

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

RFP-NIH-NIAID-DAIT-04-43

“Administrative Support Contract for DAIT Clinical Research Programs”

1. OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE FOLLOWING WEBSITE FOR ANY SOLICITATION AMENDMENTS. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE. http://www.niaid.nih.gov/contract/default.htm		
2. SECTION A – SOLICITATION/CONTRACT FORM -- PURCHASE AUTHORITY: FAR 1.602-1 NOTE: The issuance of this solicitation does not commit the government to an award.		
3. Issue Date: December 4, 2003	4. Due Date: February 4, 2004 Time: 3:00 PM, EST	5. Small Bus. Set-Aside: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No 8(a) Set-Aside: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No (See Part IV, Section L.)
6. Just In Time: <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes (See Part IV, Section L.)	7. Number of Awards: <input checked="" type="checkbox"/> Only 1 Award <input type="checkbox"/> Multiple Awards	8. Technical Proposal Page Limits: See Attachment entitled: <i>“Proposal Submission: Number of Copies, Page Limitations and Electronic File Size”</i>
9. Issued By: Barbara A. Shadrick Senior Contracting Officer Research Resources Contract Branch Contract Management Branch, DEA NIH, NIAID 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, MD 20892-7612	10. <input checked="" type="checkbox"/> We reserve the right to make awards without discussion.	
	11. Options: <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes (See Part IV, Section L.)	12. Period of Performance: 7 years beginning on or about September 30, 2004
13. Primary Point of Contact: Name : David T. Lisle Phone: (301) 451-2617 Fax: (301) 480-5253 E-Mail: dlisle@niaid.nih.gov	14. Secondary Point of Contact: Name: Elizabeth Shanahan Phone: (301) 594-6309 Fax: (301) 480-5253 E-Mail: eshanahan@niaid.nih.gov	15. Protest Officer: Brenda J. Velez Program Director, CMP Address (see Block 9.)
16. COLLECT CALLS WILL NOT BE ACCEPTED. FACSIMILE SUBMISSIONS ARE NOT ACCEPTABLE.		
17. Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled “Proposal Summary and Data Record, NIH-2043” (See SECTION J – Attachments)		
18. DELIVERY ADDRESS INFORMATION		
Hand Delivery or Overnight Service: David T. Lisle Research Resources Contract Branch Contract Management Program, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, MD 20817	U.S. Postal Service or an Express Delivery Service David T. Lisle Research Resources Contract Branch Contract Management Program, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, MD 20892-7612	
19. The Official Point of Receipt for the purpose of determining timely delivery is the address provided in Block 18, above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.		

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Background

The Division of Allergy, Immunology, and Transplantation (DAIT) of the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health, plans, sponsors, and directs national and international extramural research programs in basic immunology, asthma, and allergic and immunologic diseases. Through these programs, DAIT-supported investigators conduct basic, pre-clinical, and clinical investigations into the causes, diagnosis, prevention, and treatment of a broad range of immune-mediated disorders.

The purpose of this solicitation is to establish the Technical and Administrative Support Center for DAIT Clinical Research Programs to provide technical and administrative support to multiple ongoing clinical research networks and associated NIAID Data and Safety Monitoring Boards (DSMBs). This support will enable DAIT to fulfill its responsibilities as sponsor of a large portfolio of clinical trials conducted at many sites throughout the U.S. and internationally.

Current DAIT Clinical Research Programs: The clinical research programs to be supported under this contract include, but may not be limited to:

- **Immune Tolerance Network (ITN):** An international consortium of clinical and basic scientists to evaluate immune tolerance induction strategies for treatment of autoimmune diseases; asthma and allergic diseases; and rejection of transplanted organs, tissues, and cells. Information about the ITN can be found at www.immunetolerance.org
- **Autoimmunity Centers of Excellence (ACEs):** Nine centers engaged in a cooperative research program of integrated basic, preclinical, and clinical research including single-site and multi-site cooperative clinical trials for new immunomodulatory interventions for autoimmune diseases, and studies of mechanisms of action of these therapies.
- **Cooperative Clinical Trials in Pediatric Transplantation (CCTPT):** Supports multi-center clinical trials of novel approaches to prevent acute and chronic graft rejection in pediatric kidney transplantation, evaluate modifications of immunosuppressive drug regimens to mitigate unwanted side effects of immunosuppression, and assess pre-transplant immunotherapy to improve transplantation outcomes.
- **Inner-City Asthma Consortium (ICAC):** A network of basic scientists and clinical investigators to evaluate the efficacy of promising immune-based therapies to reduce asthma severity and prevent disease onset in inner-city children.
- **Stem Cell Transplantation Consortium (SCTC):** Three centers are developing clinical trials to assess the efficacy of hematopoietic stem cell transplantation to treat autoimmune diseases, including multiple sclerosis, systemic lupus erythematosus, and scleroderma. Studies of the underlying immune mechanisms of autoimmune diseases will be performed along with the clinical trials.

Data and Safety Monitoring Boards: The following four (4) DSMBs are currently in operation to assist DAIT in monitoring of its clinical research programs.

- Transplant DSMB
- Allergy and Asthma DSMB
- Autoimmune DSMB
- Stem Cell DSMB

This contract will support day-to-day management activities associated with DAIT's clinical research programs, logistical arrangements for small scientific meetings and workshops on critical scientific issues, and the development and maintenance of databases that contain information essential for program management. Specifically, the contract will provide support services in the following areas: administrative, technical, and logistical support for scientific meetings and conferences, and data and safety monitoring boards; logistical and technical services for conference calls; management and administrative

support for regulatory operations; and preparation of scientific and technical reports and documents. This contract will be managed by the DAIT Office of Clinical Applications, which is responsible for site monitoring and regulatory activities associated with clinical trials in solid organ and islet transplantation, autoimmune diseases, and asthma and allergic diseases.

The work to be carried out under this contract is currently being performed by Consolidated Safety Services, Inc., as a subcontract to The EMMES Corporation under contract N01-AI-95382. The work to be performed under the new contract includes support for:

1. Scientific Meetings and Conferences
2. Conference Calls
3. Meetings for DAIT DSMBs
4. Management and Administrative Support for Regulatory Operations
5. Orderly Transition to a Subsequent Contractor or to the Government

Statement of Work

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government, as needed to perform the work below. Specifically the Contractor shall:

Task 1: Meetings with DAIT Program Staff

The Contractor shall meet approximately once a month with the DAIT Program Staff at their offices in Bethesda, Maryland, and shall be available with as little as one (1) day advance notice. Meeting notices will be given by telephone or in writing. Whenever possible, the DAIT Project Officer will schedule meetings at least 5 working days in advance.

