has served to provide a broad range of clinical research support services to the ACE and the Consortium networks. Under this contract, those services will be continued and will also be expanded to provide support for DAIT-funded investigators conducting autoimmune disease clinical trials (ADCT) outside the ACE and Consortium networks through a variety of mechanisms, for example, the NIAID R34/U01 mechanism (http://www.niaid.nih.gov/ncn/clinical/R34.htm).

2) SCOPE:

A. Scope of Autoimmune Diseases, Study Populations and Clinical Research:

1. all autoimmune diseases may be studied by the supported groups and investigators;
2. study populations may include adults, children, pregnant women, and other vulnerable populations; and
3. clinical research projects include interventional studies with biologic and non-biologic agents and investigations of response to vaccination or immunization with licensed and unlicensed products, as well as non-interventional studies to support the development of interventional clinical trials. It is expected that these studies will include obtaining blood and other samples for mechanistic studies.

B. Scope of Clinical Research Support Services: The Contractor shall establish and manage the SACCC-ADCT to provide statistical, clinical, technical, regulatory and administrative support for autoimmune disease clinical trials and associated mechanistic studies, including support for the following:

1. statistical design and analysis, including interim and final analyses of study data;
2. data collection, management, quality assurance and reporting;
3. regulatory activities, including compliance with Federal and country-specific regulatory requirements and current Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and Good Manufacturing Practice (GMP) guidelines for research involving human subjects;
4. safety oversight and reporting, including support for the activities of independent Data and Safety Monitoring Boards (DSMBs) and other safety oversight structures;
5. clinical site monitoring and training for clinical site personnel;
6. preparation of study products;
7. distribution and quality control of study products; and

8. establishment and management of a repository for biological specimens.

In addition, technical and administrative support shall be provided for the ACE Steering Committee and the Consortium Operations Committee.

C. In carrying out these functions, SACCC-ADCT staff, including the SACCC-ADCT Principal Investigator (PI), shall serve as members of Study Management Teams (SMTs) established for each DAIT-approved clinical trial and shall be responsible for working with DAIT staff and DAIT-supported investigators in the development of clinical protocols and protocol-related documents, protocol/study execution, safety oversight and reporting, and statistical analysis. SACCC-ADCT staff shall also serve as members of Product Development Teams.

D. The SACCC-ADCT PI shall serve as a member of the ACE Steering Committee and the Consortium Operations Committee and shall participate in decision-making by these groups, including reviewing and prioritizing clinical trial and mechanistic study proposals, as well as developing and implementing policies, procedures and processes to guide the research activities of these programs.

3) TECHNICAL REQUIREMENTS:

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

A. STATISTICAL DESIGN

1. ACE and Consortium Clinical Trials and Mechanistic Studies

   a. Provide statistical design expertise to the ACE and the Consortium networks and participate in the preparation of: (1) Concept Proposals and Full Proposals to test the safety and/or efficacy of immunomodulatory and tolerogenic approaches to prevent and/or treat autoimmune diseases; (2) Concept Proposals and Full Proposals to elucidate the underlying mechanisms of the investigational approaches/agents being evaluated; and (3) protocols approved for implementation by DAIT. Project design expertise shall include appropriate autoimmune disease-specific and stem cell transplantation-specific medical expertise. Assistance in the preparation of Concept Proposals, Full Proposals and study-specific protocols shall include the following:

      (1) definition of the research questions to be addressed;
      (2) selection of appropriate study populations and control or comparison groups;
      (3) development of inclusion and exclusion criteria;
      (4) calculation of sample size requirements for statistical significance;
      (5) definition of clinical end-points and immune/surrogate markers;
      (6) selection of randomization and stratification methods;
      (7) definition of the number and type of patient biological samples and proposed methods for their collection; and

(8) assessment of the feasibility of recruiting and retaining adequate numbers of study participants.

b. Assistance in the preparation of Concept Proposals, Full Proposals and protocols for mechanistic studies shall also include:

(1) definition and establishment of parameters associated with the techniques and methodologies to be used to assess underlying mechanisms;
(2) determination of the type, number, and volume of patient samples required; and
(3) analyses of new techniques and methodologies, including comparison with standard approaches to the measurement of disease stage, activity and clinical outcome.

2. DAIT-Funded Investigator-Initiated Clinical Studies

Provide statistical design expertise for and participate in the development of protocols for investigator-initiated clinical trials and mechanistic studies designed to elucidate the natural history, outcomes, and treatment-related changes associated with autoimmune disease. These studies may also include investigations of individuals at high risk of developing autoimmune disease and the validation of biomarkers and other tools for assessment of individuals with autoimmune disease. Based on study progress and/or the results of interim analyses of study data, recommend modifications in the design of ongoing clinical trials and mechanistic studies with respect to statistical parameters, including sample size, control or comparison groups, clinical endpoints and immune/surrogate markers.

3. Preclinical Safety Study Evaluations:

Provide statistical expertise for and participate in evaluating the accuracy and validity of data from preclinical safety studies in support of clinical trials.

4. Assistance for clinical trials and mechanistic studies post-study initiation shall include:

a. preparing interim reports on subject accrual, retention, compliance, loss to follow-up and other statistical issues and problems relevant to the conduct of clinical trials and mechanistic studies;
b. developing recommendations for proposed modifications to study design to resolve identified issues and problems;
c. presenting of such reports, data and recommendations to Study Management Teams (SMTs); and
d. assisting in implementing SMT-approved modifications in study designs.

B. STATISTICAL ANALYSIS

In collaboration with ADCT investigators, design and conduct interim and final statistical analyses of study data, prepare reports on the status of clinical

trials and mechanistic studies, participate in the preparation of scientific manuscripts and reports for publication and presentation at scientific meetings, and submit reports to appropriate Regulatory Health Authorities. All reports shall be compliant with International Conference on Harmonization (ICH) E3 guidelines (http://www.ich.org/cache/compo/475-272-1.html#E3). This includes the following:

1. Preparation of interim and final analyses of:

    a. the safety and efficacy of investigational products/approaches evaluated in ADCT clinical trials; and
    b. the validity, reliability and specificity of techniques and methodologies used to assess underlying mechanisms and to study surrogate/biomarkers.

2. Preparation of Interim and Final Study Reports including those required by Regulatory Health Authorities within 10 business days of study analysis completion.

3. Review of the accuracy and completeness of statistical data and data analyses for all abstracts, manuscripts, and presentations reporting on the results studies conducted by the ADCT investigators prior to presentation or submission for publication.

4. Collaboration with NIAID-support entities through:

    a. sharing statistical analyses and underlying dataset(s) with collaborating groups, such as Immune Tolerance Network (ITN) (http://www.immunetolerance.org/). This may include electronic transfer of datasets in a standard format such as SAS data transfer files; and
    b. providing study completion dataset(s), in compliance with NIH data sharing requirements (http://grants.nih.gov/grants/policy/data_sharing/), to a NIAID-designated entity at the completion of the final study reports. It is expected that these files shall be transferred electronically through the Immunology Database and Analysis Portal (https://www.immport.org/immportWeb/home/home.do) supported by the NIAID Bioinformatics Integrated Support Contract (BISC) (http://www3.niaid.nih.gov/about/organization/dait/bisc.htm).

C. PROTOCOL DEVELOPMENT AND STUDY INITIATION

1. Assign a statistician to serve as a member of each SMT to provide expert advice and assistance in the development of protocols for clinical trials and mechanistic studies. This includes:

    a. developing and refining experimental study designs and statistical analysis plans;
    b. reviewing successive versions of protocols, recommending improvements and modifications in statistical design features to facilitate recruitment and retention of appropriate study participants,

and ensuring the validity and reliability of inclusion/exclusion criteria and comparator/control groups; and

c. assessing the validity and reliability of the techniques and methods to be used to delineate underlying mechanisms.

2. Assist in the preparation of protocol-related documents and materials, including:

   a. Manuals of Operations (MOOs) with specific instructions, requirements and guidelines for study conduct, including the clinical protocol, study forms, procedures for the collection, testing, storage and shipping of patient samples, and procedures for data collection, entry, verification and storage;
   b. Investigator Brochures (IBs) as described in 21 CFR 312.23 (a) (5), (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.23) using results of pre-clinical and clinical testing from reports, reprints and other data available from investigators or pharmaceutical companies;
   c. electronic or paper Case Report Forms (CRFs) and worksheets;
   d. informed consent forms;
   e. source documents, questionnaires, memory aids and subject instructions;
   f. screening and recruitment logs;
   g. order forms for clinical supplies; and
   h. test article accountability logs.

3. Plan and develop materials for study initiation meetings/teleconferences to provide training for clinical site personnel with respect to standard and protocol-specific procedures for the collection, entry and submission of clinical trial data to the central data management facility; standard and study-specific procedures and instructions for the preparation and submission of AE and SAE Reports to the Safety Reporting Center; and access to and use of internet-based Collaboration Portals. Participate in study initiation meetings/teleconferences to provide appropriate training for study site personnel.

D. REGULATORY ACTIVITIES

Provide technical and administrative assistance to the Project Officer, the DAIT Office of Regulatory Affairs (ORA), other DAIT scientific staff, investigators at DAIT-supported clinical sites and industry collaborators in carrying out the following functions relating to the sponsorship of Investigational New Drug (IND) or Investigational Device Exemption (IDE) applications. In instances where the NIAID or a DAIT-supported investigator serves as the IND or IDE sponsor, the Contractor shall provide the full spectrum of support services delineated below. In instances where a company serves as the IND or IDE sponsor, the Contractor may be responsible for carrying out a subset of the regulatory support functions delineated below.

1. Regulatory Submissions and Reports

   Prepare, submit, distribute, track, and archive all regulatory submissions and communications with Regulatory Health Authorities during the conduct of each DAIT-sponsored ADCT.

   a. Regulatory Health Authority Submissions: Provide technical and administrative assistance in the preparation, assembly, and submission of: (i) original INDs or IDEs for clinical trials to be conducted in the U.S.; (ii) original Clinical Trials Applications (CTAs) for clinical trials to be conducted outside the U.S.; (iii) all amendments to these applications including: Adverse Event Reports (e.g., IND Safety Reports and Serious Unexpected Adverse Event Reports (SUSARs)); IND or IDE Annual Reports; Protocol Amendments; and responses to Regulatory Health Authority requests for information. Assistance shall include:

      (1) Writing, editing, indexing, assembling, duplicating documents and mailing of submissions to the appropriate Regulatory Health Authorities, DAIT staff, investigators, and pharmaceutical companies. All regulatory submissions shall be prepared in compliance with U.S. Federal requirements as described in 21 CFR Part 312 and all applicable foreign Regulatory Health Authority requirements, including the European Union (EU) Clinical Trial Directive 2001/20/EC (www.eortc.be/Services/Doc/clinical-EU-directive-04-April-01.pdf).

      (2) The capacity to file regulatory submissions in electronic format when required by Regulatory Health Authorities.

      (3) Where necessary, obtaining letters from pharmaceutical company sponsors and/or individual investigators authorizing the Regulatory Health Authorities to refer to their previously submitted applications, including INDs, IDEs, CTAs, New Drug Applications (NDAs), Biologics License Applications (BLAs), Drug Master Files (DMFs), Investigational Medicinal Product Dossiers (IMPDs).

      (4) Monitoring of regulatory submissions and following-up on unresolved tasks using project management tracking tools.

   b. Regulatory Health Authority Meetings and Teleconferences: Assist in preparing materials (including information briefing packages) for and participate in meetings and teleconferences with officials of Regulatory Health Authorities to address questions and provide additional information pertinent to regulatory submissions, including statistical design and statistical analysis plans. Prepare and submit, for review and approval by the Project Officer or his/her designee, written summaries of major decisions and action items resulting from all such meetings and teleconferences within five (5) business days of meeting or teleconference completion.

   c. Inquiries from Regulatory Health Authorities: Assist in the preparation and submission of responses to correspondence from Regulatory Health Authorities relating to INDs, IDEs and CTAs held by DAIT, companies

and DAIT-supported investigators. Functions include: (i) obtaining, reviewing and assembling relevant information; (ii) preparing draft response letters for review and approval by the Project Officer or his/her designee; (iii) submitting materials to Regulatory Health Authorities; and (iv) and distributing copies of all final responses to the Project Officer and other individuals and groups as directed by the Project Officer, such as DAIT staff, individual investigators, and industry collaborators.

d. IND/CTA or IDE/CTA Annual Reports

(1) Assist DAIT and ADCT investigators in the preparation of IND, IDE and CTA sponsor's Annual Reports, as required by Regulatory Health Authorities and in accordance with 21 CFR 312.33 and all applicable foreign Regulatory Health Authority requirements, including the European Union (EU) Clinical Trial Directive 2001/20/EC (www.eortc.be/Services/Doc/clinical-EU-directive-04-April-01.pdf). This includes the following:

(a) Providing the specific information, including statistical and clinical information in the form of data tables, listing and figures, to address the following major areas for IND/CTA or IDE/CTA Annual Reports:

i. individual Study Information: Summary of trial status
ii. summary Information, including: the most frequent and most severe adverse events by body system; IND or IDE Safety Reports; list of deaths and causes; list of dropouts; new information on mechanism of action of the investigational product or device; summary of preclinical studies; and manufacturing changes
iii. updated General Investigational Plan
iv. updated Investigator Brochure
v. phase I protocol modifications not submitted as amendments
vi. relevant Publications, including the results of literature searches for relevant publications and narrative summaries of relevant publications

(b) Retrieving and summarizing information compiled from:

i. lists of all previous submissions to the Regulatory Health Authority
ii. regulatory Health Authority communication chronologies
iii. pharmaceutical company information
iv. the most recent protocol versions
v. schema depicting the protocol
vi. comparison charts of protocol requirements
vii. listings and/or summaries of relevant abstracts, posters, papers and presentations
viii. copies of adverse event summary reports

(2) Develop and submit, for Project Officer review and approval, a timeline for IND/CTA or IDE/CTA Annual Report preparation and submission; submit Draft IND/CTA or IDE/CTA Annual Reports for review and approval by the Project Officer or his/her designees according to the approved timeline; revise Draft IND/CTA or IDE/CTA Annual Reports, as necessary; submit Final IND/CTA IDE/CTA Annual Reports to Regulatory Health Authorities; and provide copies to the Project Officer and his/her designees.

e. System of Records for Regulatory Health Authority Documents

(1) Electronic System of Records for Regulatory Health Authority Documents

(a) Establish, operate, maintain and manage, using commercially available software, one or more state-of-the-art computer-based systems at a central facility for the collection, storage, tracking, updating, reporting and archiving of all Regulatory Health Authority documents, including all IND/CTA or IDE/CTA submission, correspondence, briefing materials, and written summaries of meetings and teleconferences with Regulatory Health Authorities. The system must allow for password protected, remote access to all documents to view, search, and offer customizable report capabilities to the Project Officer and his/her designees. Reports shall include the number of submissions made in a specified time period, the types of submissions filed in a specified time period, due dates for Annual Reports, status of responses to Regulatory Health Authority inquires and requests, and ADCT clinical trial start and end dates.

(b) Within one (1) month of the contract effective date, submit, for review by the Project Officer, his/her designees and DAIT ORA, a Draft Electronic Regulatory Health Authorities Records Plan that identifies the software package for the computer-based systems to be used; describes the types of reports to be generated; defines the metadata used to store and retrieve documents; and lists the documents to be filed. The Plan shall also include Standard Operating Procedures (SOPs) for maintaining the computer-based systems, including procedures for performing upgrades, validations, audit trails and monthly internal audits to support the servers, back-up servers, databases, software and network. Revise the Draft Plan in accordance with Project Officer transmitted comments, and submit the Final Plan for approval by the Project Officer, his/her designees, and for review by DAIT ORA within seven (7) business days of receipt of comments.

(c) Within two (2) months of receipt of approval of the Final Electronic Regulatory Health Authorities Records Plan, submit, for review by the Project Officer, his/her designees and DAIT ORA, a Draft Implementation Plan for the establishment, maintenance and updating of the system(s) that includes SOPs

and timelines for all activities required to fully implement the approved system(s). Revise the Draft Implementation Plan in accordance with Project Officer transmitted comments, and submit the Final Implementation Plan within 7 business days of receipt of comments. Implement the approved plan and ensure that the system(s) for all Regulatory Health Authority documents is fully operational within two (2) months of receipt of Project Officer written approval of the Implementation Plan.

(d) Update all Regulatory Health Authority documents and materials throughout the contract period of performance, and provide email notifications of the availability of new or revised documents and materials to all individuals with authorized access.

(e) Perform periodic quality assurance checks of the Regulatory Health Authority documents and materials stored in the system(s) at no less frequent intervals than bi-annually. Within one (1) month of completion of each system quality assurance check, prepare and submit, for review by the Project Officer, his/her designees and DAIT ORA, a report detailing the results obtained, including any problems or deficiencies identified and recommendations for remedial/corrective actions to resolve problems and deficiencies. Implement remedial/corrective actions within one (1) month of receipt of Project Officer approval.

(f) The electronic system of records must meet the following requirements:

i. Security against catastrophic loss of data or important software, to include an off-site secured storage facility for system back-ups and a disaster recovery plan.
ii. Quality assurance and quality control procedures to evaluate and, when necessary, improve the accuracy, timeliness and completeness of data submitted for inclusion in the Electronic System of Records.
iii. Provision for the appropriate labeling, storage, handling, and disposal of sensitive or confidential data, media, and output.

(2) Paper System of Records for Regulatory Health Authority Documents

(a) Maintain paper copy files of Regulatory Health Authority documents and materials and store in binders, in locked, limited access, fire and water-protected storage areas, in an orderly manner easily accessible to designated Contractor staff, the Project Officer and his/her designees, and DAIT ORA staff.

(b) Within one (1) month of the contract effective date, submit, for review by the Project Officer, his/her designees and DAIT

ORA, a Draft Paper Regulatory Health Authorities Records Plan for the storage of paper copies of Regulatory Health Authority documents and materials that includes SOPs for the organization, filing of documents and materials, safeguarding the confidentiality of documents and materials, access by Contractor staff, and access by DAIT staff designated by the Project Officer. Revise the Draft Paper Regulatory Health Authorities Records Plan in accordance with Project Officer transmitted comments, and submit the Final Paper Regulatory Health Authorities Records Plan for approval by the Project Officer, his/her designees and DAIT ORA within 7 business days of receipt of Project Officer transmitted comments. Implement the approved Plan and ensure that the paper system of records for all Regulatory Health Authority documents and materials is fully operational within one (1) month of receipt of Project Officer written approval of the Plan.

f. Status Reports on Regulatory Activities and Requirements

Prepare and submit to the Project Officer, his/her designees and DAIT ORA monthly status reports for tracking of regulatory activities and requirements, including:

(1) listing all IND/CTA or IDE/CTA submissions filed, categorized by type of submission;
(2) listing of the status of all IND/CTA or IDE/CTA Annual Reports, including due dates and status of preparation; and
(3) status of responses to Regulatory Health Authority requests for information.

2. Sponsor Essential Clinical Documents and System of Records

Establish and maintain the files of Sponsor Essential Clinical Documents for each clinical trial in accordance with current Good Clinical Practice (GCP) requirements (http://www.fda.gov/oc/gcp/regulations.html), and ICH E6 (http://www.ich.org/cache/compo/475-272-1.html#E6), and ensure the accuracy and completeness of each document prior to filing. Sponsor files shall be maintained both electronically and in paper form in a manner that will pass U.S. Food and Drug Administration (FDA) inspection/audit.

a. The Sponsor Essential Clinical Documents shall include all protocols-specific and site-specific documents submitted to the Contractor by participating clinical sites. Documents to be housed in these files are those required to be held by Clinical Trial Sponsors as delineated in (http://www.ich.org/cache/compo/475-272-1.html#E6) and (http://www.fda.gov/oc/gcp/regulations.html), and include the following:

(1) Protocol Master File

- protocols and protocol amendments and investigator signature pages for those documents

- protocol-specific Informed Consent Form templates and amendments
- sample Case Report Forms
- Final Study Reports
- Investigator Brochures for Study Drugs or Devices
- Sponsor correspondence to and from all clinical sites
- randomization codes
- investigational product manufacturer correspondence
- documentation of Transfer of Sponsor Obligations from IND or IDE Sponsor to Contractor.

(2) Protocol Site-Specific File

- all signed Form FDA 1572
- Curriculum Vitae and/or other relevant documentation of qualifications of investigators, including documentation of training
- site-specific Informed Consent Forms and all applicable translations
- signed Informed Consent Forms
- any information provided to clinical trial subjects
- advertisements for subject recruitment (if used)
- Institutional Review Board/Independent Ethics Committee composition
- IRB/EC Approvals for Protocols, Amendments and Informed Consent Forms and amendments
- Regulatory Health Authority(ies) authorization/approval/notification of Protocol (where required)
- IRB/EC Annual Reports/Updates
- updates of medical/laboratory/technical procedures/tests: certification, accreditation or established quality control and/or external quality assessment or other validation (where required)
- normal value(s)/range(s) for medical/laboratory/technical procedure(s)/test(s) included in the protocol
- clinical site monitoring visit reports
- notification by sponsor and/or investigator, where applicable, to Regulatory Health Authority(ies) and IRBs/ICEs of unexpected serious adverse drug reactions and other safety information
- notification by sponsor to investigators of safety information
- signed, dated and completed Case Report Forms (CRFs)
- subject screening log
- subject identification code list
- subject enrollment log
- record of retained body fluids/tissue samples (if any)
- documentation of investigational product(s) and trial-related materials shipment
- Certificate(s) of Analysis for new batches of investigational products
- investigational products accountability at clinical sites
- documentation of investigational product destruction
- correspondence with IRBs/Independent Ethics Committees (ECs)

- Serious Adverse Event Reports and disposition forms.

b. System of Records for Sponsor Essential Clinical Documents

(1) Electronic System of Records for Sponsor Essential Clinical Documents

(a) Establish, operate and manage, using commercially available software, one or more state-of-the-art computer-based systems at a central facility for the collection, tracking, updating, reporting and archiving of all Sponsor Essential Clinical Documents. The system must allow for password protected, remote access to all documents to view, search and offer customizable reporting capabilities to the Project Officer, his/her designees and DAIT ORA staff. Reports shall include documents available by site, by Protocol, and by investigator, and documentation of deficiencies by site, protocol and investigator.

(b) Within one (1) month of the contract effective date, submit, for review and approval by the Project Officer, his/her designees and DAIT ORA staff, a Draft Electronic Sponsor Essential Clinical Documents Plan to include: the computer-based system to be used; the types of reports to be generated; the metadata used to store and retrieve documents; and the documents to be filed. The Plan shall also include SOPs for performing upgrades, validations, audit trails and monthly internal audits to support the servers, back-up servers, databases, software and network. Revise the Draft Plan in accordance with Project Officer transmitted comments, and submit the Final Plan for approval by the Project Officer, his/her designees and for review by DAIT ORA within 7 business days of receipt of comments.

(c) Within two (2) months of the receipt of Project Officer approval of the Final Plan for the Electronic System of Records for Sponsor Clinical Essential Documentation, submit, for review and approval by the Project Officer, his/her designees and DAIT ORA, a Draft Implementation Plan for the establishment, maintenance and updating of the system that includes SOPs and timelines for all activities required to fully implement the approved system. Revise the Draft Plan in accordance with Project Officer transmitted comments, and submit the Final Plan and associated SOPs within 7 business days of receipt of comments. Implement the approved Plan and ensure that the system for all Sponsor Essential Clinical Documents is fully operational within two (2) months of receipt of written Project Officer approval of the Plan.

(d) Update all Sponsor Essential Clinical documents and materials throughout the contract period of performance, and provide email notifications of the availability of new or revised

documents and materials to all individuals with authorized access.

(e) Perform periodic quality assurance checks of the documents stored in the system at no less frequent intervals than bi-annually. Within one (1) month of completion of each system quality assurance check, prepare and submit, for review by the Project Officer, his/her designees and DAIT ORA, a report detailing the results obtained, including any problems or deficiencies identified and recommendations for remedial/corrective actions to resolve problems and deficiencies. Implement remedial/corrective actions approved by the Project Officer.

(f) The system must meet the following requirements.

i. Security against catastrophic loss of data or important software, to include an off-site secured storage facility for system back-ups and a disaster recovery plan.
ii. Quality assurance and quality control procedures to evaluate and, when necessary, improve the accuracy, timeliness and completeness of data submitted for inclusion in the Electronic System of Records for Sponsor Essential Clinical Documents.
iii. Provision for the appropriate labeling, storage, handling, and disposal of sensitive or confidential data, media, and output.

(2) Paper System of Records for Sponsor Essential Clinical Documents

(a) Maintain paper copies of all Sponsor Essential Clinical Documents for each trial and store in binders, in locked, limited access, storage areas protected from potential fire and water damage, in an orderly manner easily accessible to the Project Officer, his/her designees, DAIT ORA staff and appropriate Contractor staff.

(b) Within one (1) month of the contract effective date, submit, for review and approval by the Project Officer, his/her designees and DAIT ORA staff, a Draft Plan for the paper file system of Sponsor Essential Clinical Documents that includes SOPs for the organization and filing of documents, procedures for safeguarding the confidentiality of documents, access by Contractor staff, and access by DAIT staff. Revise the Draft Plan in accordance with Project Officer transmitted comments, and submit the Final Plan for approval by the Project Officer, his/her designees and for review by DAIT ORA within 7 business days of receipt of comments. Implement the approved Plan and ensure that the paper file system for all Sponsor Essential Clinical Documents is fully operational within one (1) month of receipt of written Project Officer approval of the Plan.

c. Status Reports of Sponsor Essential Clinical Documents

Prepare and submit the following status reports to Project Officer or his/her designees:

(1) monthly updates listing, by ADCT and clinical site, the records accumulated and filed to date, noting deficiencies
(2) for IND/CTA or IDE/CTA regulated studies, reports indicating status of submission of site registration documentation to Regulatory Health Authorities to allow shipment of investigational product to the site

3. Electronic Tracking of Safety Reports

a. Establish and maintain an electronic system for the tracking of the distribution and receipt of Adverse Event and other Safety Reports, including Serious Adverse Events (SAE) Reports generated for DAIT-sponsored IND, IDE and non-IND or non-IDE studies, and Safety Reports submitted to DAIT from investigational product or device manufacturers providing safety information in accordance with executed Clinical Trial Agreements.

b. Within one (1) month of the contract effective date, submit for review and approval by the Project Officer, his/her designees and for review by DAIT ORA, a Draft Plan for the design, establishment, maintenance and updating of the electronic tracking system that includes SOPs. Revise the Draft Plan in accordance with Project Officer or designee and DAIT ORA comments, and submit the Final Plan and associated SOPs within seven (7) business days of receipt of comments. Implement the approved Plan and ensure that the system for Electronic Tracking of Safety Reports is fully operational within one (1) month of receipt of written approval of the Plan by the Project Officer.

4. Audits

a. Within three (3) months of the contract effective date, submit, for review and approval by the Project Officer and for review by DAIT ORA, draft written SOPs describing procedures for responding to an audit by (i) DAIT NIAID; and (ii) a Regulatory Health Authority.

b. Revise draft SOPs in accordance with Project Officer transmitted comments, submit final SOPs, and ensure that all Contractor staff are appropriately trained in the use of approved SOPs within five (5) months of the contract effective date.

c. Comply with the requirements of all Project Officer approved audits conducted by DAIT or by Regulatory Health Authorities, including making available for all such audits necessary personnel, facilities, equipment, and records and other documents, including SOPs.

5. Compliance with Current Good Clinical Practices (GCP), Current Good Laboratory Practices (GLP), and Current Good Manufacturing Practices (GMP)

   Provide technical assistance to ensure compliance with U.S. GCP requirements (http://www.ich.org/cache/compo/475-272-1.html#E6 and http://www.fda.gov/oc/gcp/regulations.html), GLP requirements (http://www.fda.gov/ora/compliance_ref/bimo/glp/default.htm), and GMP requirements http://www.fda.gov/cder/dmpq/cgmpregs.htm

   Support in this area includes the following:

   a. Assistance in ensuring compliance with GMP requirements (U.S. Code of Federal Regulations, 21 CFR 210, 211, 820) for studies in which DAIT assumes legal responsibility for product manufacturing. Products may include small molecules, proteins, and cellular therapies. Consultation and assistance on matters related to chemistry, manufacturing, controls requirements include the following:

      (1) Standard Operating Procedures, Master Production Batch Records, Certificates of Analysis, and Project Work Instructions
      (2) executed and completed Production Batch Records
      (3) submissions to Regulatory Health Authorities related to Chemistry, Manufacturing & Controls matters
      (4) analyses of production data
      (5) inspection, reporting, and developing recommendations regarding manufacturing facilities and procedures

   b. Consultation on preclinical and nonclinical requirements for initiation of clinical trials.

   c. Consultation on country-specific regulatory requirements for specific regulatory submissions.

   d. Assistance with permits, applications, and testing requirements for shipment of investigational products to specific countries.

   e. The provision of periodic training in regulatory affairs, GCP, GMP and GLP guidelines for DAIT ORA and/or other DAIT staff. Training topics and scheduling will be determined by the Project Officer or his/her designees.

6. Regulatory Affairs Administrative and Project Management Support

   a. Plan for and participate in monthly meetings or teleconferences with DAIT ORA and the Project Officer, as necessary, to review the status of all regulatory support functions specified in SOW item D, including identified problems and deficiencies and corrective/remedial actions necessary. Prepare agendas and background materials/reports for all monthly meetings and teleconferences, and prepare brief written summaries of all decisions and action items resulting from these meeting and teleconferences and submit to the Project Officer and

DAIT ORA within five (5) business days of meeting/teleconference completion.

b. Review of investigational product labels for compliance with country-specific requirements.

c. Preparation of correspondence and mailings to clinical site investigators to include safety reports and other safety information from DAIT clinical trials and investigational product manufacturers and Investigator Brochures.

d. Provision of courier and/or express mail service, Mondays through Fridays, between the Contractor, the Project Officer, DAIT ORA, and Regulatory Health Authorities as necessary, but no less than weekly.

E. DATA MANAGEMENT AND REPORTING

Establish, administer, and maintain efficient, reliable and responsive computer-based systems for the collection, storage, management, tracking, updating, quality control, archiving and reporting of all clinical and laboratory study data, as well as a computer-based system that is compatible with DAIT computer-based systems and provides for secure electronic communication linkages among ADCT SMTs and their clinical and mechanistic study sites, the Project Officer, DAIT ORA, other DAIT staff, the ACE Steering Committee, and the Consortium Operations Committee. The Contractor shall establish and manage systems that provide for the following features:

1. The collection, computer processing, storage, electronic tracking (participant and specimen) and retrieval of all clinical and laboratory study data at a central data management facility, including the provision of a Relational Database Management System (RDBMS) for the storage and management of all clinical and laboratory data. The RDBMS must be well documented and available either commercially or through open sources. Ensure RDBMS integrity and security, including implementing firewalls and computer virus detection systems. The database shall contain, at a minimum: a) raw data and original results, and b) detailed experimental protocols. The Contractor shall provide for the following in support of the RDBMS:

   a. Bioinformatics expertise to ensure efficient and secure operation. Key bioinformatics experts shall be expected to define, disseminate, and execute Standard Operating Procedures for data management and analysis among the ADCT investigators.

   b. Training and support with the RDBMS to ADCT investigators. Bioinformatics experts shall participate as needed in ADCT meetings.

   c. The Contractor shall transfer clinical and laboratory data to a centralized database developed and maintained through the NIAID Bioinformatics Integration Support Contract (BISC; see http://www.niaid.nih.gov/contract/archive2002.htm for the most recent RFP solicitation and http://www3.niaid.nih.gov/about/organization/dait/bisc.htm for more

information) or to other NIAID Bioinformatics support contractors as designated and directed by the Project Officer.

2. Security against catastrophic loss of study data or important software, to include an off-site secured storage facility for system back-ups and a disaster recovery plan.

3. Central computerized registration and randomization, where appropriate, of all patients on ADCT protocols, or alternative non-computerized methods when appropriate and approved by the Project Officer.

4. Electronic Data Capture systems for the remote entry and transmission of patient data from clinical sites to the central data management facility, or alternative non-computerized methods when appropriate and approved by the Project Officer.

5. Quality assurance and quality control procedures to evaluate and, when necessary, improve the accuracy, timeliness and completeness of data submitted by the clinical sites, including verification of the clinical and laboratory data used to determine that study participants have reached protocol-defined endpoints.

6. Compliance with all current Federal regulations (21 CFR 11 and/or similar statutes, http://www.fda.gov/cber/guidelines.htm) and meeting current globally-accepted standards, including International Conference on Harmonization (ICH) E-2, Clinical Safety Data Management, and ICH M-5, Data Elements and Standards for Drug dictionaries (http://www.ich.org/cache/compo/475-272-1.html and http://www.ich.org/cache/compo/2196-272-1.html).

7. Provision for the appropriate labeling, storage, handling, and disposal of sensitive or controlled data, media, and output.

F. SAFETY OVERSIGHT AND REPORTING

Study Management Teams (SMTs) shall be responsible for developing formal Data and Safety Monitoring Plans (DSMPs) to ensure appropriate monitoring of the safety of all human subjects participating in DAIT-supported clinical trials, and for ensuring appropriate implementation of safety procedures and adherence to safety oversight and reporting requirements. The SACCC-ADCT shall provide the following support for safety oversight and reporting for each clinical trial or study:

1. Data and Safety Monitoring Plans: Assign an appropriately qualified senior statistician to serve as lead author in the development of DSMPs to ensure appropriate monitoring of the safety of study participants in DAIT-sponsored clinical trials in accordance with all applicable Federal and International Conference on Harmonization (ICH) (http://www.pharmacontract.ch/support/su_ich_liste.htm) standards for human subjects research.

2. NIAID Safety Oversight Structures: Assist in carrying out functions associated with ensuring the safety of clinical trial study participants

through safety monitoring by NIAID-established safety oversight structures, including Data and Safety Monitoring Boards (DSMBs), Safety Management Committees (SMCs), and Independent Safety Monitors (ISMs) as commensurate with the anticipated level of risk. The safety oversight functions to be performed include the following:

a. Final Draft and All Subsequent Protocol Amendment Reviews: Arrange for the distribution of Final Draft Protocols and all subsequent protocol amendments for ADCT to members of NIAID safety oversight structures for review and comment, particularly with respect to protocol-specific DSMPs; prepare and make oral presentations at meetings and teleconferences of NIAID safety oversight structures to summarize study plans, including study feasibility, safety considerations and power calculations; review recommendations of NIAID safety oversight structures in conjunction with the Project Officer, his/her designees and SMTs to determine appropriateness/acceptability; and modify Final Draft Protocols as necessary to implement recommendations of safety oversight structures.

b. Review of On-going Clinical Trials: In accordance with the requirements set forth in protocol-specific DSMPs and more frequently, if necessary, the Contractor shall:

   (1) prepare and distribute separate interim analyses of blinded and unblinded study data, including narrative summaries, tables, listings and graphs/figures, for review at both open and closed sessions of meetings and teleconferences of NIAID safety oversight structures;
   (2) prepare and distribute transmittal memoranda highlighting interval changes in safety, efficacy, or other parameters relevant to safety oversight by such structures;
   (3) prepare and distribute summaries of study accrual and retention data, including issues and problems associated with the recruitment and retention of study participants;
   (4) prepare and distribute summaries of study performance data, including information on the timely submission of protocol data, protocol deviations, and other measures of study performance; and
   (5) prepare and make oral presentations at meetings and teleconferences of NIAID safety oversight structures to explain the results of interim analyses and address questions on patient safety.

   All such interim analyses and oral presentations shall be submitted for Project Officer review and approval no later than three (3) weeks prior to scheduled meetings/teleconferences of NIAID safety oversight structures and shall be modified, as necessary, to accommodate Project Officer comments. Final materials for meetings and teleconferences of NIAID safety oversight structures shall be submitted to the Project Officer no later than two (2) weeks prior to scheduled meetings and teleconferences. When requested by the Project Officer, the statistician and other SACCC-ADCT personnel

responsible for preparing these interim analyses and presentations will not include participants on the SMTs for blinded studies.

c. Documentation of Recommendations of NIAID Safety Oversight Structures:
Prepare written summaries, in accordance with NIAID DSMB Policy, of the deliberations and recommendations of NIAID safety oversight structures. Draft written summaries shall be prepared and submitted to the Project Officer and his/her designees within five (5) business days of meeting/teleconference completion and revised in accordance with Project Officer comments provided. Final summaries shall be prepared and submitted to the Project Officer within three (3) business days of receipt of comments. The Project Officer may reduce the time allowed to prepare and finalize written summaries in cases where significant changes in study design of an ongoing clinical trial (e.g., stop a clinical trial or discontinue one arm of a clinical trial) are recommended.

d. Communication of Recommendations of NIAID Safety Oversight Structures:
Assist in preparing and coordinating communication of recommendations of NIAID Safety Oversight Structures to the Project Officer, DAIT ORA, other DAIT staff, clinical investigators and other study site personnel.

3. Safety Reporting: Establish and operate a Safety Reporting Center for clinical trials to carry out safety oversight functions. Ensure that all systems and procedures meet FDA guidelines relating to processing of SAE Reports and the European Union (EU) Clinical Directive (http://www.eortc.be/Services/Doc/clinical-EU-directive-04-April-01.pdf). This includes the following activities:

a. Establish, operate, maintain, and manage one or more databases for the reporting, tracking, and archiving of Adverse Event (AE) and Serious Adverse Event (SAE) Reports from DAIT-supported clinical sites participating in autoimmune disease clinical trials. This shall include an internet data entry system for submission of AE and SAE Reports from clinical sites. Paper forms for the submission of SAE Reports shall be used for sites that do not have internet access and as a "back-up system" for the paperless remote data entry and capture systems for AE and SAE Reports in cases where the paperless systems are unavailable for periods exceeding 12 hours. An analogous system for use in non-IND or non-IDE studies shall also be required.

b. Within one (1) month of the contract effective date, develop and submit, for review and approval by the Project Officer and for review by DAIT ORA, draft generic SOPs for AE and SAE reporting by clinical site personnel, including use of the internet data entry system. Revise draft SOPs in accordance with Project Officer transmitted comments, and prepare and distribute to clinical sites final generic SOPs within two (2) weeks of receipt of comments.

c. Provide training in the use of the internet data entry system for clinical site personnel and DAIT staff.

d. Prepare and distribute to participating study sites protocol-specific AE and SAE reporting forms, developed in accordance with the requirements and anticipated level of risk as defined in the Final Protocol, and protocol-specific instructions detailing events to be documented, clinical data to be recorded, and events to be assessed for seriousness and relatedness. All such SAE reporting forms shall conform to guidelines and regulations of the FDA and/or other regulatory authorities. Forms and instructions shall be submitted to the Project Officer for review and must be approved by the Project Officer prior to randomization of study participants.

e. Establish, staff, operate and maintain a toll-free telephone service for the receipt and triage of telephone calls from study site personnel and to obtain AE and SAE Report information during the hours of 8 a.m. to 6 p.m. Eastern Standard Time, Monday through Friday. Ensure that appropriately trained staff is available to respond to inquiries and obtain information. Provide an automated message service after working hours, on weekends, and on all holidays to record inquiries, and maintain one trained person to be on-call after working hours, on weekends, and on all holidays to respond to inquiries.

f. Within one (1) business day of receipt, evaluate all SAE Reports submitted, including SAE narrative and initial/follow-up data submitted by the investigator, investigator's assessment of severity, and the medical management plan employed for the event; request additional information, as necessary; and abstract a summary of the SAE narrative and enter the abstract into the safety database for the clinical trial.

g. Provide experienced clinical personnel with medical expertise in autoimmune disease and hematopoietic stem cell transplantation to evaluate SAE Reports received from clinical sites, and work with clinical site staff to clarify information, obtain follow-up information, and/or reconcile discrepancies between adverse event data reported versus adverse event data collected on study forms. Experienced clinical personnel may include nursing personnel or, for more complex clinical situations, may include physicians to be determined by the Project Officer on a protocol-specific basis.

h. Establish and implement a system for the email notification of all SAEs to members of SMTs, the Project Officer, DAIT ORA, clinical investigators, and industry collaborators. Email notification shall be distributed within 8 hours of study site notification to the SACCC.

i. Submit DAIT-approved Safety Reports to appropriate Regulatory Health Authorities for NIAID IND and NIAID-funded investigator IND studies.

j. Develop, implement and maintain quality control/quality assurance procedures and ongoing training to ensure consistency, completeness

and accuracy of adverse event reporting, coding and data entry by clinical site personnel. Draft procedures and training plans shall be submitted to the Project Officer for review and approval within one (1) month of the contract effective date, revised in accordance with Project Officer comments, and finalized to ensure implementation no later than one (1) month from receipt of comments.