Task 2: Scientific Meeting and Conference Support

The Contractor shall be responsible for making all logistical arrangements for DAIT scientific meetings and conferences, including:

- (1) pre-meeting planning;
- (2) site selection and reservation for lodging and meeting room facilities;
- (3) preparation of meeting materials, including invitation and confirmation letters, agendas, participants lists, logistical instructions, etc.
- (4) on-site logistical assistance; and
- (5) post-meeting support.

Best current estimates indicate that:

- *approximately two (2) scientific/investigator meetings or conferences will be held each year of the contract;*
- *meetings/conferences will be one (1) to two (2) days in length;*
- *number of participants will range from 10-30 per meeting/conference;*
- *each meeting/conference will require hotel accommodations and on-site support;*
- *contractor support for travel and per diem of eight (8) to ten (10) participants per meeting;*
- *meeting/conference locations will be both in and outside of the Washington, DC metropolitan area.*

The Contractor shall designate a Meeting Planner Executive who will be responsible for the management of all services required under Task 2, including resolving problems and making revisions in hotel logistics arising before and during a meeting, hotel billing and all follow-up matters.

At the time this contract is awarded, the incumbent contractor may have previously negotiated contracts with hotels for future meetings. The new Contractor must honor these contracts unless comparable or better accommodations at or below the existing contract prices, terms, and conditions can be found, or unless otherwise instructed by the Project Officer. The Project Officer and Contracting Officer must review and approve any proposed contracts for lodging, meeting room and other support services in advance.

A. Pre-Meeting/Conference Planning and Support Services

1. Planning Support

Schedule state-of-the-art teleconferences, including, but not limited to, video and internet teleconferences, and meetings, including working group meetings, ad hoc meetings, and other scientific/investigator meetings and conferences for the major DAIT clinical research programs as directed by the Project Officer. Specifically, the Contractor shall:

- a. **Meeting/Conference Request:** The Project Officer will approve and submit to the Contractor, via email or fax, a meeting or conference request form specifying considerations for meetings/conferences (i.e., date(s) if known, location, audio-visual/teleconferencing requirements, type of room set up, number of breakout rooms, etc.). Upon receipt of the meeting/conference request form, the Contractor shall develop a work plan to address the specified needs for each meeting.

- b. **Meeting/Conference Work Plan:** Within three (3) working days after receipt of the meeting/conference request form, submit, to both the program official responsible for the activity and the Project Officer, a meeting/conference draft work plan identifying, for example, planning requirements, the Contractor's Meeting Planner Executive, anticipated problems and recommended solutions, and a timetable for all activities. Discuss with the meeting requester any details that may not be clear to the Contractor at the time of submission of the meeting request form or additional items needed by the Contractor to appropriately organize the meeting. The draft work plan shall address pre-meeting planning services, on-site meeting services, and post-meeting services.
- c. If necessary, within three (3) working days after submission of the draft meeting work plan, the Contractor shall meet with the Project Officer and/or the responsible program official to discuss the draft work plan and to receive comments and suggestions, and prepare the final work plan.
- d. Within four (4) working days after the meeting specified in item c., above, or seven (7) working days after receipt of the meeting/conference request, submit to the Project Officer and program official responsible for the activity (where appropriate) a detailed itemized cost estimate that incorporates the comments and suggestions provided by DAIT. If total costs for the completion of a meeting exceed \$4,000, submit for approval a detailed itemized cost estimate to the Project Officer within 10 working days after the meeting specified in item c., above.
- e. Provide information about scheduled meetings to DAIT contractors, grantees and Program staff as designated by the Project Officer. Specifically, the Contractor shall provide meeting dates, locations, agendas, and other relevant meeting-related materials. As requested by the Project Officer, create and provide to the Project Officer, and his or her designee, a list of meeting attendees to include: names, titles, organizations, addresses, telephone and fax numbers, and internet addresses. As requested by the Project Officer, contact potential attendees and determine their availability for participation and their current telephone numbers, internet and mailing addresses.

2. Selection and Reservation of Meeting/Conference Sites and Hotel Accommodations

The Contractor shall arrange for and reserve meeting space, as specified by the Project Officer, to include the following.

- a. For meetings to be held in the Washington, D.C. metropolitan area, the Contractor shall first attempt to find space at an NIH facility (e.g., the Natcher Conference Center). If NIH space is not available, or the Project Officer determines it is not suitable for the meeting, the Contractor shall recommend a number of locations in the Washington, DC metropolitan area, preferably within a 10-mile radius of the offices of the DAIT, currently at 6610 Rockledge Drive, Bethesda, Maryland.

If NIH meeting facilities are not available, considerations in recommending alternative meeting sites shall include:

- 1) Reasonable and competitive overall costs;
- 2) Meeting rooms adequate in terms of size, lighting, ventilation, and location;
- 3) Accessibility and convenience to public transportation;
- 4) Adequate number of meeting, breakout, and lodging rooms available on desired dates;
- 5) Meeting facilities and some lodging facilities that meet Federal requirements for accessibility to handicapped participants;
- 6) Restaurant(s) available within walking distance capable of accommodating the expected number of participants;
- 7) No charge or discounts for meeting rooms based on participants' lodging reservations at commercial facilities; and
- 8) Availability of appropriate audio-visual equipment and technical support.

- b. For meetings to be held at a location outside the Washington, DC metropolitan area, submit meeting site and hotel recommendations within the geographical location specified by the Project Officer.
- c. Prior to the meeting, work with appropriate hotel staff (e.g., conference room coordinator, food services staff, hotel operators/front desk staff and hotel managers) to review the requirements for meeting room, lodging and food arrangements and to insure that these requirements are met.
- d. Following Project Officer approval of the meeting site and hotel, negotiate and execute a contract with the facility selected. The Contractor must put forth its best efforts to negotiate the most favorable terms and conditions with a facility for use by the Government. However, in the event that a cancellation clause (or additional fees) is required, the Contractor must notify the Project Officer and the Contracting Officer in advance. The Contracting Officer must review and consent to the contract cancellation clause prior to execution of the contract.
- e. The Contractor shall be responsible for resolving all problems in hotel logistics and organizational issues arising before and during each meeting. The Contractor shall also be responsible for any and all follow-up matters, revisions or changes in services received from the hotel, as well as hotel billing.
- f. Locate hotels, reserve and guarantee hotel rooms for specified meeting attendees when necessary and notify such attendees of the availability of the lodging facilities selected. The Contractor shall exert its best efforts to select hotels that will provide lodging at a cost no more than the standard federal per diem rate (all inclusive) and, whenever possible, provide meeting space free of charge or at a discount.
- g. Arrange for the availability and set-up of meeting room(s) and other services including:
 - 1) breakout rooms, if required;
 - 2) number and arrangement of chairs and tables;
 - 3) meeting breaks;
 - 4) audio-visual equipment and recording equipment when necessary;
 - 5) photocopying;
 - 6) food arrangements;
 - 7) telephone access;
 - 8) message services; and
 - 9) necessary computer equipment and connections.