G. CLINICAL STUDY INTERNET-BASED COLLABORATION PORTALS

1. Establish, maintain and update, on an ongoing basis, one or more internet-based collaboration portals to house clinical trial information and study-specific documents and materials. Protocol-specific, password protected websites must contain the following study-specific information and documents and must provide access for the Project Officer, other DAIT staff, clinical investigators and other clinical site personnel and industry collaborators:

   a. draft and final protocols and protocol amendments;
   b. informed consent forms;
   c. Investigator Brochures and/or package inserts;
   d. instructions for clinical site staff regarding study procedures;
   e. Case Report Forms for the collection of required data on study subjects, including eligibility, demographics (including age, gender and ethnicity), sequential clinical and laboratory outcome assessments, and acute and long-term adverse events;
   f. instructions for study participants;
   g. tracking and dispense logs;
   h. order forms for test articles and clinical supplies;
   i. logs of frequently asked questions with answers;
   j. real-time standard and study-specific data by site and total overall, including accrual, adverse event and serious adverse event listings, protocol deviations, missing forms, visit schedule compliance, data queries, and progress monitoring information/materials; and
   k. other materials at the discretion of the Project Officer and/or Project Officer designated relevant DAIT staff.

2. Update all website documents and materials, including new or modified versions of study-specific documents, during the course of all clinical trials, and provide e-mail notifications of the availability of new or revised documents and materials to all individuals with authorized website access.

3. Within one (1) month of the contract effective date, submit for Project Officer review and approval, a draft plan for the design, establishment, maintenance and updating of collaboration portal(s). Revise the draft plan in accordance with Project Officer comments, and submit the final plan within seven (7) business days of receipt of Project Officer comments.

4. Implement the approved plan and ensure that collaboration portals for all ongoing and planned clinical trials are fully operational within 2 months of the contract effective date.

H. CLINICAL SITE MONITORING AND REPORTING

Establish, implement and maintain a system to monitor clinical sites with respect to adherence to regulatory requirements governing human subjects research, GCP, GMP, GLP and ICH guidelines, and protocol-specific requirements. Clinical site monitoring shall be provided for clinical sites participating in the ACE and Consortium research programs, as well as clinical sites funded under investigator-initiated projects. Clinical site monitoring activities must adhere to the NIH policy for data and safety monitoring, released on June 10, 1998 (http://www.nih.gov/grants/guide/notice-files/not98-084.html).

1. Clinical Site Monitoring Visits

   Plan for and conduct a variety of clinical site monitoring visits to include the following:

   a. Site Establishment Visits:

      (1) Plan for, schedule and conduct site establishment visits for any new clinical sites to assess the adequacy of all site facilities, personnel, and operating procedures to be used for the conduct of clinical trials, including:

         (a) detailed research pharmacy review to include organization, qualifications and training of pharmacy staff and adequacy of facilities and equipment, communication between clinical and pharmacy staff, and pharmacy establishment plan;
         (b) clinical research facilities, including: space for patient screening, administration of investigational products, patient follow-up, outpatient surgical and testing facilities, and inpatient facilities; clinical laboratory facilities and accreditations; patient record storage areas; and storage facilities for biological samples and record keeping; and
         (c) education and training of site personnel with respect to: Federal regulations governing informed consent, Institutional Review Boards, responsibilities of sponsors and investigators, and protection of human subjects from research risks; GLP; and packing and shipping of biological samples. This includes verification that site personnel have completed required human subjects and other training.

      Site establishment visits shall also include a thorough explanation of ACE and Consortium policies and procedures, and, if necessary, the provision of GCP, GMP, and GLP training to appropriate site personnel.

      (2) Provide to the clinical sites undergoing site establishment a description of the personnel, facilities, equipment and other site information to be assessed and instructions on the clinical site personnel and materials to be made available. This information shall be provided to the clinical site no less than one (1) week prior to the scheduled visit.

(3) Prepare and submit, for Project Officer review and approval, written reports of each site establishment visit conducted within one (1) week of site visit completion. Such reports shall summarize the site visit findings and, where appropriate, including recommendations for corrective or remedial actions necessary to ensure the capability of clinical sites to comply with all applicable regulatory requirements, GCP, GMP, and GLP guidelines, and to provide adequately trained personnel and appropriate facilities and equipment for the conduct of clinical trials.

b. Interim Site Monitoring Visits:

(1) Interim site monitoring visits shall be conducted on a quarterly basis for the majority of clinical trials supported under this contract. More or less frequent interim site monitoring visit schedules may be used commensurate with the anticipated level of protocol risk and the characteristics of the individual participating clinical sites as determined by the Project Officer or his/her designees. Interim site monitoring assignments shall be developed quarterly by the Contractor with input and approval by the Project Officer, other DAIT scientific staff and clinical site investigators. Proposed quarterly interim site visit assignments shall be submitted to the Project Officer, other DAIT staff designated by the Project Officer, and clinical site investigators designated by the Project Officer no less than 45 days prior to the start of each quarter, modified in accordance with comments provided by the Project Officer, and finalized no less than three (3) weeks prior to the start of each quarter.

(2) Interim site monitoring visits shall assess the following:

(a) the accuracy, completeness and timeliness of data collection and entry;
(b) adherence to inclusion and exclusion criteria;
(c) accuracy and completeness of reporting of SAEs and protocol violations;
(d) documentation of informed consent and adherence to informed consent procedures;
(e) documentation of objective findings, including verification of endpoints;
(f) maintenance of appropriate source documentation;
(g) adherence to Federal and country-specific regulatory requirements, GLP, GMP, GCP and ICH guidelines, and established ACE and Consortium policies and procedures, and completeness of regulatory files;
(h) adequacy of pharmacy operations, performance and management related to protocol-specific requirements, including study product accountability;
(i) the appropriate collection, storage and transport of patient samples;
(j) clinical records maintenance; and

(k) various components of the operation and management of the clinical sites, including: site management, organization and utilization of the site staff; communication among clinical, technical and administrative staff; and the adequacy of site clinical and laboratory facilities and study equipment.

(3) For all interim site monitoring visits, the clinical sites involved shall be provided with a description of the site-specific activities/protocols to be reviewed, data and other information to be collected/assessed, and instructions on the clinical site personnel and materials to be made available. This information shall be provided to the clinical sites no less than one (1) week prior to the scheduled visit.

c. Site and Study Closeout Visits:

(1) Site and study closeout visits shall be conducted for any clinical site that discontinues participation in an ADCT protocol or discontinues participation in an ADCT research program or project to assess that the site has properly closed out all studies and has followed proper procedures for the storage of records and the disposition of remaining supplies of investigational agents.

(2) For all such visits, the clinical sites involved shall be provided with a description of the site-specific documents, facilities and other information to be reviewed/assessed, and instructions on the clinical site personnel and materials to be made available. This information shall be provided to the clinical site no less than one (1) week prior to the scheduled visit.

2. Clinical Site Monitoring Reports

a. Prepare and submit, for Project Officer review and approval, written reports of all clinical site monitoring visits within one (1) week of site visit completion. All Clinical Site Monitoring Reports shall detail the findings of each site visit, identify site-specific problems and deficiencies, and provide recommendations for improvements and, where necessary, corrective/remedial actions. Critical findings (e.g., any fraudulent findings, invalid signatures, and unreported SAEs) shall be reported to the Project Officer within 24 hours of site visit completion.

b. At the request of the Project Officer, present findings resulting from clinical site monitoring to the ACE Steering Committee and the Consortium Operations Committee.

3. Clinical Site Audits

a. Assist clinical sites in preparing for audits from Regulatory Health Authorities with respect to regulatory requirements for the conduct of human subjects research.
b. Laboratory and specimen audits shall be conducted on an as needed basis to confirm the adequacy of site performance regarding the

collection, routing, and storage of clinical specimens, particularly those specimens used as study endpoints. Such audits shall determine the location of locally stored specimens, ensure that storage facilities are consistent with current guidelines for temperature monitoring and specimen labeling, and confirm that adequate backup storage facilities are available.

4. Clinical Site Monitoring Standard Operating Procedures

   a. Within two (2) months of the contract effective date, submit, for Project Officer review and approval, Draft Standard Operating Procedures (SOPs) governing all aspects of the conduct of site monitoring visits. The Project Officer will review and provide comments and revisions to the draft SOPs within two (2) weeks for finalization by the Contractor within one (1) month of receipt of Project Officer comments.

      (1) Separate SOPs shall be provided for:

         (a) site establishment visits
         (b) interim site visits
         (c) remedial or "for cause" site visits
         (d) site and study closeout visits

      (2) Each SOP shall address the components listed below and provide the forms and templates to be used to record site visit data and other information obtained.

         (a) a description of each aspect of clinical trial conduct and clinical site operations to be reviewed;
         (b) the sources of data and other information to be used to monitor each aspect of clinical trial conduct and clinical site operations;
         (c) detailed work instructions;
         (d) the types of clinical site personnel required to participate;
         (e) scheduling process and procedures for the preparation of participating clinical site personnel, including questions and other materials to be provided to clinical site personnel in advance of site visits, as well as data, documents and other information to be gathered and made available by clinical sites; and
         (f) the average length of time of the site visit and the number of Contractor staff required.

   b. SOP Updates: Keep abreast of all changes in Federal and country-specific requirements governing human subjects research, GLP, GMP, GCP and ICH guidelines, and ACE and Consortium policies and procedures; update SOPs, as necessary, within 20 business days of the effective date of all such changes, and submit updated SOPs for Project Officer review and approval. Updated SOPs shall be implemented by the Contractor only after receipt of written Project Officer approval.

I. TRAINING

Develop and implement training programs for clinical site personnel and site monitors. This shall including the following:

1. Training for Clinical Site Personnel

   Training for clinical site personnel shall encompass: (i) regulatory requirements governing the protection of human subjects from research risks, including the protection of children (http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm); (ii) GCP, ICH, GMP, and GLP guidelines; (iii) ACE and Consortium policies and procedures for protocol development, implementation, and monitoring; (iv) NIH and NIAID policies; and (iv) protocol-specific training on the requirements for the implementation and conduct of individual clinical trials. Clinical site training programs and procedures shall be in compliance with the NIH policy for data and safety monitoring, released on June 10, 1998 (http://www.nih.gov/grants/guide/notice-files/not98-084.html). Specifically, the Contractor shall:

   a. Develop and implement a set of Standard Operating Procedures (SOPs) delineating the policies, procedures and requirements of the NIAID, the NIH, the FDA, other Regulatory Health Authorities, and the ACE and Consortium research programs with respect to the conduct and monitoring of human subjects research and compliance with all applicable regulatory requirements and GCP, GMP, and GLP guidelines. Update SOPs as necessary to reflect changes in regulatory requirements, guidelines or ACE/Consortium-specific policies and procedures; and distribute SOPs to all clinical site personnel. Plan and conduct standardized training for clinical site personnel on policies and procedures for the initiation of ACE/Consortium clinical trials via teleconferences and/or meetings.

   b. In collaboration with the Project Officer, his/her designees, and clinical site investigators, identify training needs for clinical site personnel with respect to regulatory requirements and guidelines, and arrange for and conduct training of clinical site personnel identified via teleconferences or meetings. Such training may be carried out separately or in conjunction with site monitoring visits.

   c. Assist in planning for and conducting protocol-specific training for clinical site personnel to review and ensure understanding of protocol-specific requirements and procedures, Such protocol-specific training shall be conducted via teleconferences or meetings. In carrying out this function, the Contractor shall be responsible for:

      (1) preparation and distribution of agendas, protocols-specific materials and presentations
      (2) collaborative internet platforms for sharing and archiving materials and presentations
      (3) development and implementation of tools for assessing the quality and thoroughness of the training conducted

Agendas, protocol-specific materials, presentation materials, and training assessment tools shall be provided to the Project Officer for review at least five (5) business days prior to each training session.

In addition, results of the assessments conducted shall be provided to the Project Officer within three (3) weeks of training completion, along with recommendations for modifications to improve the content and format of such training sessions.

2. Training of Site Monitors

   a. Within three (3) weeks of the contract effective date, submit, for Project Officer review and approval, a Draft Training Plan delineating all training activities to be conducted for site monitors on staff as well as newly hired site monitors. The Draft Training Plan shall include the following:

      (1) plans for initial and continuing training activities to be carried out both in-house and through non-Contractor organizations;
      (2) frequency of training;
      (3) training methods/approaches (e.g., workshops, videocasts, written materials, webcasts, etc.);
      (4) training curricula, duration and instructors both on staff and from other non-Contractor sources;
      (5) provisions for ensuring that experienced monitors accompany new monitors on initial site visits – both routine and specialized; and
      (6) plans for evaluating the training activities conducted, including evaluation and performance metrics to assess outcomes, effectiveness, and efficiency and identify areas for improvement.

      The Draft Training Plan shall be revised, as necessary, in accordance with Project Officer comments, and the Final Training Plan shall be submitted and implemented within one (1) month of receipt of Project Officer comments.

   b. Provide to the Project Officer annual written assessments of training activities conducted, along with recommendations for modifications to the approved Training Plan to improve effectiveness and efficiency and to incorporate additional training activities relevant to changes in Federal and country-specific regulatory requirements, GCP, ICH, GMP, and GLP guidelines, and ACE or Consortium policies and procedures.

   c. At the end of each year of the contract period of performance, provide to the Project Officer a listing of all training activities conducted and the names of Contractor and any subcontractor staff completing each training program.

   d. Arrange for attendance of DAIT personnel at these training sessions at the request of the Project Officer.

J. PREPARATION OF STUDY PRODUCTS

Establish, operate, manage and maintain a facility for preparation of study products. The functions to be performed at this facility are limited to the capacity for over encapsulation of pills or capsules to obscure identifying marks; relabeling materials provided by other manufacturers; and repackaging and labeling study products provided by other manufacturers. Specifically, the Contractor shall:

1. provide recommendations for labeling and packaging of study products to ensure compliance with applicable regulatory requirements;
2. label and package study products to provide supplies suitable for dispensing to individual patients at clinical sites, using, where applicable, blinding of study products and placebos, including randomization schemes with patient numbers and corresponding treatment assignments and/or labels;
3. maintain accurate records of all such labeled and packaged study products;
4. provide the capability for patient specific, unit of use packaging, including blister packaging, when required;
5. provide the capability to affix auxiliary labels for use on certain products and on outer shipping cartons;
6. provide facilities for the preparation of patient-specific solid and liquid dosage forms to include blinding of study products or placebos;
7. provide documentation of labeling and packaging as needed for regulatory submissions;
8. provide identity testing including appropriate equipment and documentation; and
9. provide SOPs for these activities.

K. RECEIPT, DISTRIBUTION AND QUALITY CONTROL OF STUDY PRODUCTS

Establish, operate, manage, and maintain a system for the distribution and quality control of study products. The Contractor or subcontractor carrying out these functions shall be qualified per all local and Federal regulations to distribute drugs and other agents, including controlled substances, in its jurisdiction. Study products shall be handled either directly by the SACCC-ADCT or shipped directly to clinical site pharmacies. For those study products shipped directly to clinical site pharmacies, the Contractor shall work with site pharmacists to assure both appropriate distribution of study products and quality control. These services shall be available during the hours of 8 am to 6 pm Eastern Standard Time, Monday through Friday.

Specifically, the Contractor shall carry out the following activities:

1. Receipt and Storage of Study Products:

    a. receive shipments of study products from a variety of sources, including domestic contract manufacturers or packagers, commercial pharmaceutical companies, and foreign pharmaceutical companies and suppliers; track and reconcile shipping lists, noting conditions of

receipt; and notify the Project Officer of any discrepancies or problems;
b. receive and process through U.S. Customs any shipments from foreign suppliers;
c. store products as indicated on the manufacturer's label, including providing the necessary storage facilities and equipment;
d. monitor storage conditions to guarantee and document continuous proper storage; and
e. ensure that all applicable FDA GMP regulations are met.

2. Inventory Control/Quality Assurance:

a. perform a physical inventory of supplies for each protocol at least monthly;
b. notify the Project Officer within one (1) business day of any discrepancies that cannot be reconciled with the current inventory;
c. monitor use rate and notify the Project Officer within one (1) business day of low inventories or unusual increases in product requests from clinical sites; and
d. develop, implement, operate and maintain inventory management systems and ensure that such systems allow for publication of files and reports on DAIT secure intranet and/or internet on a regular basis, and provide hard copies of these reports, as directed by the Project Officer. Examples of database files include the following:

(1) Authorized Investigator File;
(2) Manufacturer Name File;
(3) Investigational Agent File;
(4) Drug Inventory File;
(5) Drug Shipment File;
(6) Drug Receipt File; and
(7) Return Drug Shipment File.

3. Shipment and Distribution of Study Products:

a. process Investigational Agent Request forms on a daily basis, confirming that the order is from an authorized ADCT clinical site, fill orders and package the appropriate protocol-specific study product, dosage and quantity;
b. supply shipping cartons, cushioning materials, necessary labels (e.g., fragile), sealing tape, insulation materials, and all other supplies necessary to ensure safe and intact arrival of study products;
c. supply sufficient quantities of appropriate packaging (e.g., wet ice, dry ice, cold packs, temperature recorders) to ensure the safe and intact arrival of study products requiring maintenance at low temperatures;
d. supply reusable, electronic monitoring devices for temperature and humidity monitoring during transit if needed. Provide the software for downloading, reading and reviewing data from the electronic monitoring devices. Evaluate electronic monitoring device data to ensure that clinical agents have been shipped within product specifications. Notify the Project Officer and supplier of any shipping deviations within 24 hours of receipt of the returned electronic

monitoring device. The Project Officer will determine if the clinical agent is acceptable for use;

e. ship study products to ADCT clinical sites so that shipments are received in a timely fashion. Shipments shall arrive at the ADCT clinical site within 24 hours of receipt of Investigational Agency Request Forms unless a longer shipping period is approved by the Project Officer;
f. obtain the appropriate licenses and permits required by local, State and Federal authorities for the safe import, storage and distribution of drugs, as well as the appropriate interstate, intrastate and foreign import/export shipping licenses and permits for transporting biologics and drugs;
g. on occasion, make shipments after hours or on weekends, as required. Except for emergency shipments or other extraordinary tasks, the Contractor/subcontractor shall be open and accessible during the hours of 8 am to 6 pm Eastern Standard Time, Monday through Friday; and
h. provide storage for and package and ship reports, documents, and other relevant materials related to the study products distributed. Retain all original Investigational Agent Request forms for the duration of the contract and ensure their accessibility for audits.

4. Pharmaceutical Services:

a. review ADCT clinical protocols and provide the Project Officer with a written protocol evaluation, usually 1-2 pages in length, including estimates of the quantity of study products needed and comments regarding product handling concerns and/or packaging requirements;
b. provide support to DAIT clinical staff designated by the Project Officer for responding to ad hoc questions related to pharmaceutical services and product information;
c. provide product information (e.g., special handling or shipping, study product preparation) to clinical site pharmacists or study participants with every shipment;
d. provide product ordering, transfer or return information to clinical site pharmacists or study participants;
e. authorize the transfer of products designated for one protocol to another protocol, as permitted by FDA regulations and/or the pharmaceutical sponsor, and maintain copies of Investigational Agent Transfer forms for the duration of the contract;
f. provide evaluations of current study product usage and projections of anticipated requirements to manufacturers on a quarterly basis or as directed by the Project Officer. These evaluations shall be reviewed and approved by the Project Officer prior to forwarding to the manufacturers;
g. prepare protocol-specific documents providing information regarding study product packaging, dosage strength and labeling for distribution to clinical site pharmacists; and
h. establish and maintain a secure website of information, forms and procedures for clinical site pharmacists, including: study products; procedures and forms for ordering study products; procedures and requirements for the return of study products; and instructions to be provided to study participants.

5. Security/Safety and Procedures:

    a. provide 24-hour security to prevent theft, misuse or damage including locked and controlled access to authorized personnel only for study products, records, and logs;
    b. provide an automated 24-hour temperature monitoring system to ensure maintenance of appropriate temperature storage conditions, and programs or systems for fire protection; and
    c. provide training on safety, security and appropriate handling of investigational agents to all personnel with access to the drug storage facility.

    The Contractor shall also be required to meet the requirements of the Drug Enforcement Agency for the storage of controlled substances (http://www.usdoj.gov/dea/pubs/csa.html).

6. Processing and Disposal of Returned Drugs:

    a. identify and notify affected investigators in the event that a lot of study product is recalled by the manufacturer or reaches the limit on its useful shelf life;
    b. receive recalled, expired or unused study products returned from clinical sites and process returns in conformance with local, state and Federal regulations;
    c. provide for the quarantine of returned products from other inventory;
    d. prepare computerized documentation of returns; and
    e. dispose of returned products in a manner prescribed by local, state and Federal regulations.

7. Tracking System: Maintain a dedicated computerized data tracking system for study product inventories and distribution records. All documentation shall be made available for annual audits as required by Federal regulations.

8. Audits by Regulatory Health Authorities and Other Regulatory Agencies: Within two (2) months of the contract effective date, submit to the Project Officer for review, draft SOPs for preparation for, participation in, reporting on, and responding to audits by Regulatory Health Authorities and other regulatory agencies with respect to the facilities, equipment and operating procedures carried out for study product receipt, quality control, distribution, inventory and disposal functions. Revise draft SOPs in accordance with Project Officer comments and submit final SOPs for Project Officer approval within two (2) weeks of receipt of comments.

9. Study Product Resources and Plans: Within three (3) weeks of the contract effective date, submit, for Project Officer review and approval, a Draft Study Product Services Plan comprised of the following: (i) a list of technical and administrative personnel with percent effort and role descriptions; (ii) an administrative framework showing lines of authority and responsibility; (iii) plans and SOPs for each of the functions to be performed; and (iv) timelines for the implementation of plans and SOPs to ensure full functioning of study product services no later than six (6)

weeks from the contract effective date. Revise the Draft Study Product Services Plan in accordance with Project Officer comments, and submit the Final Study Product Services Plan within fifteen (15) business days of receipt of Project Officer comments.

L. REPOSITORY OF BIOLOGICAL SPECIMENS

Establish, operate, manage, and maintain a central repository facility for biological specimens from DAIT-funded clinical trials and mechanistic studies. Specimens may include whole blood, serum, plasma, tissue, isolated cells, urine and other bodily fluids, DNA, and RNA. This shall include the following functions:

1. Secure, receive, catalogue, process, and store human biological specimens from subjects participating in DAIT-sponsored clinical trials and mechanistic studies.

2. Disburse biological specimens to DAIT-approved sites for mechanistic studies. This may include preparing aliquots of samples.

3. Provide shipping materials and documents, technical assistance and training to site personnel on specimen handling and shipping.

4. Develop and implement Standard Operating Procedures (SOPs) and Quality Assurance systems for the central repository facility, including facility operations, procedures for specimen storage, shipping materials and instructions, and personnel in accordance with all applicable Federal, State, and local regulatory requirements.

5. Provide a computerized specimen tracking and inventory database management system, using commercially available software.

6. Provide a technical and administrative infrastructure to ensure efficient planning, initiation, implementation, and management of repository activities. Within fifteen (15) business days of the contract effective date, submit, for Project Officer review and approval, a plan for providing these functions.

7. Provide all equipment, including monitoring systems and security systems, and personnel needed to store biological specimens in the repository in accordance with all applicable Federal, State, and local regulatory requirements.

M. OTHER TECHNICAL AND ADMINISTRATIVE SUPPORT

1. NIAID Safety Oversight Structures: Coordinate and provide technical and administrative support for the activities of NIAID-established safety oversight structures, including Data and Safety Monitoring Boards (DSMBs), Safety Monitoring Committees (SMCs), and Independent Safety Monitors (ISMs). This shall include the following:

    a. Within 3 months of the contract effective date, submit, for Project Officer review and approval, Draft Conflict of Interest (COI) disclosure

forms for all permanent and ad hoc members of NIAID safety oversight structures; revise draft forms in accordance with Project Officer comments and submit Final COI disclosure forms within 10 business days of receipt of Project Officer comments; coordinate the distribution and receipt of completed forms; and provide all completed forms to the Project Officer.

b. Schedule, arrange lodging and meeting room facilities, and arrange teleconferencing services for meetings and conference calls of NIAID safety oversight structures.

c. Distribute copies of all protocols and protocol-related materials for clinical trials and mechanistic studies to members of NIAID safety oversight structures for review.

2. ACE Steering Committee, Consortium Operations Committee and Study Management Teams: Coordinate and provide technical and administrative support for the activities of the ACE Steering Committee, the Consortium Operations Committee, and DAIT-funded Study Management Teams. This shall include:

a. Develop and revise, as necessary, Conflict of Interest (COI) and disclosure forms for all members of the ACE Steering Committee, the Consortium Operations Committee, and investigators serving on Study Management Teams; coordinate the distribution and receipt of completed forms; and provide all forms to the Project Officer for approval.

b. Schedule, arrange lodging and meeting room facilities, and arrange teleconferencing services for:

(1) two 2-day meetings for the ACE Steering Committee per year;
(2) two 2-day meetings of the Consortium Operations Committee per year; and
(3) bi-monthly conference calls for ADCT SMTs.

c. Independently prepare, or assist in the preparation of, and distribute a variety of materials for meetings and teleconferences of the ACE Steering Committee, the Consortium Operations Committee, and SMTs. This shall include:

(1) proposed Concept Proposals for interventional clinical trials, non-interventional studies supportive of clinical trials and mechanistic studies;
(2) detailed draft protocols for such trials and studies;
(3) proposals for modifications in the design of such trials and studies;
(4) status of and issues surrounding FDA approval of INDs or IDEs;
(5) status reports on the implementation of approved clinical trials, mechanistic studies and non-interventional studies, including accrual, retention, loss to follow-up, problems and issues with respect to data management and quality assurance, and

recommendations for modifications/improvements where necessary; and

(6) interim and final analyses of the results of such trials and studies, including recommendations for study modifications to ensure the validity, reliability and feasibility of completing approved studies.

d. Prepare brief summaries of all decisions, recommendations and action items resulting from meetings and teleconferences of the ACE Steering Committee, the Consortium Operations Committee and the SMTs within three (3) business days of meeting/teleconference completion, and distribute to the Project Officer, other DAIT staff, and members of these groups.

e. Assist DAIT, the ACE Steering Committee, the Consortium Operations Committee, and independent ADCT investigators in the preparation of Standard Operating Procedures to govern the research activities of these programs. This shall include policies and procedures for:

(1) the development, review, modification and approval/disapproval of Concept Proposals and Full Proposals for clinical trials and mechanistic studies, detailed protocols for clinical trials, and detailed research designs for mechanistic studies, including the development of criteria for the evaluation;
(2) monitoring progress with respect to the implementation of approved clinical trials and mechanistic studies, including appropriate reporting requirements for ongoing progress reviews and criteria for expanding, curtailing or discontinuing approved studies;
(3) the development and implementation of criteria and procedures for the evaluation of clinical and mechanistic study site performance, as well as policies for correcting site deficiencies and/or curtailing or eliminating approved sites;
(4) requests for interim and final analyses of clinical and laboratory study results;
(5) the addition of clinical and mechanistic study sites to accommodate new knowledge and scientific opportunities; and
(6) the authorship, preparation and review of scientific reports, manuscripts, abstracts and presentations of study results.

In circumstances where the NIAID is responsible for product manufacture, similar support shall be provided to ADCT Product Development Teams.

N. SCIENTIFIC AND TECHNICAL PERSONNEL

Provide and maintain qualified scientific and technical personnel necessary to carry out the functions specified in the Statement of Work, including:

1. Principal Investigator should be a senior statistician with experience in (a) statistical design, development and analysis of clinical trials of experimental treatment and prevention approaches for immune-mediated diseases; (b) management, coordination and oversight of statistical design and analysis components of IND or IDE submissions; (c) design,

management and oversight of computer-based systems and databases for clinical trials and studies; (d) management and coordination of safety oversight and reporting functions for human subjects research; (e) management, coordination and oversight of support services for study product distribution, clinical site monitoring and training, biological specimen repository functions; and (f) working with government sponsors, clinical investigators, clinical trial networks and industry collaborators in protocol design, development, execution, oversight and analysis.

2. Other Scientific and Technical Personnel:

   a. Statisticians to evaluate concept proposals, assist in development of statistical design and analysis plans and DSMPs, and prepare interim and final analyses of study data. This should include at least one senior statistician in addition to the Principal Investigator.

   b. Protocol Development Personnel with expertise in medical writing for clinical/study protocol development and regulatory submissions.

   c. Chemistry, Manufacturing and Control Personnel for the preparation and/or evaluation of manufacturing procedures and methods for generating investigational products.

   d. Safety Oversight Personnel, including physicians and other clinical experts to carry out safety oversight functions, including evaluations of AEs and SAEs.

   e. Regulatory Affairs Personnel for assistance in: (i) preparation of IND/CTA or IDE/CTA submissions, IND/CTA or IDE/CTA amendments and Annual Reports; (ii) briefings with Regulatory Health Authorities and responding to Regulatory Health Authority inquiries; (iii) tracking regulatory submissions and maintaining regulatory records and retrieval systems; (iv) safety reporting; and (v) assisting in ensuring compliance with GCP, GLP and GMP guidelines.

   f. Database and Website Design and Management Personnel for the development and operations of computer-based systems, plans and procedures for data collection, entry and quality control of clinical and laboratory data, the design and maintenance of clinical study websites and regulatory collaboration portal(s), the inventory and management of study products, and the inventory and management of biological specimens.

   g. Clinical Site Monitors for conducting and reporting on various types of site monitoring visits, recommending improvements and corrective/remedial actions, and providing training for clinical site personnel.

   h. Other Technical Personnel for study product preparation, distribution and quality control of study products, and the functions of the biological specimen repository.

3. Personnel Coverage and Replacement Plan:

   Within fifteen (15) business days of the contract effective date, submit, for Project Officer review, a draft plan for providing coverage and replacement for personnel for the following functions: (a) statistical analysis, (b) safety oversight, (c) regulatory affairs, and (d) clinical site monitoring. Within (10) business days of receipt of comments, submit a revised plan to the Project Officer for approval.

O. FACILITIES, EQUIPMENT AND OTHER RESOURCES

Provide and maintain the following facilities, equipment and other resources necessary to carry out the requirements set forth in the Statement of Work for the entire contract period of performance:

1. A central facility for the collection, computer processing, quality control, storage, tracking and retrieval of all study data, and an off-site, separate, secure and access-controlled facility for back-up copies of clinical study data, including all computer equipment, hardware and software, and servers and resources to provide controlled access for secure storage of study data and confidential information.

2. Provide and maintain secure IT systems and network architecture, development and production environments, and computational infrastructure, including electronic systems of records, electronic tracking of safety reports, internet-based collaboration portals, and inventory management systems.

3. A central facility for receipt, storage, management, inventory and disbursement of biological specimens.

4. Facilities, equipment and other resources for the receipt, storage, distribution and inventory of study products and for study product preparation.

5. Access-controlled and password protected systems for: (i) housing and tracking regulatory submissions, protocol amendments, correspondence with and materials prepared for briefings with Regulatory Health Authorities, and summaries of Regulatory Health Authority meetings and teleconferences; (ii) Sponsor Essential Clinical Documents; (iii) Safety Reports, and (iv) other safety information and summaries.

6. Field equipment, including laptops and other digital electronic devices, for clinical site monitoring visits.

7. Web-cast and video-cast capabilities that can be uploaded to the internet for training and other activities carried out by the ACE Steering Committee, the Consortium Operations Committee, Study Management Teams, and Product Development Teams, including subcommittees of these groups.

The Government will not provide any direct costs under this contract for the purchase of equipment without the prior written approval of the Project Officer and the Contracting Officer.

P. QUALITY ASSURANCE/QUALITY CONTROL

1. Develop and implement a Quality Assurance/Quality Control (QA/QC) Plan designed to: (i) standardize contract processes; (ii) ensure that the conduct of all contract activities complies with domestic and country-specific regulations governing human subjects research, GCP, ICH, GMP, of and GLP guidelines, and DAIT, ACE and Consortium policies and procedures; and (iii) provide for the assessment of Contractor performance and the quality and timeliness of the clinical research support functions conducted. The QA/QC Plan and its implementation shall apply to contract functions performed directly by the Contractor, as well as functions carried out by subcontractors.

   Specifically, the Contractor shall:

   a. Within eight (8) weeks of the contract effective date, prepare and submit, for Project Officer and Contracting Officer review and approval, a Draft QA/QC Plan detailing the following:

      (1) standard processes to be used to ensure internal QA/QC with respect to the timeliness, accuracy and completeness of the functions specified in the Statement of Work;
      (2) measures/metrics to be used to assess performance and the quality of contract products;
      (3) approaches/methods to document and address problems and deficiencies identified, including improvements in the internal QA/QC Plan; and
      (4) plans for training Contractor staff on standard processes and measures used for internal QA/QC.

   b. Provide, at six (6) month intervals, reports on the results of internal QA/QC to the Project Officer, including all problems and deficiencies identified, recommended approaches/actions to be taken to correct deficiencies and resolve problems, and any proposed modifications to the QA/QC Plan. All QA/QC Plan modifications must be approved by the Project Officer prior to implementation.

   c. Any major QA/QC deficiencies/problems (e.g., inadequate training of Contractor personnel, late preparation and submission of required reports and other deliverables, inadequate technical knowledge of Federal and country-specific regulations, etc.) as defined in approved SOPs, shall be reported to the Project Officer within one (1) business day of identification and shall include Contractor recommendations for resolution. A brief report on the implementation of Project Officer-approved resolution actions shall also be submitted within time frames to be specified in the approved QA/QC Plan.

2. The Project Officer may authorize, at any time during the contract period of performance, independent audits of contract functions/activities,

including processes, procedures and operations. The Project Officer will notify the Contractor of plans for independent audits two (2) weeks in advance of the scheduled audit. For audits conducted at Contractor and any subcontractor facilities, the Contractor shall ensure that all appropriate staff, facilities, and necessary documentation are available.

For cause audits may be performed at any time and without advance notice to the Contractor in instances of suspected non-performance and/or non-compliance with Federal and country-specific regulatory requirements.

Q. PROJECT MANAGEMENT

Provide for the overall management, integration and coordination of all contract activities, including the technical and administrative infrastructure to ensure the efficient planning, initiation, implementation and timely completion of all activities carried out under this contract.

1. Overall Project Management: Provide for the following:

   A Principal Investigator responsible for overall project management and communications, tracking performance and cost, monitoring and reporting on project status and progress, and recommending modifications to project requirements and timelines, including:

   a. Activities undertaken by subcontractors.

   b. Effective and efficient communications with the Project Officer and the Contracting Officer and effective and efficient communications and coordination of specified functions in collaboration with the Project Officer, other DAIT staff designated by the Project Officer, the ACE Steering Committee, the Consortium Operating Committee, other DAIT clinical research contractors (BISC, ITN), Study Management Teams, Product Development Teams, and ADCT investigators and clinical and laboratory site personnel.

   c. The provision of word processing capabilities compatible with DAIT-supported systems and software to carry out the requirements of the Statement of Work, including Microsoft Word, Excel and the capacity to create portable documents format (PDF) files. This may require frequent updating of systems.

   d. Subcontract Management and Reporting:

      (1) solicit, evaluate, award and manage subcontracts, in accordance with the requirements established by Federal contracting regulations (FAR Clause 52.244.2), including overseeing and assessing performance of the technical, administrative and operational activities of subcontractors; auditing subcontractor facilities, services, and financial expenditures; and tracking deliverables and reporting requirements;
      (2) Quarterly Technical Reports shall include an assessment of subcontractor performance and progress toward achievement of

defined tasks and responsibilities within established timelines; and identify and resolve problems and deficiencies with subcontractor performance;

(3) ensure that subcontractor personnel, equipment and facilities are compliant with all NIAID, NIH, DHHS, and Federal regulatory requirements in effect throughout the contract period of performance;

(4) ensure the complete and effective transfer of technology by the subcontractors to the Contractor, the Government, or a third party designated by the Project Officer and the Contracting Officer; and

(5) perform all necessary transition and closeout functions on each subcontract.

e. Develop and implement internal SOPs for safeguarding the confidentiality and intellectual property of materials, data and other information provided to the Contractor by third parties either directly or through DAIT. This shall include the following:

(1) Within three (3) month of the contract effect date, submit draft SOPs for Project Officer and Contracting Officer review and approval.

(2) Revise draft SOPs in accordance with comments received and submit final SOPs to the Project Officer and the Contracting Officer within three (3) weeks of receipt of comments.

(3) Conduct training for Contractor and subcontractor staff to ensure adherence to approved procedures.

2. Meetings and Teleconferences/Video-conferences:

a. *Contract Initiation Meeting*: Within ten (10) business days of the effective date of the contract, participate in a one-day Contract Initiation Meeting with the Project Officer, the Contracting Officer and other DAIT personnel designated by the Project Officer, to be held in the Bethesda, MD area. The purpose of the Contract Initiation Meeting shall be to: (i) introduce Contractor and DAIT staff; (ii) discuss the terms and conditions of the contract; (iii) review transition plans and activities and materials to be prepared and submitted within the first three (3) months of the contract period of performance; and (iv) establish priorities and timelines for specific activities.

b. *Project Status Teleconferences/Video-conferences*:

(1) Participate in weekly telephone or video conferences with the Project Officer and other DAIT staff designated by the Project Officer, to: (i) review the status of ongoing and in development clinical trials and mechanistic studies; (ii) identify and develop approaches to resolving problems encountered in study design, initiation and conduct with respect to SDCC-ADCT responsibilities; (iii) review plans for the design, development and initiation of recently approved clinical trials and mechanistic studies; and (iv) discuss any issues or problems associated with clinical site monitoring and reporting and clinical site performance, training of clinical site personnel, management of the biological specimen

repository, study product distribution and management, and management of the databases for clinical and laboratory study data and for safety oversight and reporting.

(2) Prepare and distribute teleconference/video-conference agendas and background materials no later that two (2) business days in advance of the conference.