3. Pre-Meeting Materials

Prepare, reproduce, and distribute necessary advance materials to attendees by mail or fax (if necessary) prior to the meeting, according to the timetable established in meeting work plan [See paragraph A.1.b., above]. These materials include, but are not limited to, the following:

- a. invitation and confirmation letters;
- b. agenda;
- c. meeting background materials;
- d. itineraries;
- e. travel guide information with directions and maps from local airports and local transportation and parking services;
- f. hotel reservation information (including hotel brochures, addresses, telephone numbers and rates);
- g. information on availability of preferred rates and procedures to obtain preferred rates; and
- h. briefing materials, pamphlets, and other background materials provided by the Project Officer.

Drafts of necessary advance materials require approval by the Project Officer prior to distribution. In addition, the Contractor shall be responsible for confirming receipt of advance materials by attendees.

i. Meeting Agendas

- 1) Work with the Project Officer, DAIT Program staff, study chairpersons, principal investigators, and other DAIT contractors to prepare draft agendas and distribute to individuals designated by the Project Officer for comment.
- 2) Incorporate comments and suggestions into the draft agenda and send a final agenda out for review within two (2) working days after receipt. The final agenda shall be included in the invitation mailings.

4. On-Site Meeting and Conference Services

Registration Fees and Materials

- 1) Collect participant registration fees (if appropriate) to cover the costs directly associated with meeting activities, as requested by the Project Officer. The amount and procedures for collection of conference registration fees are subject to Project Officer approval and shall be established at the specific meeting to develop and review the work plan. (See paragraph A., above).
- 2) Design, edit, and provide registration materials and services to include: name tags, program agenda, posters, schedules and a list of conference attendees. Registration materials shall be organized in folders or binders.
- 3) Provide registration desk and message center services as approved by the Project Officer.
- 4) Process applications for Continuing Medical Education (CME) credits for approximately one (1) to two (2) meetings a year, if requested by the Project Officer.

5. Monitoring of Meeting Rooms

As requested by the Project Officer, provide a Meeting Planner Executive who shall attend all or portions of specified meetings and provide meeting support services to ensure that multiple arrangements are carried out as specified, including:

- table set-up (i.e., open hollow square, class room, etc.)
- registration desk set-up, conference signs, badges, name cards
- arrangements for visual aids (insure availability of slide projectors, overheads, LCD monitor, flip charts, white boards, pointers, indelible markers and chalk)
- provision of pencils, pens, writing pads, etc.
- coffee breaks and meals
- documentation and delivery of messages
- assistance in operating audiovisual and recording equipment

6. Audiovisual Equipment

Provide audiovisual equipment, e.g., slide projector, overhead projector, LCD projector, charts, pointers, as required by the Project Officer, either through the conference facility or local vendors.

7. Portable Copier Equipment

Provide portable desktop copier equipment, as required by the Project Officer, either through the Contractor or from the conference facility at a Government rate not to exceed \$.05-\$.07/page. The Contractor shall arrange for last minute photocopying on site, if necessary. If additional last minute photocopying is required, there is a limitation of 250 total page reproductions per meeting or conference. If photocopying exceeds the 250-page limitation, the requester will be responsible for all costs accrued beyond the photocopy page limitations.

8. Minutes, Summaries, Transcripts and Action Items

At the direction of the Project Officer, the Contractor shall provide minutes/transcription services for approximately two (2) scientific meetings per year.

Specifically, the Contractor shall:

- a. Provide a high-quality tape recording system and/or a meeting transcriber to ensure the preparation of high-quality transcriptions of meeting proceedings. Typed transcript shall be completed and provided to the Project Officer within fourteen (14) working days after the scientific meeting.
- b. Prepare minutes, as requested by the Project Officer, to reflect the scientific and administrative issues of the meeting and the decision(s) and action item(s) made to resolve these issues. Minutes shall also contain action items/outstanding issues that may require further action at future meetings. The first draft of the minutes shall be available within seven (7) working days after the meeting. Minutes shall be distributed via email, or as requested by the Project Officer.
- c. Prepare and provide minutes or summaries of the DAIT Staff/Contractor meetings (See Task 1) within three (3) to five (5) working days after the meeting. The minutes/summaries shall contain a brief summary of issues discussed, decisions and action item(s), and any unresolved matters needing further attention.
- d. In preparing minutes/transcripts, the Contractor must ensure that when dealing with confidential or proprietary information, such information is kept in a secure location where only designated staff shall have access. Specific meeting plans should include a comprehensive description of the location for housing minutes/transcripts, who will have access, and the disposition of confidential or proprietary information, as directed by the Project Officer or responsible program official.

B. Post-Meeting/Conference Services

1. Provide draft proceedings and summaries of the meeting within time periods established in paragraph A.8., above.
2. Prepare and distribute post-conference materials (e.g., transcripts, summaries, minutes/action items and the meeting comments) to participants as requested by the Project Officer.
3. Prepare and submit to the Project Officer, within thirty (30) days following the conclusion of the meeting, a final meeting report showing total costs incurred during the meeting.

C. Mailing Lists

1. Maintain an up-to-date electronic rolodex in a system, compatible with Microsoft Outlook, of all names, titles, organizations, addresses, telephone and fax numbers, internet addresses and other information, as required by the Project Officer, of all contacts made by the Contractor regarding meetings/conferences, as well as other investigators, contractors and consultants as specified by the Project Officer. The Contractor shall develop and implement a method for maintaining the integrity of this database.
2. This database shall be available to DAIT staff, contractors, and grantees, as directed by the Project Officer, in an on-line format. The Contractor shall update this database at least every six (6) months and provide updated information to DAIT by electronic transfer or delivery of a disk. The Contractor shall develop and maintain an operation manual for the database system to be made available to the DAIT upon request. The database shall have the ability to select specific fields for particular reporting needs. Rosters shall be made available by the Contractor as required by the Project Officer.

Task 3: Provide Conference Call Services

Designate a Conference Call Coordinator(s) who shall be responsible for arranging conference calls in support of the DAIT clinical research programs. Best current estimates indicate approximately twenty-five (25) conference calls per month, each of 1.5 – 2.0 hours duration, with approximate usage of twenty (20) to twenty-five (25) telephone lines per conference call.

Specifically, the Contractor shall:

- A. Develop and implement written guidelines and procedures for handling conference call requests from DAIT staff. These guidelines and procedures shall provide a list of checkpoints designed to maintain quality control.
- B. If the date and time of the conference call has not been predetermined by the DAIT staff conference call originator, arrange dates and times by surveying all participants upon request from the call originator.
- C. E-mail or fax a conference call reminder to the call originator, appropriate DAIT staff and conference call participants. The reminder shall include:
 - 1. the list of participants for the conference call (including participants telephone and fax numbers and email address)
 - 2. the date and time of the conference call along with the 800 number and access code (or provide the operator with the telephone numbers of participants to be contacted)
 - 3. a written outline of the conference call agenda.

The conference call reminder shall be distributed or faxed at least one (1) week prior to the scheduled conference call.

- D. On the third Monday of each month, email or fax the monthly list of all upcoming regularly scheduled and ad hoc conference calls to the Project Officer and designated Program staff, indicating:
 - 1. the date and time of call
 - 2. name of call {i.e., working group title or subject of call}
 - 3. originator of call, 800 dial-in number and access code.
- E. On the first Monday of each month, e-mail or fax the previous month's conference call activity report to the Project Officer. This report shall include a list of all conference calls scheduled and canceled during the previous month reporting period.

Task 4: Administrative Support for DAIT Data and Safety Monitoring Boards (DSMBs)

The Contractor shall provide administrative support for a minimum of four (4) DAIT DSMBs, including the Transplant DSMB, Allergy and Asthma DSMB, Autoimmune DSMB, and the Stem Cell DSMB. Best current estimates indicate that there will be 8 DSMB meetings per year, in the Washington, DC metropolitan area (i.e., 2 meetings per year for each of the 4 DSMBs), as well as quarterly conference calls for each of the 4 DSMBs.

The DSMBs are currently composed of approximately 10 members (all non-federal), appointed by DAIT to oversee the clinical trials of the ITN, ACEs, SCTC, and ICAC. The DSMBs meet semi-annually in the Bethesda, MD area to review clinical and laboratory data. The Contractor shall pay for transportation, meals, lodging, incidental expenses, and an honorarium of \$200 per day for non-federal DSMB members. Specifically, the Contractor shall:

- A. **Conflict of Interest and Financial Disclosure:** At the request of the Project Officer, develop and revise, as necessary, Conflict of Interest (COI) and financial disclosure forms for all permanent and ad hoc DSMB members; coordinate distribution and receipt of completed forms; identify potential conflicts of interest and provide this information and the forms to the Project Officer. Review and identify any potential conflicts of interest for permanent DSMB members on an annual basis or more frequently as directed by the Project Officer.
- B. **DSMB Meetings and Conference Calls:** Schedule and confirm meeting and teleconference dates, and arrange travel and lodging for participating DSMB members. Teleconferences should take place over a secure telephone line.

Arrange DSMB meetings in the Bethesda, MD area to include, but not be limited to:

1. appropriate meeting room facilities;
 2. food services;
 3. audiovisual equipment;
 4. on-site support;
 5. minutes of the open session and of the closed session (if requested by the Project Officer); and
 6. secure teleconference line for members participating in the meeting via teleconference.
- C. **DSMB Meeting Materials:** Distribute in advance to DSMB members copies of protocols and protocol-related documents to be discussed during the DSMB meetings and conference calls.
- D. At the direction of the Project Officer, provide editing and formatting assistance in preparing responses to DSMB comments.

Task 5: General and Regulatory Management and Administrative Support

- A. Provide expert medical/science writers to assist in the preparation of an estimated eight (8) to ten (10) Clinical Trial Agreements (U.S. and non-U.S.) (CTAs) per year, one (1) to (2) Collaborative Research and Development Agreements (CRADAs) per year, and Material Transfer Agreements (MTAs).
- B. Provide expert medical/science writers to assist in the preparation of an estimated ten (10) to twenty (20) formal responses to requests for information on DAIT sponsored INDs from the U.S. Food and Drug Administration (FDA), European regulatory authorities, the DHHS Office for Human Research Protections (OHRP), and the NIH.
- C. Assist DAIT staff in the development of a minimum of twenty (20) protocols and ten (10) protocol amendments per year, including formatting, duplication and collating, and distribute these protocol documents to DAIT staff, DAIT-supported investigators, FDA and European regulatory officials, and others as designated by the Project Officer.
- D. Assist DAIT staff in the preparation of presentations utilizing Power Point, Excel, and project management software packages. It is anticipated that there will be approximately five (5) to eight (8) requests per month for slide preparation and/or project management documents (e.g., Gantt charts).
- E. Provide twice daily, Monday through Friday, courier services between the Contractor and the Project Officer, and to other offices as requested by the Project Officer.
- F. Provide a Project Director who shall serve as the principal point of contact with the Project Officer and who shall be responsible for preparing reports and plans, directly supervising and coordinating project staff and consultants, issuing assignments, monitoring contract progress, providing deliverables and maintaining cost control. The Project Director shall be available to facilitate any or all of the six (6) designated tasks when required by the Project Officer. All tasks assigned to the Contractor will be coordinated and implemented by the Project Director.
- G. Establish a multi-disciplinary staff and available consultants responsible for:
1. planning, coordinating and conducting scientific meetings, conferences and workshops;
 2. preparing minutes, summaries and/or proceedings of scientific meetings, conferences and workshops;
 3. arranging conference calls;
 4. scientific writing, editorial, document and brochure preparation for scientific meetings, conferences and or workshops;
 5. preparation of organized scientific materials (e.g., notebooks of relevant materials for distribution to meeting participants);
 6. duplication and dissemination of protocol information and related documents to DAIT staff, other DAIT contractors, clinical investigators, contractors, grantees, the FDA, and other federal agencies, as requested by the Project Officer; and
 7. duplicating and disseminating DAIT clinical research Standard Operating Procedures (SOPs) to DAIT staff, coordinating centers, clinical investigators, contractors, grantees, the FDA, and other federal agencies, as requested by the Project Officer.

- H. Receive and send electronic documents in Microsoft Word for Windows XP. Supply PC compatible computers in order to electronically communicate effectively with DAIT. Software versions may have to be upgraded during the course of this contract.

Task 6: Provide for an Orderly Transition

Six (6) months prior to the completion date of this contract, the Contractor shall develop a written draft transition plan, for Project Officer's approval, to ensure the orderly, efficient, smooth and timely transfer of all or part of this project to a designated contractor, if other than the incumbent, or to the Federal Government. Specifically, the Contractor shall:

- A. Ensure that any manuals, databases and directories developed by the Contractor are accurate and current, and provide these materials to the new contractor or the Federal Government, together with complete documentation needed to understand their content, operation and maintenance.
- B. Transfer all contract-developed or government-acquired publications, reprints, abstracts and other documents, results of searches, databases and necessary files to the new contractor or the Federal Government.
- C. Transfer all Government purchased or furnished computer hardware, software and other related government equipment, computer books, and impart the knowledge of its functions to the new contractor or the Federal Government.
- D. Carry on operations at full staffing levels until the designated transition period has ended. At the request of the Project Officer, certain tasks will be relinquished by the current Contractor during the transition period.