(3) Prepare and distribute brief summaries of major decisions, recommendations and action/follow-up items resulting from weekly teleconferences/video-conferences within three (3) business days of each teleconference/video-conference.

c. *Site Visits*:

At a minimum, one site visit, to be held at the Contractor's facility, shall be conducted each year to review contract progress, policies and procedures, discuss identified problems and deficiencies and their resolution, and review future plans. Participants in annual site visits shall include the Project Officer, other DAIT staff as designated by the Project Officer, the Contracting Officer, and key Contractor and subcontractor personnel. In collaboration with the Project Officer, the Contractor shall be responsible for planning and conducting site visits, including:

(1) preparation and distribution of site visit agendas and background materials;
(2) preparation and presentation of data and other information on contract activities; and
(3) within five (5) business days of site visit completion, preparation and submission to the Project Officer of a written summary of major outcomes, action items, decisions and recommendations resulting from each site visit.

The Project Officer and the Contracting Officer may elect to conduct additional site visits to the Contractor's facilities or request Contractor participation in reverse site visits, to be held in the Bethesda, MD area, at any time during the contract period of performance. In such instances, the Contractor shall be notified ten (10) business days in advance and shall be provided with the agenda and items for discussion.

R. INITIAL AND FINAL TRANSITIONS

1. Initial Transition

a. In the event of a new contractor, plan, coordinate and implement an orderly, secure and efficient initial transition of contract-generated data, other documents and materials, and standard operating procedures. A copy of the transition plan of the incumbent contractor will be provided and will include detailed instructions on the data management and quality control system(s), as well as specific study records and datasets, including studies open for enrollment, in follow-

up, closed, and in analysis. Contract-generated data and materials to be transitioned include the following:

(1) draft protocols for clinical trials in development, final protocols and protocol amendments for ongoing clinical trials, and final protocols and protocol amendments for completed clinical trials;
(2) all study-related materials for ongoing and completed clinical trials, as well as clinical trials in development, including CRFs, MOOs, IBs, etc.;
(3) data and other information contained in study-specific websites and procedures for access control;
(4) all regulatory files: (i) Sponsor Essential Clinical Documents files for each ADCT; (ii) all Regulatory Health Authority submission files; and (iii) any tracking databases associated with these files;
(5) user manuals and all written instructions for utilization of the SACCC-ADCT data management system;
(6) instructions and Standard Operating Procedures for safety reporting;
(7) site monitoring reports, records, forms, templates and procedures;
(8) pharmacy records, files and study product inventory; and
(9) repository biological specimens, associated electronic files, and other records.

Similar materials will be transitioned for mechanistic studies.

The Contractor must be prepared to receive all data and study-related documents for ongoing clinical trials within five (5) business days of the effective date of the contract via a secure electronic file transfer. Paper records shall be transferred by a method to be approved by the Project Officer post-award. In the event that the Project Officer and the Contracting Officer determine that the volume of data is too great for electronic transfer, an alternative method shall be proposed by the Contractor and approved by the Project Officer and the Contracting Officer. Any such alternative method of data transfer shall be completed within seven (7) business days of the effective date of the contract.

b. Draft Initial Transition Plan

Within ten (10) business days of the effective date of the contract, submit the Draft Initial Transition Plan for Project Officer review and approval. This Plan shall detail the specific transition activities to be undertaken, provide a timeline for implementation of each transition activity, and describe the capabilities and responsibilities of Contractor staff who shall be assigned to implement the plan. The Draft Initial Transition Plan shall encompass the requirement for the Contractor to have in place, no later than two (2) months from the contract effective date, the following: (i) study-specific internet-based collaboration portals; (ii) computerized systems for data collection, verification and management for all ongoing ADCT studies; (iii) the Safety Reporting Center, including computerized database system(s) for AE and SAE reporting; and (iv) the Sponsor Essential Clinical Documents database.

For data transfer for both clinical trials and collaboration portals, first priority will be given to high-priority studies; second priority will be given to studies open to enrollment; third priority will be given to studies in development and nearing finalization; and last priority will be given to closed studies and those in early development. The Project Officer will determine the priority for each trial. In addition, the Draft Initial Transition Plan shall encompass the requirement for the Contractor to be capable of performing data mining and analysis on transferred datasets within this time frame.

The Project Officer will review and provide comments on the Draft Initial Transition Plan within five (5) business days of receipt of the Draft Plan.

c. Final Initial Transition Plan

Revise the Draft Initial Transition Plan in accordance with Project Officer comments, submit the Final Initial Transition Plan within five (5) business days of receipt of Project Officer comments, and complete all Initial Transition activities in accordance with the approved Plan within three (3) months of the contract effective date.

2. Final Transition

The Contractor shall plan, coordinate and implement an orderly, secure and efficient transition of contract-generated data, protocol-related documents, Standard Operating Procedures and other materials to a successor contractor or to the Government. This shall include the following:

a. Draft Final Transition Plan

No later than twelve (12) months prior to the completion date of the contract, prepare and submit, for Project Officer review and approval, a Draft Final Transition Plan. The Draft Final Transition Plan shall detail the transition activities to be carried out, provide a timeline for the implementation of each transition activity, and describe the capabilities and responsibilities of Contractor staff who shall be assigned to implement the plan. Contract-generated materials and data to be transitioned shall include the following:

(1) all items listed in item R.1.a. above;
(2) if not already provided, clean, edited public use dataset (including cleaned data with or without images, raw data if cleaned data are not available) and copies of all data management tools, including data documentation, data dictionaries and data entry software and editing programs to allow reading and analysis of the data for all studies managed or analyzed under the contract, including:

(a) all computer programs used for reading, cleaning, manipulating, graphing and analyzing data and programs used for generating new datasets;

(b) audit trails of all data corrections, hard copies of the original data, if collected under this contract, and all logs and records related to data collection, entry, editing, verification, analysis and transfer;
(c) final summaries of analyses performed during the contract period of performance;
(d) all electronic files transferred and documentation of format to a location specified by the Project Officer by the contract completion date; and
(e) all hard copy files, including all reports submitted to DAIT, in an organized manner, providing clear documentation of contents, date of origin, and purpose to a location specified by the Project Officer prior to the contract completion date.

(3) for the transition of clinical site monitoring functions, briefings for new contractor clinical site monitoring staff on procedures and standards in current use, schedule for site visits for the first quarter of the contract period of performance, and site-specific information, including: (i) organization and staffing; (ii) working relationships and communication mechanisms; (iii) overall site performance, including problems and deficiencies identified and corrective/remedial actions taken or recommended; and

(4) for functions relating to the management and distribution of study products and the repository of biological specimens, briefing sessions for new contractor staff on Standard Operating Procedures and the provision of accurate, complete and up-to-date Standard Operating Procedures.

b. Final Transition Plan

(1) Revise the Draft Final Transition Plan as necessary to accommodate Project Officer comments, and submit the Final Transition Plan no later than six (6) months prior to the completion date of the contract.

(2) Maintain full operational capacity until the completion date of the contract. The Final Transition must be fully completed by the expiration date of the contract.

[END OF STATEMENT OF WORK]

ATTACHMENT 4: REPORTING REQUIREMENTS AND DELIVERABLES

STATISTICAL AND CLINICAL COORDINATING CENTER FOR AUTOIMMUNE DISEASE CLINICAL TRIALS (SACCC-ADCT)
RFP-NIAID-DAIT-NIHAI2008049

ARTICLE C.2. REPORTING REQUIREMENTS

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

Technical Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the Deliveries Article in Section 3.

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

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

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

1) Monthly Progress Reports

This report shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full 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 also include the following:

A. Accrual and site registration for each open clinical protocol for the ACEs, the Consortium, and each investigator-initiated clinical trial project:

1. For each clinical site enrolling study participants in open clinical protocols: projected overall accrual at each site; date of first enrollment; actual accrual to date; summary of all eligible patients per month and to date; and reasons for non-entry of eligible patients;

2. For each clinical site in the process of registering and obtaining approval to participate in open clinical protocols: outstanding requirements for approval; anticipated date of approval; projected accrual; and any anticipated problems with protocol approval/implementation;
3. Summary of the projected versus actual accrual to date for all approved clinical sites, and reasons for non-entry of eligible patients;
4. For each approved mechanistic study associated with an open clinical protocol: status of implementation; status of collection, shipping and receipt of patient samples; problems and/or issues associated with the collection, shipping or receipt of patient samples; and recommendations for resolving any such issues or problems; and
5. Recommendations for modifications in study design, clinical site monitoring, or clinical site training appropriate to improve overall or site-specific accrual, including recommendations for increasing the number of participating clinical sites.
6. Recommendations on the impact of adverse events on operational function of the SACCC-ADCT.

2) Quarterly Progress Report

This report shall include a summation of the Monthly Progress Reports and a description of the activities planned for the ensuing reporting period. The first reporting period consists of the first full three months of performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full calendar months.

Quarterly Progress Reports shall also include the following:

A. A summary of the status of the following activities for the ACEs, the Consortium and investigator-initiated clinical trial projects, separately and in composite:

1. Concept Proposals and Full Proposals for clinical trials and mechanistic studies, including: lead investigator(s); stage of development; step within the NIAID, the ACE and other DAIT-supported ADCT activity review process; actions required for final approval, modification or disapproval, including unresolved issues, questions or problems; and timeframe for him completion of review, approval, modification or disapproval;
2. Approved clinical trials and mechanistic studies under development, including: lead investigator(s); stage of development; step within the NIAID, the ACE and other DAIT-supported ADCT activity development process; actions required for final approval, modification or disapproval, including unresolved issues, questions or problems; and timeframe for completion of NIAID and ACE or Consortium approval or disapproval;
3. Clinical protocols and mechanistic studies open to enrollment, including: lead investigator(s); stage of patient enrollment; actions required to meet enrollment projections, including any protocol modification(s) and unresolved issues, questions or problems; and timeframe for completion;
4. Copies of all pending and approved concepts;
5. Proposed or ongoing interim and final analyses of the results of clinical trials and mechanistic studies for the ACEs, the Consortium, and investigator-initiated clinical trial projects. This shall include:

a. Title, author(s), brief description and status of approved analyses, including any pending issues, problems or modifications; and
b. Recommendations for additional interim and final analyses for clinical trials and mechanistic studies;

6. A summary of issues or problems encountered with respect to the NIAID and/or the ACEs, the Consortium or investigator-initiated clinical trial project review and decision-making process, including recommendations for modifications and improvements to enhance the timeliness, efficiency or thoroughness of the review processes;
7. Any other information the SACCC determines that the NIAID Project Officer should be advised about;
8. A Financial Status Report including (i) spending for each work area (clinical trial support, regulatory support, pharmacy support services, site monitoring, etc.), and (ii) a breakdown of expenditures by protocol, including: personnel (number of hours expended for each study and cumulative overall), consultants (identify specific protocol and role), materials and supplies, equipment (specify), staff travel (identify protocol and purpose of travel), other direct costs.

B. A Monthly Progress report shall not be submitted for the final month of a quarter.

3) Annual Progress Report

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

The Contractor shall provide the Project Officer and Contracting Officer with two copies of the Annual Progress Report in draft form, in accordance with the Deliveries Article in Section 3 of this contract, 30 calendar days prior to the delivery date for the Final Version of the Annual Progress Report. The Project Officer will review the draft report and provide the Contractor with comments within 10 calendar days after receipt. The Annual Progress Report shall be corrected by the Contractor, if necessary and the final version delivered as specified in the above paragraph.

Annual Progress Reports shall address the topics specified for the Quarterly Progress Reports and, in addition, shall include each of the following issues:

A. Statistical Design Considerations:

1. The advantages and disadvantages of the various approaches to the statistical design of ongoing and completed ACE and other autoimmune disease clinical trials and mechanistic studies relevant for the assessment of the safety and efficacy of tested approaches or agents, including: control and comparison groups; inclusion and exclusion criteria; sample size; research questions addressed; clinical end-points and immune/surrogate markers measured; number and type of patient samples; and other relevant statistical design issues; and

2. Recommendations for improved statistical approaches and methods to enhance the ability to assess disease stage and activity, therapeutic effect and underlying mechanisms.

B. Development or Changes in Standard Operating Procedures, including:

1. Development and review Concept Proposals and Full Proposals for clinical trials and mechanistic studies, including criteria for evaluation and prioritization;
2. Development, review and implementation of approved protocols and mechanistic studies, including criteria for evaluation and prioritization;
3. Monitoring and training at clinical sites with respect to adherence to protocol requirements, data collection and quality assurance, adherence to regulatory requirements, and other relevant monitoring and training;
4. Preparation, review and approval of requests for statistical analyses;
5. Review and approval of publications, abstracts, reports and presentations;
6. Monitor and evaluate the performance of clinical and mechanistic study sites and procedures for addressing performance problems; and
7. Development of other policies and procedures in conjunction with the NIAID and ACE Steering Committee and the Consortium Operations Committee.

C. Clinical Site Monitoring and Training:

1. Clinical site training activities conducted, including written materials on ACE and Consortium-specific standard operating procedures and protocol-specific requirements;
2. Issues and problems encountered in the training and monitoring of ACE and Consortium clinical sites and studies;
3. Recommendations for modifications/improvements in training materials and/or standard operating procedures to ensure adherence to protocol requirements, standard operating procedures and regulatory requirements; and
4. All reports from clinical site establishment and interim site visits, including documentation of site capabilities and deficiencies and remedies implemented to assure the sites are in compliance with all appropriate Federal regulations and ACE and Consortium procedures.

D. A description of Distribution and Quality Control of Study Products activities conducted, including: receipt, labeling, storage, distribution, security, inventory quality assurance, shipping, evaluations of usage, and disposition of returned investigational agents.

E. Regulatory Functions and Requirements:

1. Status of INDs and IDEs, issues and problems in the development;
2. FDA review and approval of INDs and IDEs; and
3. Recommendations for improvements/modifications in ACE and DAIT-supported ADCT study regulatory procedures.

F. NIAID Safety Oversight Structures Responsibilities:

1. Any modification to the procedures for the review of interim and final analyses of study data; and
2. Recommendations for improvements in the analyses prepared for DSMB review and the nature and type of study data generated by ACE and Consortium sites and by investigator-initiated clinical projects.

G. Assessments of the policies and procedures used by the ACEs and Consortium, and recommendations for improvements.

H. Annual Automated Information System Security Report, including, Automated Information System (AIS) Security Profile, which at a minimum shall include: the System's Security Plan (SSP); the Risk Analysis (RA); the Continuity of Operations Plan (COOP; also known as the Contingency Plan).

I. Financial Status Report including (i) Direct costs for each work area (clinical trial support, regulatory support, pharmacy support services, site monitoring, etc.), and (ii) a breakdown of direct costs by protocol, including: personnel (number of hours expended for each study and cumulative overall), consultants (identify specific protocol and role), materials and supplies, equipment (specify), staff travel (identify protocol and purpose of travel), and other direct costs.

4) Annual Technical Progress Report for Clinical Research Study Populations

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. The Contractor shall submit this information in the format indicated in the attachment entitled, "Inclusion Enrollment Report," which is set forth in Section J of the contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the Final Report.

The Contractor shall submit the report in accordance with the Deliveries Article in Section 3 of this contract.

In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October 2001, applies. If this contract is for Phase 3 clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website: http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol as approved by the IRB, and provide a description of the progress in the conduct of these analyses, as appropriate, in the Annual Progress Report and the Final Report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

5) Final Report

This report is to include a summation of the work performed and the results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted in accordance with the Deliveries Article in Section 3 of the contract. An Annual Progress Report shall not be required for the period when the Final Report is due.

The Contractor shall provide the Project Officer and Contracting Officer with two copies of the Final Report in **draft** form, in accordance with the Deliveries Article in Section 3 of this contract, 60 calendar days prior to the completion date of this contract. The Project Officer will review the draft report and provide the Contracting Officer with comments within 15 calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary, and the final version delivered as specified in the above paragraph.

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) Human Subjects IRB Annual Report (Form OMB No. 0990-0263-formerly Optional Form 310).
2) Invention Report Requirement **-** Use when Patent Rights (FAR 52.227-11 or 52.227-13) may be included in the contract.
3) Source Code and Object Code **-** Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

   On or before the completion date of the contract, the Contractor shall provide:

   A. Clean, edited public use dataset and copies of all data management tools, including data documentation, data dictionaries and date entry software and editing programs to allow reading and analysis of the data for all studies managed or analyzed under this contract;
   B. All computer programs used for reading, cleaning, manipulating, graphing and analyzing data and programs used for generating new datasets;
   C. Audit trail of all data corrections, hard copies of the original data if collected under this contract and all logs and records related to data collection, entry, editing, verification, analysis and transfer;
   D. Final summaries of analyses performed during the contract period;
   E. All electronic files in a format that is well-documented to a location specified by the Project Officer by contract completion date. This shall include transfer of the specimen inventory with documentation to institute a new or modified specimen tracking system; and
   F. All hard copy files, including all reports submitted to DAIT, in an organized manner, providing clear documentation of contents, date of origin, and purpose to a location specified by the Project Officer prior to contract completion.

SECTION D - PACKAGING, MARKING AND SHIPPING

1. Temperature controlled environment is required.
2. Shipments will be time sensitive/time critical.
3. International shipping will apply.
4. Shipping insurance is required.
5. Hazardous Materials shipping is applicable.

ARTICLE F - DELIVERIES

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

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

a. Technical Progress Reports

Item	Reports	Recipients	Delivery Schedule
1.	Monthly Progress Report	1 elec. copy to PO 1 original to CO	The first report is due on the 30th of the month following the first full month of performance plus any fractional part of the initial month. Thereafter, each report is due on/before the 30th of the month following each anniversary date of the contract.
2.	Monthly Financial Expenditure Reports	1 elec. copy to CO and PO	The first report is due on the 30th of the month following the first full reporting period. Thereafter, each report is due on/before the 30th of each month following each reporting period.
3.	Quarterly Progress Report	1 hard copy to PO 1 original to CO 1 elec. copy to PO and CO	The first report is due on the 30th of the month following the first full reporting period. Thereafter, each report is due on/before the 30th of each month following each reporting period. Monthly Progress Reports shall not be submitted the month the Quarterly Progress Report is due.
4.	Draft Annual Progress Report	1 hard copy to PO 1 original to CO 1 elec. copy to PO and CO	Draft Annual Progress Report is due 1 month prior to the due date of the Final Annual Progress Report.
	Annual Progress	1 hard copy to PO	The first report is due on the 30th of the

Item	Reports	Recipients	Delivery Schedule
5.	Report	1 original to CO 1 elec. copy to PO and CO	month following each anniversary date of the contract. Quarterly Progress Reports will not be submitted the month the Annual Progress Report is due.
6.	Final Invention Statement	1 copy to CO	Due on/before completion date of the contract.
7.	All reports and documentation including the invention disclosure report, the confirmatory license, and the government support certification	1 copy to OPERA	As required by FAR Clause 52.227-11.
8.	Draft Final and Final Report	1 hard copy to PO 1 original to CO 1 elec. copy to PO and CO	Draft Final Report is due 60 calendar days prior to the completion date of contract. Final Report is due on/before the completion date of the contract.

b. Other Reports and Deliverables

Item	Deliverables	SOW Reference	Recipient	Delivery Schedule
1.	Interim and Final Study Reports	Item B.2	1 hard copy and 1 elec. copy to PO-designated Medical Officer (MO) 1 elec. copy to PO	Within 10 business days of study analysis completion.
2.	Information System Security Plan (ISSP)		1 hard copy to PO and NIAID Information System Security Officer (ISSO); 1 elec. copy to PO and NIAID ISSO	Due on/before 30 calendar days after the effective date of contract. Thereafter, due annually on/before 30 calendar days following the anniversary date of the contract.
3.	Risk Analysis (RA)		1 hard copy to PO and NIAID ISSO; 1 elec. copy to PO and	Due on/before 30 calendar days after the effective date of contract. Thereafter, updated every 3

			NIAID ISSO	years or in advance of implementing major system modifications or enhancements
4.	Continuity of Operations Plan (COOP)		1 hard copy and Elec. to MO	At least every 6 months starting with the second quarterly report
5.	Regulatory Health Authority Submissions and Meeting and Teleconference Summaries	Item D.1.b	1 hard copy to DAIT Office of Regulatory Affairs (ORA) 1 elec. Copy to MO, PO and DAIT ORA	(1) INDs, IDEs, CTAs and all amendments to IND/CTA or IDE/CTA submissions as directed by DAIT ORA; (2) Meeting and Teleconference Summaries due 5 business days after completion
6.	IND/CTA Annual Reports	Item D.1.d	1 hard copy and 1 elec. copy to PO and DAIT ORA	(1) Timeline for IND/CTA annual report preparation and submission as directed by PO and DAIT ORA; (2) Draft and Final IND/CTA Annual Reports in accordance with approved timeline
7.	Systems of Records for Regulatory Health Authority Documents	Item D.1.e	1 hard copy and 1 elec. copy to PO and DAIT ORA	(1) Draft Electronic Records Plan, Draft Paper Records Plan, and Draft Electronic Sponsor Essential Clinical Documents Plan within 1 month of contract effective date; (2) Final Electronic, Paper and Sponsor Essential Clinical Documents Records Plans within 7 business days of receipt of Project Officer comments; (3) Draft Implementation Plan for Electronic and Sponsor Essential Clinical Documents Records System within 2 months of approval of Final Plans; (4) Final Implementation Plan

				for Electronic and Sponsor Essential Clinical Documents Records System within 7 business days of receipt of Project Officer comments; (5) Full implementation of Electronic, Paper and Sponsor Essential Clinical Documents Records Systems within 3 months of contract effective date
8.	Quality Assurance Checks of Sponsor Essential Clinical Documentation	Item D.2.b.	1 hard copy and 1 elec. copy to DAIT ORA	(1) Quality assurance checks at least bi-annually; (2) reports on results of quality assurance checks due 1 month after completion
9.	Status Reports on Sponsor Essential Clinical Documents	Item D.2.c.	1 hard copy and 1 elec. copy to PO and DAIT ORA	Due monthly
10.	Electronic Tracking of Safety Reports	Item D.3	1 hard copy and 1 elec. copy to DAIT ORA	(1) Draft Plan for tracking system, including analogous system for non-IND studies, due within 1 month of contract effective date; (2) Final Plan due 7 business days after receipt of Project Officer comments; (3) fully operational tracking system within 1 month of receipt of Project Officer approval of Final Plan
11.	SOPs for Responding to Audits	Item D.4, H.3, and K.9	1 hard copy and 1 elec. copy to DAIT ORA	(1) Draft SOPs within 3 months of contract effective date; (2) Final SOPs and completion of training of all Contractor staff within 5 months of

				contract effective date
12.	Written and Oral Materials for Presentation at Meetings of NIAID Safety Oversight Structures	Item F.2.b	1 elec. copy to MO	(1) Draft interim analyses and materials due no later than 3 weeks prior to scheduled meetings; (2) Final analyses and materials due no later than 2 weeks prior to scheduled meetings
13.	Documentation of Recommendations of NIAID Safety Oversight Instructions	Item F.2.c	Elec. copy to MO	(1) Draft written summaries due within 5 business days of meeting completion; (2) Final written summaries due within 3 business days of receipt of Project Officer comments.
14.	Serious Adverse Event and Unanticipated Event Reporting	Item F.3	1 elec. copy to PO and DAIT ORA 1 elec. copy to MO	(1) Draft SOPs for AE and SAE reporting within 1 month of contract effective date; (2) Final SOPs within 2 weeks of receipt of Project Officer comments (3) Evaluation of SAE Reports within 1 business day of receipt
15.	QA/QC Procedures and Training Plans for Safety Reporting by Clinical Sites	Item F.3.j	1 elec. copy to PO and DAIT ORA	(1) Draft procedures and training plans due within 1 month of contract effective date; (2) Implementation of final procedures and plans within 1 month of receipt of Project Officer comments
16.	Internet-Based Collaboration Portals	Item G	1 hard copy and 1 elec. copy to DAIT ORA and PO	(1) Draft Plan design, establishment and maintenance within 1 month of contract effective date; (2) Fully operational collaboration portals within 2 months of approval by Project Officer
17.	Transmittal to	Item H. 1.b.(3)	1 elec. copy	Due no less than 1

	clinical sites of description of site-specific activities, protocols and data to be reviewed during interim and site and study closeout visits		to PO and PO-designated clinical site investigators	week prior to scheduled visits
18.	Written Site Visit Reports (To include: Site Establishment, Interim Site Monitoring, and Site and Study Closeout Visits)	Item H.3	1 elec. copy to PO-designated DAIT Staff	Due within 1 week of site visit completion
19.	Written Clinical Site Monitoring SOPs and SOP updates	Item H.4	1 elec. copy to PO and DAIT ORA	(1) Draft SOPs due within 2 months of contract effective date; (2) Final SOPs due within 2 weeks of receipt of PO comments; (3) SOP updates due within 20 business days of effective date of changes
20.	Training of Site Monitors	Item I.2	PO and DAIT ORA	(1) Draft Training Plan within 3 weeks of contract effective date; (2) Final Training Plan within 1 month of receipt of PO comments; (3) written assessments and recommendations for improvements in Training Plan due annually; (4) Listing of all training activities conducted due at the end of each year of the contract
21.	Physical Inventory of Supply of Study Products	Item K.2	1 elec. copy to PO	(1) physical inventories to be conducted on a monthly basis; (2) PO notification of

				discrepancies within 1 business day of inventory completion
22.	Quarterly Technical Reports on Inventory Control and Quality Assurance of Study Products	Item K.2	1 elec. copy to PO	Attachments to the Quarterly Progress Report
23.	Written Protocol Evaluation for Pharmaceutical Services	Item K.4	1 elec. copy to PO-designated DAIT staff	As directed by PO
24.	SOPs for Audits Related to Study Products	Item K.8	1 elec. copy to PO-designated DAIT staff	(1) Draft SOPs within 2 months of the contract effective date; (2) Final SOPs within 2 weeks of receipt of PO comments
25.	Study Product Services Plan	Item K.9	1 elec. copy to PO	(1) Draft Plan due within1 month of contract effective date; (2) Final Plan due within 15 business days of receipt of PO comments
26.	Plan for Provision of Repository Services	Item L.6.	1 elec. copy to PO	Due within 15 business days of the contract effective date
27.	Conflict of Interest (COI) Disclosure Forms	Item M.1.a.	1 elec. copy to PO	(1) Draft COI disclosure forms due 3 months of contract effective date; (2) Final COI disclosure forms due within 10 business days of receipt of PO comments
28.	Summaries of Meetings and Tele-conferences for ACE Steering Committee, Consortium Operations	Item M.2.d.	1 elec. copy to PO and PO-designated DAIT staff	Due within 3 business days of meeting or teleconference completion

	Committee and SMTs			
29.	Personnel Coverage and Replacement Plan	Item N.3	1 elec. copy to PO	(1) Draft Plan due within 15 business days of the contract effective date; (2) Final Plan due within 10 business days of receipt of PO comments
30.	Quality Assurance/ Quality Control	Item P.1	1 elec. copy to PO	(1) QA/QC Plan due within 8 weeks of contract effective date; (2) reports on results of internal QA/QC due at 6-month intervals
31.	Internal SOP's for Safeguarding the Confidentiality and Intellectual Property	Item Q.1.e	1 elec. copy to PO	(1) Draft SOPs due within 3 months of contract effective date; (2) Final SOPs due within 3 weeks of receipt of PO comments
32.	Contract Initiation Meeting	Item Q.2.a		Within 10 business days of the effective date of the contract
33.	Project Status Tele-conferences/ Video-conferences	Item Q.2.b.	1 elec. copy to PO	(1) Distribution of agendas and background materials within 2 business days in advance of teleconferences/ video-conferences; (2) Summaries of major decisions and action/follow-up items due within 3 business days of each teleconference/video-conference
34.	Written Site Visit Summaries	Item Q.2.c	1 elec. copy to PO	Within 5 business days of the site visit completion
35.	Draft Initial Transition Plan	Item R.1.b	1 hard copy and 1 elec. copy to PO	Due within 10 business days of the effective date of the contract
36.	Final Initial Transition Plan	Item R.1.c	1 hard copy and 1 elec. copy to PO	Due within 5 business days of receipt of PO comments
37.	Draft Final	Item R.2.a	1 hard copy	No later than 12

	Transition Plan		and 1 elec. copy to PO	months prior to contract completion date
38.	Final Transition Plan	Item R.2.b	1 hard copy and 1 elec. copy to PO	At least 6 months prior to the contract completion date

[END OF REPORTING REQUIREMENTS AND DELIVERABLES]

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

STATISTICAL AND CLINICAL COORDINATING CENTER FOR AUTOIMMUNE DISEASE CLINICAL TRIALS (SACCC-ADCT)

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

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

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

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

Offerors are reminded that the total page limitation for the entire Technical Proposal is 300 pages including all appendices and attachments. Any pages in excess of this limit will be expunged from the proposal and will not be considered in the technical review.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1:

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

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

Provide a brief overview of the proposed Statistical and Clinical Coordinating Center for Autoimmune Disease Clinical Trials (SACCC-ADCT), including descriptions of the following:

1) The activities to be performed by the offeror and all proposed subcontractors, including the identification of proposed subcontractors and a list of key personnel of the offeror and the proposed subcontractors with degrees and titles.
2) The key features of the proposed computer-based systems for data management and safety reporting.
3) The facilities and equipment to be made available by the offeror and all proposed subcontractors, including: the central data management facility, the Safety Reporting Center, the repository of biological specimens, facilities and equipment for the receipt and distribution of study products, and off-site back-up facilities.

SECTION 3: TECHNICAL PLAN / APPROACH

The Technical Proposal must (i) include detailed work plans indicating how each aspect of the Statement of Work will be accomplished in sufficient detail to fully explain the technical plans, approaches and/or methods proposed, and (ii) describe relevant organizational experience in carrying out the functions of the contract.

1) Statistical Design (SOW item A)

   Describe organizational experience with and provide proposed plans and procedures for performing the statistical design support functions listed below. For <u>each</u> function, include a discussion of (i) statistical design considerations and approaches of particular relevance to evaluating the safety and efficacy of investigational approaches/products for autoimmune diseases and elucidating underlying mechanisms, and (ii) common statistical design problems associated with such clinical studies and approaches recommended and implemented to overcome and/or minimize identified problems.

   A. Clinical Trial Concept Proposals and Full Proposals:

      Assessing the feasibility of Concept Proposals and Full Proposals for clinical trials with respect to experimental statistical design and data analysis plans. Include a list of relevant clinical trial Concept Proposals and/or Full Proposals assessed over the past 5 years indicating: (i) clinical trial phase, (ii) overall experimental design; (iii) type of study product; (iv) study population/disease; and (v) sponsor.

   B. Clinical Protocols:

      Developing and refining experimental study designs and data analysis plans for clinical protocols. Include a list of relevant clinical protocols for which statistical design and data analysis support has been provided over the past 5 years indicating: (i) clinical trial phase; (ii) number of participating clinical sites; (iii) type of study product; (iv) the study population/disease; (v) sample size; (vi) overall experimental design; (vii) the status of the clinical trial; and (viii) sponsor.

C. Mechanistic and Non-Interventional Studies:

Assessing the feasibility of: (i) Concept Proposals and Full Proposals and developing and refining experimental study designs and data analysis plans for mechanistic studies, including the utility of techniques and methods used to delineate underlying mechanisms of disease, and (ii) non-interventional studies that are anticipated to support the development of interventional clinical trials. Include a list of relevant mechanistic and non-interventional studies for which statistical design and data analysis support has been provided over the past 5 years indicating: (i) study population; (ii) techniques and methods utilized; (iii) the major design features addressed with respect to validity and reliability; (iv) study status; and (v) sponsor.

D. Preclinical Safety Study Evaluations:

Evaluating the statistical accuracy and validity of preclinical safety studies in support of clinical trials.

2) Statistical Analysis (SOW item B)

Describe organizational experience with and provide proposed plans and procedures for performing the statistical analysis functions listed below. Include the following: (a) a list of clinical trials for which statistical analysis support has been provided over the past 5 years indicating: (i) clinical trial phase; (ii) type of study product; (iii) study population/disease; (iv) sample size and number of participating sites; (v) overall experimental study design; (vi) study status; and (vii) sponsor; (b) a list of mechanistic studies for which statistical analysis support has been provided over the past 5 years with a brief description of: (i) study population; (ii) techniques, methods and surrogate/biomarkers utilized; (iii) overall experimental design; (iv) study status; and (v) sponsor; and (c) a list of non-interventional studies for which statistical analysis support has been provided over the past 5 years with a brief description of: (i) study population; (ii) techniques, methods, and measures utilized; (iii) overall experimental design; (iv) study status; and (v) sponsor.

A. Interim statistical and trend analyses for evaluating ongoing clinical trials with respect to safety, toxicity, pharmacokinetics, pharmacology, efficacy, and/or exploratory endpoints.
B. Comprehensive final statistical analyses of all clinical trial data.
C. Analyses of mechanistic studies.
D. Analyses of non-interventional studies.

3) Protocol Development (SOW item C)

Describe organizational experience with and provide proposed plans for assisting in the preparation of protocol-related documents for clinical trials. Include a list of clinical trials for which support for the development of protocol-related documents has been provided over the past 5 years and describe the level of assistance provided (e.g., provision of common templates, review of draft documents, contributing author, primary author, etc.).

4) Regulatory Activities (SOW item D)

Describe organizational experience with and provide proposed plans and procedures for providing support for regulatory activities and related Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), and Good Laboratory Practice (GLP) compliance. As appropriate for each of the support functions listed below, describe relevant organizational experience over the past 5 years, including: (i) the scope of support provided; (ii) a description of databases established and managed for these support services; (iii) clinical trial sponsors and regulatory authorities involved; and (iv) the scope of compliance review and training activities carried out.

A. Regulatory Submissions and Reports
B. Maintenance of Sponsor Essential Clinical Documents and System of Records
C. Electronic Tracking of Safety Reports
D. Audits
E. Compliance with GCP, GLP and GMP
F. Regulatory Affairs Administrative and Project Management Support

5) Data Management and Reporting (SOW item E)

Describe the proposed computer-based systems and provide proposed plans and procedures for system implementation, operation, management, maintenance and the provision of quality control and reporting of all clinical and laboratory data. Include a description of the capacity of all proposed systems to meet the features and capabilities specified in the Statement of Work, a discussion of the capacity of all proposed systems to comply with all current Federal regulations and current globally-accepted standards, and data storage plans, including back-up procedures, disaster recovery procedures and query abilities.

A. Data Collection, Storage and Management: The proposed computer-based system(s) for all clinical and laboratory data and for the management of data and other information for clinical trials. Describe system capabilities for:

1. management of all clinical/laboratory data at a central data management facility;
2. central computerized registration and randomization and system for non-computerized data entry when necessary;
3. computerized study forms and systems for remote data entry and transmission via the internet of subject data from study sites and laboratories, and non-computerized methods when necessary.

B. Data Quality Control:

1. Describe proposed plans to provide quality control of all clinical and laboratory data. This includes proposed plans and procedures for:

a. monitoring the accuracy, completeness and timeliness of 100 percent of data submitted by study sites;
b. providing for computerized validation and error-checking to evaluate and improve data accuracy, completeness and timeliness;
c. evaluating data derived from ongoing quality assurance checks;
d. manual reconciliation of AE versus SAE data entries; and

e. preparation and implementation of manuals and procedures documenting data collection, editing and validation procedures and standards.
f. ensuring compatibility with DAIT, ACE and Consortium data systems.

2. Describe experience over the past 5 years with the establishment and management of similar data management systems and procedures in support of clinical research programs.

3. Describe the relational database management system to be established and maintained by the Contractor. The management system must be well documented and available commercially or through open sources.

6) Safety Oversight and Reporting (SOW item F)

Describe organizational experience with and provide proposed plans and procedures for carrying out the following safety oversight and reporting functions. As appropriate for each function, include a discussion of organizational experience in terms of the scope of clinical investigators/clinical trial networks, sponsors, safety oversight structures and regulatory authorities involved.

A. Data and Safety Monitoring Plans (DSMPs):

1. Describe procedures for developing DSMPs for autoimmune disease clinical trials that ensure appropriate monitoring and compliance with all applicable Federal and international regulations. Include any characteristics unique to autoimmune disease clinical trials that would affect DSMP design and describe procedures for addressing these issues.
2. Provide a list of relevant clinical trials for which support for DSMP preparation has been provided over the past 5 years identified by: (i) clinical trial phase; (ii) type of study product; (iii) study population/disease; (iv) overall experimental design; (v) sample size and number of participating clinical sites; (vi) type of responsible safety oversight structure; (vii) study status; and (viii) sponsor. Also identify the specific responsibilities carried out with respect to the design and development of DSMPs versus responsibilities carried out by others, including clinical investigators and sponsors.

B. NIAID Safety Oversight Structures: Describe relevant organizational experience over the past 5 years in the following areas:

1. Assisting in presenting final draft protocols, informed consent forms and DSMPs to safety oversight structures.
2. Preparing responses to comments and inquiries from safety oversight structures.
3. Preparing separate interim analyses of blinded and unblinded study data for review at both open and closed sessions of meetings of safety oversight structures, including memoranda highlighting interval changes in safety, efficacy or other parameters relevant to safety oversight.
4. Making oral presentations at meetings of safety oversight structures to explain results of interim analysis and address questions on patient safety, and assisting in the preparation of responses to safety oversight structures.

5. Preparing written summaries of the deliberations and recommendations of safety oversight structures and assisting in the preparation and coordination of communications among multiple parties to implement accepted recommendations.

C. Safety Reporting:

Describe organizational experience with and provide proposed plans and procedures for establishing and operating a Safety Reporting Center, including the following:

1. Proposed computer-based system for reporting and monitoring AEs and SAEs.
2. Standard Operating Procedures (SOPs) for AE and SAE reporting, including grading and attribution, and procedures for ensuring compliance with all regulatory requirements and GCP guidelines.
3. Protocol-specific AE and SAE reporting forms, including events to be documented, clinical data to be recorded, grading and attribution.
4. Quality control of all SAE data submitted, evaluation of SAE Reports and preparation and entry of abstracts of SAE Reports into the safety database.
5. Telephone help-line and on-call, back-up support services.
6. Notification of medical monitors and others that an SAE had occurred.
7. Distribution of Safety Reports to regulatory authorities, clinical sites, and safety oversight structures.

In addition, discuss problems and deficiencies encountered in ensuring the accuracy, completeness and timeliness of AE and SAE reporting by clinical sites and recommendations developed and implemented to overcome identified problems and deficiencies.

7) Clinical Study Internet-based Collaboration Portals (SOW item G)

Describe organizational experience with and provide proposed plans and procedures for establishing, maintaining and updating clinical study collaboration portals to house clinical trial information and study-specific documents and materials, including plans and procedures for:

A. Protocol-specific, password protected website(s).
B. Real-time standard and study-specific data by site and total overall, including accrual, AE and SAE listings, protocol deviations, missing forms, visit schedule compliance, data queries and progress monitoring information.
C. Updates to all website documents and materials and electronic notification of availability of new or revised documents and materials.

8) Clinical Site Monitoring and Reporting (SOW item H)

Describe organizational experience with planning, conducting and reporting for the clinical site monitoring functions specified in the Statement of Work, and provide proposed plans and procedures for carrying out these clinical site monitoring functions, including: (i) site establishment visits; (ii) interim site visits; (iii) site and study closeout visits; (iv) laboratory and specimen audits; and (v) remedial and “for cause” site visits. Include the following:

A. A listing of clinical trials for which clinical site monitoring support has been provided over the past 5 years indicating: (i) clinical trial phase; (ii) number of subjects and number of participating sites; (iii) scope of site monitoring functions performed; (iv) study status; and (v) sponsor.