[END OF STATEMENT OF WORK]

REPORTING REQUIREMENTS and OTHER DELIVERABLES

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with ARTICLE F.1, DELIVERIES of this contract:

The reports shall be brief, factual and prepared in the following format:

1. Interim Reports/Other Deliverables

- a. Update mailing list database every six months to be delivered to NIAID by electronic transfer or disc (see Task 2, paragraph C.)
- b. Prepare and submit to the Project Officer, a draft meeting work plan within three (3) working days following the receipt of the meeting request form and a final meeting work plan within four (4) working days following a meeting with the Project Officer, if necessary as described in Task 2, paragraphs A.1.b. and a.1.d., respectively. In addition to the items described under Task 2, the work plan shall include:
 - 1) meeting title
 - 2) meeting planner
 - 3) DAIT meeting contact
 - 4) dates
 - 5) location
 - 6) brief description of the substance of the meeting
 - 7) a tentative list of participants
 - 8) a brief description of services provided
 - 9) estimated total costs for the meeting
- c. Prepare and submit to the Project Officer, within thirty (30) days following the conclusion of the meeting, a final meeting report showing total costs incurred during the meeting referred to in item 1.b., above (see Task 2., paragraph B.).
- d. Prepare and submit to the Project Officer, within three (3) to five (5) working days following the conclusion of the DAIT Staff/Contractor meeting, a summary or minutes that includes a brief summary of issues discussed, decisions and action(s) items and any unresolved matters needing further attention (see Task 2., paragraph A.8.c.).
- e. Prepare and submit to the Project Officer draft minutes of meetings/conferences within seven (7) working days after the completion of the meeting/conference.
- f. Prepare and submit to the Project Officer transcripts of meetings/conferences within fourteen (14) working days after completion of the meeting/conference (see Task 2, paragraph A.8.a.).
- g. Prepare and submit to the Project Officer a Draft Transition Plan six (6) months before the completion date of the contract.

2. Technical Progress Reports

a. Monthly Progress Report(s)

The Contractor shall prepare and submit as appropriate, the three monthly reports listed below to include, but not be limited to, the following:

- 1) Meeting/Conference Activity Report
 - a) meeting/conference title
 - b) date(s) of meeting/conference
 - c) location of meeting/conference
 - d) number of attendees

- e) meeting Planner
- f) DAIT meeting contact
- g) issues, problems and status of meeting (i.e., completed, planning phase, etc.)

The Monthly Meeting/Conference Activity Report will be revised and updated as meetings/conferences are planned and is due one (1) week after the end of each month. A report is not due if no meetings/conferences are being planned.

2) Scheduled Conference Call Reports

- a) working group title
- b) date
- c) time
- d) chairperson/originator of call
- e) 800 dial-in number
- f) access code

The Scheduled Conference Call Report is due on the third Monday of each month and should be study-specific.

3) Conference Call Activity Reports

- a) working group title
- b) date
- c) time
- d) actual length of call
- e) chairperson/originator of call
- f) other comments

The Conference Call Activity Report is due on the first Monday of each month and all conference call activity must be combined in this report.

b. Quarterly Progress Reports

The Contractor shall prepare and submit a Quarterly Progress Report, The first Quarterly Progress Report shall cover any fractional part of the initial month plus the following three months and shall be due on/before the 30th of the month following the end of that reporting period. Thereafter, reports shall be due on/before the 30th of the month following each quarterly reporting period. A Quarterly Progress Report is not due when an Annual or Final Report is due. The quarterly progress report should be factual, concise and consist of the following:

1) Title Page containing:

- a) contract number and title
- b) sequence of report; e.g., "Year 1, Second Quarterly Report"
- c) period of performance being reported
- d) contractor's name, title and address
- e) date of submission

2) Reports shall include but are not limited to the following information:

- a) brief introduction stating the objectives and scope of the contract effort
- b) description of the overall work accomplished during the reporting period plus detailed activity reports which were generated during that quarter
- c) description of any technical or performance problems encountered and corrective actions planned or taken.
- d) any additional information that the Project Officer may require.

c. Annual Progress Report

The Contractor shall prepare and submit an Annual Progress Report. The first Annual Progress Report shall be due on/before the 30th of the month following each anniversary date of the contract. An Annual Progress Report is not due when the Final Report is due. The Annual Report shall be factual, concise and reflective of the summarized progress for the entire contract year, following the same format as the Quarterly Progress.

d. Final Report and Summary of Salient Results

This report shall be in sufficient detail to describe comprehensively the results achieved and include a summation of the work performed and results obtained for the entire period of performance. It shall be written in a detailed manner, clearly stating the comprehensive progress of the contract and shall be received no later than on/before the completion date of the contract. The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

3. Addressees

Project Officer
 Division of Allergy, Immunology and Transplantation
 NIAID, NIH
 6610 Rockledge Drive
 Room 3059, MSC 6601
 Bethesda, MD 20892-6601

Contracting Officer
 Research Resources Contracts Branch
 Contract Management Program, DEA
 NIAID, NIH
 6700-B Rockledge Drive
 Room 2230, MSC 7612
 Bethesda, MD 20892-7612

4. Delivery Schedule and Number of Copies

Item	Description	Quantity	Delivery Schedule
1.a.	Updated Mailing List	1 – Project Officer	Every six months to be delivered to NIAID by electronic transfer or disc.
1.b.	Interim Report – Draft/Final Meeting Work Plan	1 – Project Officer 1 – Electronic copy *	DRAFT: Within 3 working days following receipt of meeting request form. FINAL: Within 4 working days following work plan meeting.
1.c.	Interim Report – Final Meeting Report	1 – Project Officer 1 – Electronic copy *	Within 30 calendar days following conclusion of meeting(s).
1.d.	Interim Report – Minutes of DAIT Staff/Contractor Meetings	1 – Project Officer 1 – Electronic copy *	Within 3-5 working days following conclusion of meeting.
1.e.	Interim Report – Draft Minutes of Meetings/Conferences	1 – Project Officer 1 – Electronic copy *	Within 7 working days after meetings/conferences.

1.f.	Interim Report – Transcripts of Meeting Conferences	1 – Project Officer 1 – Electronic copy *	Within 14 working days following conclusion of meeting/conference.
2.a.1)	Monthly Meeting/Conference Activity Reports	1 – Project Officer 1 – Electronic copy *	Due 1 week after end of each Month. Not due if no activity during that Month.
2.a.2)	Monthly Scheduled Conference Call Reports	1 – Project Officer 1 – Electronic copy *	Due the 3 rd Monday of each Month. Not due if no activity during that Month.
2.a.3)	Monthly Conference Call Activity Reports	1 – Project Officer 1 – Electronic copy *	Due the first Monday of each Month. Not due if no activity during that Month.
2.b.	Quarterly Progress Report	2 – Project Officer 1 – Contracting Officer 1 – Electronic copy *	Due the 30 th of the Month following each Quarterly period of performance. Not due when Annual or Final Report is due.
2.c.	Annual Progress Report	2 – Project Officer 1 – Contracting Officer 1 – Electronic copy *	Due the 30 th of the Month following each Anniversary date of the Contract. Not due when the Final Report is due.
2.d.	Final Report and Summary of Salient Results	2 – Project Officer 1 – Contracting Officer 1 – Electronic copy *	Due on/before the completion date of the contract.