B. Proposed processes, Standard Operating Procedures, forms, templates, work instructions for site monitors, and preparatory instructions for clinical site personnel to be used for all required site monitoring visits, including a description of procedures to assess compliance with regulatory requirements and GCP, GLP and GMP and ICH guidelines, protocol-specific procedures and requirements, as well as overall clinical site operations.

C. Proposed templates showing the content and format for Site Visit Reports by type of site visit.

D. A description of clinical site performance and compliance problems and deficiencies that have been encountered in the past, and remedial actions recommended and implemented to correct identified problems and deficiencies.

E. Proposed plans and procedures for and a description of organizational experience in preparing clinical sites for audits by regulatory authorities.

9) Training (SOW item I)

A. Training of Clinical Site Personnel:

Describe organizational experience over the past 5 years in planning and conducting training for clinical site personnel with respect to regulatory requirements and guidelines governing human subjects research, and in providing assistance for and participating in training of clinical site personnel with respect to protocol-specific requirements and procedures. Include a description of the various training methods utilized, e.g., webcasts, face-to-face training sessions, etc., and provide samples of written materials developed and used for such training.

B. Training of Site Monitors:

1. Provide a proposed Training Plan delineating methods and approaches for the initial and ongoing training of site monitors and for evaluating training activities.

2. Identify problems and deficiencies encountered in the past in ensuring necessary and effective training for site monitors and recommendations developed and implemented to address these problems and deficiencies.

10) Preparation of Study Products (SOW Item J)

Describe organizational experience over the past 5 years and provide proposed plans and procedures for the following:

A. Over-encapsulation of pills or capsules and performance of associated release and stability testing.
B. Repackaging of study product provided by other manufacturers.
C. Labeling or relabeling of study products provided by other manufacturers.
D. Identity testing.
E. Providing documentation of manufacturing activities for regulatory filings.

Include a description of the SOPs maintained for these activities.

11) Receipt, Distribution and Quality Control of Study Products (SOW item K)

Describe organizational experience over the past 5 years and provide proposed plans and procedures for the provision of the following study product receipt, distribution and quality control services:

A. Pharmaceutical Services:

1. Reviewing and evaluating clinical trial protocol documents with regards to pharmaceutical needs and practice.
2. Providing technical assistance to clinical research site pharmacists for establishing research pharmacies, SOPs, and QA programs.

B. Pharmaceutical Operations:

1. Receipt, tracking, storage, and quarantine of study products at temperatures as defined by manufacturer's label or United States Pharmacopeia.
2. Repackaging study products into a variety of packaging types in accordance with protocol plans.
3. Monitoring inventory to determine usage rates, expiration dates and performing physical inventories.
4. Generating all required shipping documents.
5. Obtaining required import and export documents.
6. Maintaining current licenses and permits for storing, handling, transporting, distribution of drugs, biologics, controlled substances, and study products containing ethanol.
7. Identifying study products that need to be removed from stock at the study product distribution center and at research sites.
8. Processing and documenting returned study products from clinical research site pharmacists.
9. Handling, disposal and documenting of the disposition of returned products in accordance with all applicable local, state and Federal laws and regulations.
10. Establishment and maintenance of websites for clinical site pharmacists.

C. Security and Safety of Study Products:

1. Procedures for securing study products to protect them from theft, heat, light, water, fire; and monitoring and documenting appropriate temperature conditions.
2. Provision of continuous power through the use of a generator or other systems.
3. Provision of cold storage in the event of a freezer or refrigerator failure.

4. Handling controlled substances in compliance with U.S. Drug Enforcement Agency requirements.

12) Repository of Biological Specimens (SOW item L)

Describe organizational experience with and provide proposed plans and procedures for operating, managing and maintaining a biological specimen repository, including:

A. Procedures and processes to be used from specimen receipt to storage and final distribution to investigators.

B. Computerized specimen tracking and inventory database management system for biological specimens.

C. Operational and risk reduction capabilities, as well as quality assurance systems to ensure the safe storage of specimens, including back-up and disaster recovery contingencies.

13) Other Technical and Administrative Support (SOW item M)

A. NIAID Safety Oversight Structures

Describe organizational experience over the past 5 years and provide proposed plans and procedures for supporting NIAID safety oversight structures. As appropriate for each support function listed below, include a discussion of organizational experience in terms of the scope of safety oversight structures involved.

1. Coordinating administrative aspects for the management of Conflict of Interest.
2. Handling logistical arrangements for meetings and teleconferences.
3. Distributing and managing confidential documents and other materials.
4. Use of access-controlled and password-protected systems for providing information to safety oversight structures.

B. ACE Steering Committee, Consortium Operations Committee and Study Management Teams

Describe organizational experience over the past 5 years and provide proposed plans and procedures for the provision of technical, administrative and logistical support for the ACE Steering Committee, the Consortium Operating Committee, and Study Management Teams. As appropriate for each support function listed below, include a discussion of organization experience in terms of the types of clinical trial network governing bodies and Study Management Teams involved.

1. Coordinating administrative aspects for the management of Conflict of Interest.
2. Handling logistical arrangement for meetings and teleconferences.
3. Preparing, or assisting in the preparation of, and distributing materials, reports, analyses, and recommendations.

4. Assisting in the preparation of Standard Operating Procedures for: (i) the development, review and decision-making with respect to Concept Proposals and Full Proposals for clinical trials and mechanistic studies; (ii) monitoring progress with respect to the implementation of approved clinical trials and mechanistic studies; (iii) the development and implementation of criteria and procedures for the evaluation of clinical and mechanistic study site performance; (iv) requests for interim and final analyses of clinical and laboratory study results; (v) the addition of clinical and mechanistic study sites; and (vi) the authorship, preparation and review of scientific reports, manuscripts, abstracts and presentations of study results.
5. Preparing summaries of meeting/teleconference decisions and action/follow-up items.

14) Initial Transition (SOW Item R).

Proposed plan for the secure, orderly and efficient transfer and/or receipt of clinical and laboratory data, study-related materials, and other contract-generated resources, including (i) timelines and detailed plans to ensure a seamless transition of currently enrolling studies; (ii) detailed plans for database transition; and (iii) plan to provide final study reports and other required regulatory reports for all studies in transition.

SECTION 4: SCIENTIFIC AND TECHNICAL PERSONNEL (SOW item N)

The Technical Proposal should include all information relevant to document individual training, education, experience, qualifications and expertise of all proposed scientific and technical personnel for the offeror and all proposed subcontractors necessary for the successful completion of all contract requirements. Clearly identify who is proposed as Key Personnel. Limit CVs to 2-3 pages, provide selected references for publications relevant to the scope of the RFP, and include experience with projects of similar scope, size and complexity carried out by the offer and any proposed subcontractors over the past 5 years.

1) Principal Investigator (PI): Include experience and qualifications of the PI to plan, manage, coordinate and direct the activities to be carried out under this contract:

   A. Statistical design, development, implementation and analysis of all phases of clinical trials as well as mechanistic studies.

   B. Statistical design and analysis components of IND submissions and interacting with the FDA and other regulatory authorities on pre- and post-IND submission requirements and deliberations.

   C. The design, operation and oversight of state-of-the art computer-based systems for clinical, including safety oversight, and laboratory data, and systems for ensuring quality control of clinical and laboratory.

   D. Safety oversight and reporting functions, including the preparation and presentation of safety data and analyses to safety oversight structures and regulatory authorities.

E. Clinical research support services for study product receipt, distribution and quality control, clinical site monitoring and training, and biological specimen repository functions.

F. Working with government sponsors, government-supported clinical investigators and clinical trial networks, and industry collaborators in protocol design, development, execution, oversight, reporting and analysis.

2) Other Scientific and Technical Personnel:

A. statisticians
B. protocol development personnel
C. clinical site monitors
D. research pharmacists and other personnel for study product receipt, management and distribution and preparation of study products
E. technical personnel for biological specimen repository functions
F. regulatory personnel
G. chemistry, manufacturing and control personnel
H. safety oversight personnel
I. database and website design and management personnel

SECTION 5: FACILITIES, EQUIPMENT AND OTHER RESOURCES (SOW item O)

Provide a description and document the availability and adequacy of facilities, equipment, space and other resources necessary to carry out the Statement of Work. Identify the location and describe the features of facilities, including a floor plan and a list of equipment and other resources dedicated to the project, for the offeror and any proposed subcontractors (lease or ownership information should be provided). Include the following:

1) Repository for Biological Specimens
2) Facilities, equipment and other resources for study product receipt, management and distribution
3) Controlled access areas for secure storage of confidential study and regulatory files
4) Central data management facility and off-site back-up facility
5) The central facility to serve as the Safety Reporting Center
6) Clinical Study internet-based collaboration portals
7) Resources to ensure secure internet access for all data systems
8) All support resources, including Information Technology systems, which will be required to effectively carry out the functions specified in the Statement of Work
9) Webcast and video capability for training purposes that can be uploaded to the internet

The Government may provide direct cost funds from this contract to purchase equipment for specific use on this contract with the prior approval of the Project Officer and Contracting Officer.

SECTION 6: QUALITY ASSURANCE/QUALITY CONTROL (SOW item P)

Provide a proposed Quality Assurance/Quality Control (QA/QC) Plan for all functions to be carried out by the offeror and proposed subcontractors to: (i) standardize contract processes; (ii) ensure that the conduct of all contract activities complies

with domestic and country-specific regulations governing human subjects research, GCP, GMP, GLP and ICH guidelines; and (iii) provide for the assessment of Contractor performance and the quality and timeliness of the clinical research functions carried out. Include: (i) measures/metrics to be used to assess performance and the quality of contract products; (ii) approaches/methods to document and address problems and deficiencies identified, including improvements in the internal QA/QC Plan; and (iii) plans for training Contractor staff on standard processes and measures used for internal QA/QC.

SECTION 7: PROJECT MANAGEMENT (SOW item Q)

1) Provide a plan for project organization, staffing, and management, including a detailed description of the responsibilities and level of effort for all proposed personnel who will be assigned to the contract, including proposed subcontractors and consultants, and an administrative framework indicating clear lines of authority and responsibility for all proposed personnel. If consultants and/or subcontractors are proposed, include a plan to manage, coordinate, and oversee the work performed by consultants and/or subcontractor(s). Include a chart of the proposed organizational/management structure for the project.
2) Describe the project management systems that will be used to track activities and to keep multiple activities on time and budget.
3) Outline how the PI will communicate with the Project Officer and the Contracting Officer and how the PI will communicate, monitor and manage the project both internally and externally (at subcontractor facilities).
4) Provide a plan for soliciting, evaluating, negotiating, awarding and managing subcontracts in accordance with FAR Clause 52.244-2. Include organizational experience with the identification and remediation of subcontractor performance problems or noncompliance with subcontract terms and conditions of award.
5) Describe experience and education of contract management staff, including the acquisition and management of subcontracts under Federal contracts.

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

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

2) Obtaining and Disseminating Biomedical Research Resources**:**
   Section L of the RFP specifies the minimum documentation requirements for this element. The Technical Proposal should document all information necessary to evaluate this issue.

3) Sharing Research Data (Plan):

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

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

[END OF ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS]

ATTACHMENT 6: ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS

STATISTICAL AND CLINICAL COORDINATING CENTER FOR AUTOIMMUNE DISEASE CLINICAL TRIALS (SACCC-ADCT)

BUSINESS PROPOSAL – TABLE OF CONTENTS

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

SECTION 2 – COST OR PRICE SUPPORT

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

SECTION 3 – UNIFORM COST ASSUMPTIONS

1) Technical Cost Assumptions

A. **General Technical Cost Assumptions:**

1. **Stem Cell Therapy Consortium:** Assume the following:

   a. the 2 active clinical trials being conducted by the Consortium will be supported through completion;
   b. for the SCOT clinical trial, (i) 5 clinical sites in Canada will be added prior to the contract effective date, (ii) last randomization will be completed in December 2009, and (iii) last protocol visit will occur 44 months after randomization;
   c. for the HALT-MS clinical trial, last transplant will occur in December 2009 and last protocol visit will occur 60 months after transplant; and
   d. no new clinical trials will be developed or implemented by the Consortium during the contract period of performance.

2. **Investigator-Initiated Projects:** Although the Statement of Work encompasses support for a fairly broad range of research for investigator-initiated projects, Budget Proposals are to be based on an assumption of support for 3 new clinical trials to be conducted under individual-investigator projects for the entire contract period of performance.

3. **Clinical Trial Duration, Enrollment Period and Visit Schedule:** For each clinical protocol in development on the contract effective date and for all new clinical trials, assume the following:

   a. an average duration of 25 months for Phase 1 clinical trials, and 25 months for Phase 2 clinical trials;
   b. enrollment will occur over a 12-month period;
   c. a total of 2 screening visits;
   d. screening assessments will take place over a 1-month period;

e. the last protocol visit will occur 12 months after initiation of study treatment; and
f. a total of 12 visits during treatment and follow-up.

4. **Mechanistic Studies:** Assume the following:

   a. all ACE clinical protocols in development on the contract effective date, all new ACE clinical trials, and all investigator-initiated projects will include associated mechanistic studies that will be conducted over the duration of each clinical trial.
   b. an average duration of 25 months for the execution and completion of independent mechanistic studies to be conducted by the ACEs.

5. **Study Initiation Meetings, Teleconferences and Videoconferences:** Assume the following:

   a. a one-day study initiation meeting or teleconference/videoconference for each new clinical trial and for all ACE clinical trials in development on the contract effective date;
   b. one-half of these activities will be conducted via face-to-face meetings, and one-half will be conducted via teleconference/videoconference; and
   c. participation in each study initiation meeting or teleconference/videoconference by 4 Contractor/subcontractor personnel.

6. **Safety Monitoring:** Assume the following:

   a. presentation to and Data and Safety Monitoring Board (DSMB) review of final draft clinical protocols for all new clinical trials for clinical trials in development on the contract effective date;
   b. presentation to and DSMB review of: (i) interim analyses of clinical study data at 6-month intervals for ongoing and new Phase 1, 2 and 3 clinical trials; and (ii) final statistical analyses at study completion for all clinical trials.
   c. preparation of monthly summaries of AEs and SAEs for review by the DAIT Medical Monitors, Study Management Teams (SMTs) and individual Principal Investigators for all ADCT.

7. **Interim Study Status Reports:** For all clinical trials and mechanistic studies in development, ongoing and new, assume the preparation of monthly interim study status reports on subject accrual, retention, compliance, loss to follow-up and other statistical issues and problems for SMTs and individual Principal Investigators for all ADCT.

8. **Clinical Site Monitoring Visits:** Assume an average duration of 3 days, including travel, for all interim and specialized clinical site monitoring visits, and for site initiation and site closeout visits.

9. **Training Workshops for Clinical Site Personnel:** Assume the following: (a) development and conduct of 3 one-day training programs/year for a total of 45 clinical site personnel/year; and (b) 3

training programs/year conducted via teleconference/videoconference, and 1 training program/year conducted via face-to-face meeting.

10. **Collaboration Portals:** Assume the following: (a) collaboration portals for 6 ongoing ACE clinical trials and 2 ongoing Consortium clinical trials; and (b) collaboration portals for all new clinical trials.

11. **Other Technical and Administrative Support:** Assume the following:

    a. **DSMBs:** (i) support for two DSMBs - the Hematopoetic Stem Cell DSMB, consisting of 10 members, and the Autoimmunity DSMB, consisting of 10 members; (ii) two 1.5-day meetings per year for each DSMB; and (iii) two teleconferences per year for each DSMB.
    b. **SMTs:** (i) SMTs for each clinical trial in development, ongoing and new; and (ii) three 1-day SMT meetings and 50 SMT teleconferences for each clinical trial from protocol development through completion and analysis of final study data.
    c. **ACE Steering Committee and Consortium Operations Committee:** Assume the following for <u>each</u> group: (i) two 2-day meetings per year; and (ii) bi-monthly teleconferences.

B. **Additional Technical Cost Assumptions**

CONTRACT ACTIVITY	ONGOING ACTIVITIES ON CONTRACT EFFECTIVE DATE (assume the following)	NEW ACTIVITIES FOR CONTRACT PERIOD OF PERFORMANCE (assume the following)
1. Statistical Design for Concept Proposals	none	<u>ACEs only</u>: (i) 6 Concept Proposals/year for clinical trials with associated mechanistic studies. (ii) 3 Concept Proposals/year for independent mechanistic studies.
2. Statistical Design for Full Proposals	none	<u>ACEs only</u>: (i) 4 Full Proposals/year for clinical trials with associated mechanistic studies. (ii) 2 Full Proposals/year for independent mechanistic studies.
3. Protocol Development	<u>ACEs only</u>: (i) 3 clinical trial protocols in development; 1 Phase 1 and 2 Phase 2. (ii) 1 independent mechanistic study protocols in development.	<u>ACEs</u>: (i) 3 new clinical trial protocols/year; 1 Phase 1 and 2 Phase 2. (ii) 1 new independent mechanistic study/year. <u>Investigator-Initiated Projects</u>: 3 new clinical trial protocols for the entire contract period of performance: 1 Phase 1 and 2 Phase 2.
4. Protocol Implementation	<u>ACEs</u>: (i) 6 ongoing clinical trials: 1 Phase 1 clinical trial; 5 Phase 2	<u>ACEs</u>: 3 new clinical trials/year: 1 Phase 1 clinical trial/year at a

	clinical trials at a total of 15 clinical sites and for a total of 195 subjects. (ii) 1 ongoing independent mechanistic studies involving 200 samples. Consortium: (i) SCOT is a Phase 2/3 clinical trial at 5 transplant sites and 50 other sites involving 226 subjects; (ii) HALT-MS is a Phase 1/2 clinical trial at 4 transplant sites involving 30 subjects.	total of 3 clinical sites and for a total of 20 subjects; and 2 Phase 2 clinical trial/year at a total of 5 clinical sites and for a total of 60 subjects. Investigator-Initiated: For each of the 3 new clinical trials, assume: (i) 3 clinical sites; and (ii)80 subjects.
5. Statistical Analyses	ACEs: final statistical analyses of: (i) 2 completed clinical trials; and (ii) 1 completed independent mechanistic study.	Interim and final statistical analyses for all new clinical trials as specified in section A.5. above.
6. Data Management	ACEs: (i) Of the 6 ongoing clinical trials, 5 will continue to use a web-based electronic data entry system; 1 will continue to use paper CRFs. (ii) Assume transfer of final clinical and mechanistic study data to BISC. Consortium: (i) Both clinical trials will continue using paper CRFs, except electronic randomization for both studies and electronic adverse event reporting for SCOT. (ii) Assume transfer of final clinical and mechanistic study data to BISC.	(i) For all new ACE clinical trials and associated mechanistic studies, assume a web-based electronic data entry system and transfer of final clinical and mechanistic study data to BISC. (ii) For all new ACE independent mechanistic studies, assume that data will be submitted as electronic files of known structure using comma separated value format, and final data will be submitted to BISC. (iii) For all new investigator-initiated clinical trials, assume a web-based electronic data entry system and transfer of final clinical and mechanistic study data to BISC.
7. Clinical Site Monitoring		ACEs and Investigator-initiated Projects: (i) Interim Visits: conducted quarterly for all ongoing and new clinical trials with review of 20% of records. (ii) Specialized Site Visits: a total of 7 visits for the entire contract period of performance. (iii) Site Closeout Visits: a total of 10 visits for the entire contract period of performance. (iv) Site Initiation Visits: a total of 15 visits for the entire contract period of performance. (v) Laboratory/Specimen

		Audits: a total of 5 visits for the entire contract period of performance. (vi) Audit Preparatory Assistance: assistance in preparing for audits for a total of 3 sites over the entire contract period of performance. Consortium: (i) Interim Visits: conducted on a quarterly basis with review of 20% of records. (ii) Specialized Site Visits: a total of 3 visits for the entire contract period of performance. (iii) Site Closeout Visits: a total of 10 visits for the entire contract period of performance.
8. GMP Facility Monitoring		Annual GMP monitoring for 8 Consortium cell processing laboratories.
9. Support for Regulatory Activities	(i) Archived regulatory files/documents for 3 completed ACE clinical trials - 1 IND clinical trials and 2 non-IND clinical trials. (ii) Continuation of regulatory support for 5 ongoing ACE clinical trials - 4 IND clinical trials and 2 non-IND clinical trials.	(i) Regulatory support for 21 new ACE clinical trials - 14 IND clinical trials and 7 non-IND clinical trials – for the entire contract period of performance. (iii) Regulatory support for 3 new investigator-initiated clinical trials – all under INDs. (iv) Support for GMP compliance for 7 clinical trials in which DAIT will assume product manufacturing responsibility. (v) 3 DAIT audits and 1 Regulatory Health Authority audit for the entire contract period of performance. (vi) two 4-hour training sessions per year for DAIT personnel.
10. Preparation of Study Products	none	Preparation of a total of 7 lots of study products for the entire contract period of performance.
11. Study Product Receipt, Distribution & Quality Control	For ongoing and in development ACE clinical trials	For all new clinical trials.
12. Repository of Biological Specimens	For all completed and ongoing clinical trials: (i) a total of 3,800 biological specimens stored. (ii) approximately 1,300 samples are peripheral blood mononuclear cells (PBMC), purified subsets of PBMC, or cells derived from CSF. The remaining samples are serum, plasma, whole blood, or CSF.	A total of 26,000 biological specimens for all new clinical trials and mechanistic studies for the entire contract period of performance.