* plus one copy on 3.5 inch, high-density computer diskette or other digital medium approved by the Project Officer.

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

A Sample Uniform Contract Format may be found at the following website:

<http://rcb.cancer.gov/rcb-internet/wkf/sample-contract.htm>

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses 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. Also, the full text of a clause may be accessed electronically at this URL: <http://www.arnet.gov/far/>.

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

FAR

<u>Clause No.</u>	<u>Date</u>	<u>Title</u>
52.202-1	Dec 2001	Definitions
52.203-3	Apr 1984	Gratuities (Over \$100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over \$100,000)
52.203-6	Jul 1995	Covenant Against Contingent Fees (Over \$100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over \$100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over \$100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over \$100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over \$100,000)
52.204-4	Aug 2000	Printing/Copying Double-Sided on Recycled Paper (Over \$100,000)
52.209-6	Jul 1995	Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over \$25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over \$100,000)
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over \$500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over \$100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Dec 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee

52.219-8	Oct 2000	Utilization of Small Business Concerns (Over \$100,000)
52.219-9	Jan 2002	Small Business Subcontracting Plan (Over \$500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over \$500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over \$100,000) (NOTE: The dollar amount in paragraph (a) of this clause is \$0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	May 2002	Buy American Act - Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over \$100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data – General
52-232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over \$100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Feb 2002	Prompt Payment
52.232-25	Feb 2002	Prompt Payment, Alternate I (Feb 2002)
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	July 2002	Disputes
52.233-3	Aug 1996	Protest After Award
52.242-1	Apr 1984	Notice of Intent to Disallow Costs

52.242-3	May 2001	Penalties for Unallowable Costs (Over \$500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over \$100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B., Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over \$100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over \$100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays

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

<u>HHSAR Clause No.</u>	<u>Date</u>	<u>Title</u>
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity

END OF GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH
AND DEVELOPMENT CONTRACT – Rev. 4/2003]

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

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.

FAR Clause 52.219-9, SMALL BUSINESS SUBCONTRACTING PLAN (JANUARY 2002) is deleted in its entirety.

FAR Clause 52.219-16, LIQUIDATED DAMAGES--SUBCONTRACTING PLAN (JANUARY 1999) is deleted in its entirety.

FAR Clause 52.232-20, LIMITATION OF COST, 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

FAR 52.215-17, Waiver of Facilities Capital Cost of Money (OCTOBER 1997).

FAR 52.219-6, Notice of Total Small Business Set-Aside (JULY 1996).

FAR 52.219-14, Limitations on Subcontracting (DECEMBER 1996).

FAR 52.224-1, Privacy Act Notification (APRIL 1984).

FAR 52.224-2, Privacy Act (APRIL 1984).

FAR 52.227-14, Rights in Data - General (JUNE 1987)

FAR 52.227-17, Rights in Data--Special Works (JUNE 1987).

FAR 52.239-1, Privacy or Security Safeguards (AUGUST 1996).

FAR 52.242-3, Penalties for Unallowable Costs (OCTOBER 1995).

FAR 52.246-23, Limitation of Liability (FEBRUARY 1997).

FAR 52.247-63, Preference for U.S. Flag Air Carriers (JANUARY 1997).

FAR 52.251-1, Government Supply Sources (APRIL 1984).

- b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION/PUBLIC HEALTH SERVICE ACQUISITION REGULATION (HHSAR)/(PHSAR) (48 CHAPTER 3) CLAUSES:

HHSAR 352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities (APRIL 1984).

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

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

NIH (RC)-7, Procurement of Certain Equipment (APRIL 1984) (OMB Bulletin 81-16).

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:

FAR Clause 52.244-6, SUBCONTRACTS FOR COMMERCIAL ITEMS (MAY 2002)

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

Commercial item, has the meaning contained in the clause at 52.202-1, Definitions.

Subcontract, includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

- (b) To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or nondevelopmental items as components of items to be supplied under this contract.

- (c) (1) The Contractor shall insert the following clauses in subcontracts for commercial items:

- (i) 52.219-8, Utilization of Small Business Concerns (OCT 2000) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds \$500,000 (\$1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
- (ii) 52.222-26, Equal Opportunity (APR 2002) (E.O. 11246).
- (iii) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (DEC 2001) (38 U.S.C. 4212(a)).
- (iv) 52.222-36, Affirmative Action for Workers with Disabilities (JUN 1998) (29 U.S.C. 793).
- (v) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (JUN 2000) (46 U.S.C. Appx 1241) (flowdown not required for subcontracts awarded beginning May 1, 1996).

- (2) While not required, the Contractor may flow down to subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

- (d) The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

PROPOSAL SUBMISSION INSTRUCTIONS – see: <http://www.niaid.nih.gov/contract/eproposal.htm>

PROPOSAL SUBMISSION: NUMBER OF COPIES AND PAGE LIMITATIONS (Attached to this listing)

PROPOSAL INTENT RESPONSE SHEET (Attached to this listing)

[NOTE: Your attention is directed to the "Proposal Intent Response Sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified in the Attachment. The receipt of this form is critical as it contains information essential for CMP's coordination of the electronic submission and review of proposals.]

RFP FORMS AND ATTACHMENTS:

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE:

<http://www.niaid.nih.gov/contract/ref.htm>

APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):

- **Technical Proposal Cover Sheet**
- **NIH-1688-1, Project Objectives**
- **Technical Proposal Cost Information**
- **Summary of Related Activities**
- **Government Notice for Handling Proposals**

APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):

- **NIH-2043, Proposal Summary and Data Record**
- **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours**
- **Offeror's Points of Contact**

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)**
- **Privacy Act System of Records**
- **Disclosure of Lobbying Activities, OMB Form LLL**

PROPOSAL SUBMISSION: NUMBER OF COPIES, PAGE LIMITATIONS AND ELECTRONIC FILE SIZE

Please refer to <http://www.niaid.nih.gov/contract/eproposal.htm> for delivery instructions for the submission of both PAPER and ELECTRONIC COPIES of your proposal.

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

ELECTRONIC SUBMISSION: In addition to the paper submission, you are requested to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided at the above-referenced weblink. You must certify that both the original paper and electronic versions of the proposal are identical.

The electronic submission is solely for the benefit of the Agency. Such submission is still in a "test" stage, and the electronic submissions may or may not be utilized, at the sole discretion of the Agency.

If you experience difficulty or are unable to transmit, you may submit your proposal on a CD-Rom or ZipDisk by an express delivery service. We can then upload your proposal into the electronic system.

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.

SUBMISSION OF ONLY ELECTRONIC PROPOSALS WITHOUT PAPER COPIES IS NOT ACCEPTABLE.

NUMBER OF COPIES:

The number of copies required of each part of your proposal are as specified below.

Document	Number of Copies	Page Limits	File Size
Technical Proposal	One (1) unbound signed original. Five (5) unbound copies.	Limited to not-to-exceed 100 pages	Limited to not-to-exceed 5 mega-bytes
Business Proposal	One (1) unbound signed original. Five (5) unbound copies.	Limited to not-to-exceed 100 pages	Limited to not-to-exceed 5 mega-bytes
Representations and Certifications	One (1) Original required to be submitted with the Original Business Proposal. (Extra copies are optional.)	N/A	N/A
Proposal Appendices	Ten (10) unbound copies of all materials not available electronically (i.e. SOPs, Pertinent Manuals, Non-scannable Figures or Data, and Letters of Collaboration/Intent).	Included in page limits.	N/A

WARNING: You are advised to read and carefully follow the instructions listed in each RFP. Failure to adhere to these instructions and to the specified limitations for size of paper and electronic proposals may result in the rejection of your proposal.

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DAIT-04-43

RFP Title: Administrative Support Contract for DAIT Clinical Research Programs

Please review the attached Request for Proposal. Furnish the information requested below and return this page by January 7, 2004. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

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

DO INTEND TO SUBMIT A PROPOSAL

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

Company/Institution Name (print): _____

Address (print): _____

Project Director's Name (print): _____

Title (print): _____

Signature/Date: _____

Telephone Number and E-mail Address (print clearly):

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

Name: _____

Title: _____

E-Mail Address: _____

Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):

(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:

RRCB, CMP, NIAID, NIH

Room 2230

6700-B Rockledge Drive, MSC 7612

Bethesda, MD 20892-7612

Attn: David T. Lisle

RFP-NIH-NIAID-DAIT-04-43

FAX# (301) 402-0972

Email : dlisle@niaid.nih.gov

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).

1. REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following address:

<http://rcb.cancer.gov/rcb-internet/forms/rcneg.pdf>

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

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE AND SUBMIT ONE ORIGINAL OF THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT IT AS PART OF YOUR ORIGINAL BUSINESS PROPOSAL. ADDITIONALLY, A COMPLETED ORIGINAL MUST BE SUBMITTED FOR ANY PROPOSED SUBCONTRACTORS.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Clause 52.215-1 (May 2001)]

(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*" 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).

[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]

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

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

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

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

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

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

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

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

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

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

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

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

in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

- (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.
- (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.
- (7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.
- (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.
- (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
- (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.
- (11) The Government may disclose the following information in postaward debriefings to other offerors:
 - (i) The overall evaluated cost or price and technical rating of the successful offeror;
 - (ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
 - (iii) A summary of the rationale for award; and
 - (iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(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

- (a) **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.

(b) **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 541710.
- (2) The small business size standard is 500 employees.

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

It is anticipated that one award will be made from this solicitation and that the award will be made on/about September 30, 2004.

It is anticipated that the award from this solicitation will be a multiple-year, cost reimbursement, completion type contract with a period of performance of seven (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 a total of approximately 4.58 total FTEs or 9,526 labor hours 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 the Project Officer or 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. COMPARATIVE IMPORTANCE OF PROPOSALS

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

j. CONCEPT REVIEW

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

k. PREPARATION COSTS

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

l. SERVICE OF PROTEST (AUGUST 1996) - FAR 52.233-2

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

Contracting Officer: [See Block 15 of RFP Cover Page]
Address: [See Block 9 of RFP Cover Page]

(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)

m. LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70

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

(End of provision)

n. USE OF INTERNET WEB SITE ADDRESSES (URLs) IN PROPOSALS

Unless otherwise specified or required in NIAID solicitations, internet Web Site addresses (URLs) may not be used to provide information necessary to the conduct of the review of the proposal. Direct access to an internet site by a Reviewer who is examining and reviewing the proposal on behalf of the NIAID could compromise their anonymity during the review process. If a URL contains information pertinent to the proposal content, the offeror must provide access to the website via a temporary website portal which allow reviewers the capability to view and interact with the site.

The proposal must clearly identify the URLs to be accessed and the procedure for accessing the temporary website portal. Access must not require the identity of the individual.

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, PROPOSAL SUBMISSION: NUMBER OF COPIES AND PAGE LIMITATIONS, 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, identification of the proposal part, and indicate whether the proposal is an original or a copy.

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:"

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

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

(4) Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION). 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) 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 conditions 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>.

(10) Privacy Act (Treatment of Proposal Information)

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

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

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

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

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

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

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

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

(11) Selection of Offerors

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

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

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

While it is this Institute's policy to conduct discussions with all offerors in the competitive range, the Institute 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 sources in accordance with HHSAR 315.370.

- e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.
- f) The Institute 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 the Institute's requirements. Synopses of awards exceeding \$25,000 will be published in the FedBizOpps.

(12) Reimbursement of Costs for Independent Research and Development Projects (Commercial Organizations Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

(13) Salary Rate Limitation in Fiscal Year 2004

NOTE: This award is intended to be made in Fiscal Year 2004. The current Fiscal Year 2003 Salary Rate Limitations should be adhered to in the preparation of your proposal. All costs associated with any resultant award will be required to be in compliance with the current Fiscal Year 2003 limitations and will be subject to change based on Fiscal Year 2004 Salary Rate Limitations.

Offerors are advised that pursuant to P.L. 108-7, no NIH Fiscal Year 2003 (October 1, 2002 - September 30, 2003) 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, patent 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. 108-7 applies only to Fiscal Year 2003 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 108-7 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 extramural mechanism at a rate in excess of Executive Level I."

LINK TO EXECUTIVE SCHEDULE SALARIES: <<http://www.opm.gov/oca/PAYRATES/index.htm>>
(click on "Executive Schedule" for the current Fiscal Year's salary rate or scroll down to the "General Schedule Salary Tables from Previous Years" to locate the Executive Level salary rates from previous years).

(14) Institutional Responsibility Regarding Conflicting Interests of Investigators

EACH INSTITUTION MUST:

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

- (c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.
- (d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.
- (e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.
- (f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
- (g) Certify, in each application/proposal for funding to which the regulations applies, that:
 - 1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;
 - 2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;
 - 3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and
 - 4) the Institution will otherwise comply with the regulations.