	All samples are being stored at -70 C.	

2) Travel

Specific Activity	Cost Assumptions
1. Contract Initiation Meeting	One 1-day Contract Initiation Meeting within 10 business days of the contract effective date, to be held in Bethesda, MD and attended by all Contractor key personnel.
2. Site Visits	a. Annual 1.5-day site visits, to be held at the Contractor's facility and attended by all Contractor and subcontractor key personnel. b. 2 additional 1.5-day site visits during the contract period of performance for all Contractor and subcontractor key personnel; one to be held at the Contractor's facility and one to be held in Bethesda, MD.
3. ACE Steering Committee Meetings	Two 2-day meetings per year to be attended by 4 Contractor/subcontractor personnel; 1 meeting per year to be held in Bethesda, MD, and 1 meeting/year to be held at a location in the central U.S.
4. Consortium Operations Committee Meetings	Two 2-day meetings per year to be attended by 4 Contractor/subcontractor personnel; 1 meeting per year to be held in Bethesda, MD, and 1 meeting per year to be held at a location in the central U.S.
5. SMT Meetings	Five 1-day SMT meetings per year to be attended by 3 Contractor/subcontract personnel; 3 meetings per year to be held in Bethesda, MD, and 2 meetings per year to be held at a location in the central U.S.
6. Study Initiation Meetings	One face-to-face study initiation meeting for each new study will be held in Bethesda, MD
7. DSMB Meetings	Participation of the senior SACCC statistician for each clinical trial for presentation of final clinical protocols and interim and final statistical analyses to DSMBs at: (i) 2 meetings per year for the Autoimmunity DSMB to be held in Bethesda, MD; and (ii) 2 meetings per year for the Hematopoetic Stem Cell DSMB to be held in Bethesda, MD.
8. General Scientific Meetings	A total of $3,750 per year for the PI and selected Contractor personnel to attend general scientific meetings for presentations on work conducted under this contract.

3) Special Shipping and Packaging

No special shipping instructions in addition to requirements for shipping of clinical study products and repository specimens as described in the Technical Cost Assumptions and Statement of Work.

4) Storage

No special storage instructions in addition to requirements for the biological samples repository as described in the Technical Cost Assumptions and Statement of Work.

5) Government Furnished Equipment (GFE)

No Government Furnished Equipment will be available to be transferred from incumbent contractor.

☐ The purchase of Government Furnished Equipment will not be permitted as a direct charge under this contract without prior written approval by the Project Officer and the Contracting Officer.

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

1) 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.

ATTACHMENT 7: ADVANCED UNDERSTANDINGS

STATISTICAL AND CLINICAL COORDINATING CENTER FOR AUTOIMMUNE DISEASE CLINICAL TRIALS (SACCC-ADCT)
RFP-NIAID-DAIT-NIHAI2008026

☐ There are ***NO*** Advance Understandings applicable to this solicitation.

☒ The below Advance Understandings are applicable to this solicitation.

Review of Press Releases

The Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. In accordance with NIH Manual Chapter 1754, misrepresenting contract results or releasing information that is injurious to the integrity of NIH may be construed as improper conduct. The complete text of NIH Manual Chapter 1754 can be found at: http://www1.od.nih.gov/oma/manualchapters/management/1754/. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The Contractor shall ensure that the Project Officer has received an advance copy of any press release related to this contract not less than five (5) calendar days prior to the issuance of the press release.

ATTACHMENT 8: ADDITIONAL RFP-SPECIFIC MATERIALS

STATISTICAL AND CLINICAL COORDINATING CENTER FOR AUTOIMMUNE DISEASE CLINICAL TRIALS (SACCC-ADCT) RFP-NIAID-DAIT-NIHAI2008049

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

1) AUTOIMMUNITY CENTERS OF EXCELLENCE: CLINICAL TRIALS AND MECHANISTIC STUDIES

Protocol Number	Protocol Name	Area of Study	Projected Start Date / Site Activation Date / Projected Completion Date	Protocol Status	Target Enrollment / # of Sites	Protocol Chair(s)
ALN01	Double-blind RCT, PH II, Treatment of Lupus Nephritis by Inhibition of Tumor Necrosis Factor-alpha, Using Etanercept Vs. Placebo	Lupus Nephritis	SAD: 01/08 PCD: 07/10	Active	28/6	M. Dall'Era D. Wofsy
APV01	A randomized, Double-Blind, Placebo Controlled Phase II Trial of Infliximab in Subjects with Pemphigus Vulgaris Receiving Prednisone.	Pemphigus Vulgaris	SAD: 03/06 PCD 03/10	Active	20/4	R. Hall
ARA04	Treatment of Early RA with a Monoclonal Antibody to CD20	Rheumatoid Arthritis	SAD: 06/07 PCD: 06/09	Active	10/1	C. Striebich
ARA02	Double Blind Lovastatin Therapy in Rheumatoid Arthritis	Rheumatoid Arthritis	SAD: 08/06 PCD: 12/10	Active	80/6	B. Diamond C. Aranow
ALE01	Rituximab in SLE: Understanding Long Term Responses and the Impact of B Cell Depletion on T Cells	Systemic Lupus Erythematosus	PSD: 07/08 PCD: 07/11	In Development	32/2	I. Sanz R.J. Looney
ALE 02	Effect of Vitamin D_3 on the IFNα Signature in Patients with Systemic Lupus Erythematosus	Systemic Lupus Erythematosus	PSD: 07/08 PCD: 07/10	In Development	57/6	C. Aranow D. Kamen
ARA03	TNF-alpha Blocking Agents: Mechanisms of Failure in RA Patients	Rheumatoid Arthritis	PSD: 07/08 PCD: 07/09	In Development	TBD	L. Moreland
ARA05	Switching Anti-TNF-α Agents in Patients with RA with an Inadequate Response to TNF-α Inhibition	Rheumatoid Arthritis	PSD: 08/08 PCD: 02/11	In Development	144/15	L. Moreland M. Genovese
ARA06	Mechanism of Action of Anti-TNF agents in RA	Rheumatoid Arthritis	PSD: 09/08 PCD: 03/11	In Development	60/1	J. Anolik

ASC01	Treatment of Systemic Sclerosis-Associated Pulmonary Arterial Hypertension (SSPAH) with a Monoclonal Antibody to CD20 (Rituximab)	Scleroderma	PSD: 10/08 PCD: 10/11	In Development	50/6	M. Nicolls D. Badesch
AC002	Phase I Open-label Safety and Efficacy Study of an Anti-CD20 Antibody (Rituximab, Rituxan) for Anti-B cell Therapy in the Treatment of Systemic Lupus Erythematosus	Systemic Lupus Erythematosus	SAD: 01/01	Closed	30/3	R. Eisenberg
AMS01	Treatment of Multiple Sclerosis with Copaxone and Albuterol	Multiple Sclerosis	SAD: 07/01	Closed: Final report in preparation	40/1	S. Khoury
AMS02	A Phase I/II, Open-label, Pilot Trial To Evaluate the Safety of Rapamune (Sirolimus) in Patients with Multiple Sclerosis	Multiple Sclerosis	SAD: 05/03	Closed: Final report in preparation	15/1	S. Khoury
AMS03 (Mechanistic Study)	Effects of IL-12 neutralization on cytokine, chemokine and adhesion molecule pathways in relapsing-remitting multiple sclerosis	Multiple Sclerosis	SAD: 04/05	Closed: Final report in preparation	70/5 11 - healthy controls	B. Segal I. Sanz
ASJ01	An Open-Label, One Arm, Phase I Safety Study of Anti-CD20 Antibody (rituximab, Rituxan) Therapy in the Treatment of Primary Sjogren's Syndrome.	Sjogren's	SAD: 09/05	Closed: Final report in preparation	12/2	P. Cohen B.H. St. Clair

2) HEMATOPOIETIC STEM CELL TRANSPLANTATION CONSORTIUM: CLINICAL TRIALS AND MECHANISTIC STUDIES

Protocol Number	Protocol Name	Area of Study	Projected Start Date / Site Activation Date / Projected Completion Date	Protocol Status	Target Enrollment / # of Sites	Protocol Chair(s)
SCSSC (SCOT)	A Randomized, Open-Label, Phase II/III Multi-Center Study of High-Dose Immunosuppressive Therapy Using Total Body Irradiation, Cyclophosphamide, ATGAM, and Autologous Transplantation with Auto-CD34+HPC versus Intravenous Pulse Cyclophosphamide for the Treatment of Severe Systemic Sclerosis	Severe Systemic Sclerosis	SAD: 05/05 PCD: 12/12	Active	226	P. McSweeney D. Furst R. Nash K. Sullivan
ITN033AI	A Phase I/II Immune Ablation using BEAM and Thymoglobulin and Autologous Hematopoietic Stem Cell Transplant in Poor Prognosis Multiple Sclerosis	Multiple Sclerosis	SAD: 06/06 PCD: 12/13	Active	30/3	R. Nash
SCSLE-01	A Randomized, Open Label, Phase II Multi-Center Study of Non-Myeloablative Autologous Transplantation with Auto-CD34+HPC Versus Currently Available Immunosuppressive/ Immunomodulatory Therapy for Treatment of Systemic Lupus Erythematosis	Systemic Lupus Erythematosus	SAD: 03/06	Closed	no enrollment/5	R. Burt A. Traynor B. Hahn K. Kalunian

3) DAIT-FUNDED CLINICAL RESEARCH SUPPORT SERVICES CONTRACTS

A. Bioinformatics Integration Support Contract (BISC)

(http://www3.niaid.nih.gov/about/organization/dait/bisc.htm)

Northrop Grumman Information Technology, located in Rockville, MD, provides information technology support in the production, analysis, archiving, exchange and integration of genomic, proteomic and related data to DAIT-funded research programs via the Immunology and Data Analysis Portal (ImmPort at http://www.immport.org/immportWeb/home/home.do). Specific responsibilities of the Contractor include, but are not limited, to the following:

1. Accelerate a more collaborative and coordinated research environment.
2. Create an integrated database that broadens the usefulness of scientific data and advances hypothesis-driven and hypothesis-generating research.
3. Integrate relevant data sets from participating laboratories, public and government databases, and private data sources.
4. Provide analysis tools to advance immunological research.

4) NIH-FUNDED CLINICAL RESEARCH PROGRAMS

A. Autoimmunity Centers of Excellence (ACE)

Nine Autoimmunity Centers of Excellence (ACE) conduct collaborative basic and clinical research on autoimmune diseases, including single-site and multi-site pilot clinical trials of immunomodulatory therapies and mechanism-of-action studies (http://www.autoimmunitycenters.org/). The ACE support close interaction between clinicians and basic researchers, which should facilitate the identification of effective tolerance induction and immune modulation strategies to treat or prevent disease, and accelerate the translation of scientific advances to the clinic. Examples of ACE-supported clinical trials include: anti-CD20 for systemic lupus erythematosus; sirolimus for multiple sclerosis; and a double-masked study of the combination of copaxone and albuterol versus copaxone alone for multiple sclerosis. The ACE are co-sponsored by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and the NIH Office of Research on Women's Health.

The nine currently funded ACEs are:

- Robert Carter, University of Alabama at Birmingham
- Leonard Chess, Columbia University
- Betty Diamond, Feinstein Institute for Medical Research
- Michael Holers, University of Colorado
- Samia Khoury, Brigham and Women's Hospital
- Eugene W. St. Clair, Duke University
- Ignacio Sanz, University of Rochester
- Massimo Trucco, Children's Hospital of Pittsburgh
- David Wofsy, University of California at San Francisco

B. Hematopoietic Stem Cell Transplantation Consortium (HSCT)

In 1999, NIAID awarded contracts for the creation of a consortium to study hematopoietic stem cell transplantation (HSCT) for the treatment of autoimmune diseases. The contracts resulted in the development of clinical protocols by 3 distinct clinical trial groups using high dose immunosuppressive therapy (HDIT), followed by HSCT for the treatment of Severe Systemic Sclerosis (SSc), and Multiple Sclerosis (MS). In addition to clinical outcomes, mechanisms of disease, remission and relapse will be evaluated as part of all three studies. The SSC trial has two treatment arms (an active control regimen and a transplant regimen) and is a phase II/III pivotal trial evaluating safety and clinical success in subjects with severe, rapidly progressive systemic sclerosis (http://www.sclerodermatrial.org/). The phase II single arm MS trial (http://clinicaltrials.gov/ct2/show/NCT00288626) focuses on safety and the assessment of biological activity using MRI measures and clinical outcomes.

The leads for the HSCT Consortium are:

- Keith M. Sullivan, Duke University
- Richard A. Nash, Fred Hutchinson Cancer Research Center

C. Immune Tolerance Network (ITN)

The Immune Tolerance Network (ITN) was established in 1999 and is currently under a contract to the University of California, San Francisco (http://www.immunetolerance.org/). The ITN involves approximately 70 investigators from more than 40 institutions within the U.S., Canada, Western Europe, the United Kingdom, and Australia. The overall goal of the ITN is to accelerate the evaluation of promising approaches for the induction and maintenance of immune tolerance in four clinical areas: solid organ transplantation, islet cell transplantation, autoimmune diseases, and asthma and allergic diseases. The scope of research carried out by the ITN includes: Phase I, II, III and IV clinical trials conducted at domestic and non-domestic sites; investigations of the mechanisms underlying immune tolerance; studies to identify and evaluate potential immune/surrogate markers of the induction, maintenance, and loss of tolerance in humans; and the operation of several core resources for assays and bioinformatics. Under the contract awarded in FY 2007, the ITN will participate in additional research activities, including non-clinical safety and efficacy evaluations and, on a limited basis, manufacture of investigational products.

5) CURRENT SACCC-ADCT SOFTWARE SYSTEMS

Currently, the SACCC-ADCT uses 5 distinct software systems plus a variety of websites. The two systems used for clinical data management are the RhoDBMS™ for paper-based case report forms and RhoEDC™ for electronic data capture. Both are proprietary systems and are described briefly below. The SACCC-ADCT also uses the proprietary systems RhoRAND™ for registration and randomization and RhoLAB™ for specimen tracking. Finally, the SACCC-ADCT uses a commercial system ARISg for safety reporting. Each of these systems is described briefly below.

Rho*DBMS*

The Rho Clinical Trials Data Management System (CT-DBMS), version 6.05, is used to process paper CRF data using true independent, double-data entry with a third-party referee. This system maintains a complete electronic audit trail of data changes, starting at the point of keyed data. The Rho CT-DBMS is an internally developed system that operates on a SAS® Version 8 platform. Rho completed 21 Code of Federal Regulations (CFR), Part 11 certification of its CT-DBMS in 2002 and maintains that certification for new system releases.

Rho*EDC*

The Rho*EDC* is validated software developed at Rho for data collection and query management for clinical trials of all phases. A protocol-specific database is developed within Rho*EDC* for each such study, and all electronic entry will take place on an Internet browser connected to Rho via a 128-bit encrypted Internet connection; the Rho*EDC* system can support all standard browsers including Internet Explorer, OmniWeb, and Safari, and sites can access the system through either a Windows or Mac operating system. Rho's secure Web site and database servers run from a restricted access co-location facility with local mirroring/backup services. At this time all entered and submitted data are stored in an Oracle® version 9ir2 relational database. Any data management tasks that are not automated in Rho*EDC* are performed using SAS version 8.2 or later.

Rho*RAND*

Rho*RAND* is a subject registration and randomization system that leverages state-of-the-art interactive voice response and/or Web user interface technology to facilitate clinical trials research. The database for the system is maintained on an Oracle platform and the system operates through either standard web browsers or touch-tone telephone connections. The Rho*RAND* application provides a framework in which specific studies can be created. It provides building blocks that studies can use to achieve specific needs through the manipulation of metadata and study data, thereby allowing staff to minimize protocol-specific programming and use components that have been rigorously tested as part of the Rho*RAND* application in setting up the system for specific protocols. It provides 24-hour, 7 day-a-week multilingual central randomization across multiple clinical studies. Key functions of Rho*RAND* include (1) patient registration at screening or enrollment; (2) randomization; (3) subject tracking; (4) drug assignment; (5) investigator notification of activity; (6) emergency code break; and (7) medication and inventory management.

Rho*LAB*

Rho*LAB* is a laboratory and specimen tracking system designed for use in studies that involve the collection of specimens at study sites with shipment of the specimens to 1 or more centralized laboratories for processing. Rho*LAB* uses state-of-the-art technologies and methodologies; the user interfaces conform to the XHTML 1.0 standard, ensuring support across standard Internet browsers such as Microsoft Internet Explorer. All information is stored centrally in a secure and reliable Oracle Enterprise Server database.

Rho*LAB* provides an efficient data entry and management system for all specimens associated with a study. The system is designed to manage any number of study sites, labs, and ancillary facilities. Rho*LAB* supports data entry via barcode and manual entry, and generates a variety of labels that can be used throughout the laboratory, including sub-zero freezer environments. The system can be customized to simply coordinate and track the movement of specimens between study sites and laboratories; however, the system also has the capability of managing the flow of specimens through a series of laboratory tests. Additionally, it provides tracking and notification systems that provide users at the sites, labs, the SACCC-ADCT, and other associated contractors with (a) specimen collection information; (b) tracking of protocol-specific specimen characteristics; (c) site-to-lab and lab-to-lab shipment forms and tracking logs; (d) generation of packing slips; (e) automated notification of shipments sent and received; and (f) reporting of damaged, extra, and missing specimens.

ARISg

ARISg 5.1 is an off-the-shelf, Web-based software package purchased from Aris Global for the purpose of collecting, validating, tracking, reporting, and analyzing adverse events for drugs, biologics, devices, and vaccines in accordance with international regulatory guidelines including federal regulation 21 CFR Part 11. It ensures the integrity, reliability, and confidentiality of safety data used in support of regulatory submissions. The high level features of the system are:

A. Record details related to adverse events caused by drugs, biologics, medical devices, or vaccines through user defined data entry

B. Control data related to adverse events through follow-up tracking

C. Comprehensive query management tools

D. Generate various regulatory and management reports for internal and external review

E. Provide complete security of all data

F. Facilitate worldwide regulatory compliance