INSTITUTIONAL MANAGEMENT OF CONFLICTING INTERESTS

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

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

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

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

(15) Electronic and Information Technology Accessibility

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

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

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

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

(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.arnet.gov/far/>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).
- b) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
- c) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).

(17) Prohibition on Contractor Involvement with Terrorist Activities

The Offeror/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 any resultant contract(s).

(18) Office of Health and Safety – Laboratory Registration / Select Agent Transfer Program

The awardee is responsible for ensuring that all work under this grant, cooperative agreement, or contract complies with all Federal requirements related to select agents including CDC's that can be found at <http://www.cdc.gov/od/ohs/lrsat.htm> and NIH's OBA that can be found at <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html> .

b. TECHNICAL PROPOSAL INSTRUCTIONS

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

(1) Technical Discussions

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

a) Statement of Work

(1) Objectives

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

(2) Approach

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

(3) Methods

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

(4) Schedule

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

b) Personnel

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

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

(1) 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 (Key Personnel)

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

(2) Technical Evaluation

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

(3) Additional Technical Proposal Information

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

(4) Other Considerations

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

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

- b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
- c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- d) Other factors you feel are important and support your proposed research.
- e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

(5) Information Technology Systems Security

If this project involves Information Technology, the proposal must present a detailed outline of its proposed Information Technology systems security program which complies with the requirements of the Statement of Work, the Computer Security Act of 1987 Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems," and the DHHS Automated Information Systems Security Program Handbook (Release 2.0, dated May, 1994). The proposal will also need to include similar information for any subcontract proposed.

NOTE: OMB A-130 is accessible via web site: <http://www.whitehouse.gov/WH/EOP/OMB/html/circular.html>

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.
10. Whether you will require the use of Government property in the performance of the contract, and, if so, what property;
11. Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
12. The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403-5(b)(1) and Table 15-2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;

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 proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. **Travel**

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

10. **Other Costs**

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

(4) Cost and Pricing Data

1. General Instructions

- A. In submitting your proposal, you must include an index, appropriately referenced, of all the cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.
- B. As part of the specific information required, you must submit, with your proposal, cost or pricing data (that is, data that are verifiable and factual and otherwise as defined at FAR 15.401). You must clearly identify on your cover sheet that cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including--
 - (1) The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
 - (2) The nature and amount of any contingencies included in the proposed price.
- C. You must show the relationship between contract line item prices and the total contract price. You must attach cost-element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.
- D. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.
- E. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.
- F. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.
- G. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

2. Cost Elements

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

- A. **Materials and services.** Provide a consolidated priced 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.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor cost or pricing data as part of your own cost or pricing data as required in paragraph 2.A.(2) of this table. These requirements also apply to all subcontractors if required to submit cost or pricing data.
 - (1) *Adequate Price Competition.* Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205-26(e)).

- (2) *All Other*. Obtain cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either \$10,000,000 or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. The Contracting Officer may require you to submit cost or pricing data in support of proposals in lower amounts. Subcontractor cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's cost or pricing data is required as described in this paragraph, it must be included along with your own cost or pricing data submission, as part of your own cost or pricing data. You must also submit any other cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.
- B. **Direct Labor**. Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.
- C. **Indirect Costs**. Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.
- D. **Other Costs**. List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.
- E. **Royalties**. If royalties exceed \$1,500, you must provide the following information on a separate page for each separate royalty or license fee:
- (1) Name and address of licensor.
 - (2) Date of license agreement.
 - (3) Patent numbers.
 - (4) Patent application serial numbers, or other basis on which the royalty is payable.
 - (5) Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
 - (6) Percentage or dollar rate of royalty per unit.
 - (7) Unit price of contract item.
 - (8) Number of units.
 - (9) Total dollar amount of royalties.
 - (10) If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).
- F. **Facilities Capital Cost of Money**. When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

3. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (SECTION J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

4. There is a clear distinction between submitting cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.
 5. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.
- (5) 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)

(6) 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.

(7) Other Administrative Data

a) **Property**

- (1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:
 - (a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.
 - (b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.
- (2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.
- (3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

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

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

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

c) **Financial Capacity**

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

d) Incremental Funding

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

HHSAR 352.232-75, Incremental Funding (January 2001)

- (a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.
- (b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

e) Facilities Capital Cost of Money, FAR 52.215-16, (October 1997)

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

- (a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.
- (b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

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

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

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

(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/PDPclausecover.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

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(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 Visa's 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 territories, then the offeror must indicate in the proposal that these individuals have the required visas.

(13) Guidance Regarding Federal Government Collaborations

In keeping with FAR 3.6 and recent legal decisions involving conflict of interest issues, it is the policy of the NIAID that any proposal either submitted by a Federal agency or submitted by an offeror that includes the collaboration of a Federal agency or Federal employee must include a letter describing the role and effort being provided by that government agency and/or employee and stating that: (1) no actual or potential conflict of interest exists with the proposed effort; and (2) the collaborator's supervisor is aware of and approves of the effort. This letter **must** be signed by **both** the agency's ethics official and the head of the agency (or his/her designate). The NIAID reserves the right to reject a proposal that includes effort by Federal government employees in order to avoid any actual or apparent conflict of interest.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against two factors. The factors, in order of importance, are: technical and cost/price. Past performance is NOT an evaluation factor but will be considered in determining an offeror's responsibility in accordance with FAR 9.104-3(b). (Reference Section L.) All evaluation factors other than cost/price, when combined, are significantly more important than cost/price. The trade-off process described in FAR 15.101-1 will be employed. This process permits trade-offs among cost/price and non-cost factors and allows the Government to consider award to other than the lowest priced or highest technically rated offeror. In any event, the Government reserves the right to make an award to that offeror whose proposal provides the best 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 carefully evaluated. 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. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. Proposals will be judged solely on the written material provided by the Offeror. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

CRITERIA

WEIGHT

a. Technical Approach

45 points

- 1) Soundness and practicality of technical approach: **(20 points)**

Documented soundness and practicality of technical approach for carrying out each of the designated requirements specified in the Statement of Work, for handling the projected needs of the DAIT program, with adequate explanation, details and justification.

Specifically:

- (1) Plan for successfully executing all aspects of project management of scientific meeting support for DAIT.
- (2) Plan to provide project management of conference call support for DAIT.
- (3) Plans to support the DAIT Data and Safety Monitoring Boards.
- (4) Plans to provide administrative support to DAIT regulatory operations.
- (5) Plan for an orderly, efficient, smooth and timely transfer of all or part of this project to a successor contractor.

- 2) Adequacy of administrative framework for timely and successful performance of services: **(15 points)**

- a) Proposed administrative framework to perform the tasks outlined in the Statement of Work, with lines of authority, duties and responsibilities clearly delineated.
- b) Plan for successful management of multiple concurrent activities and meeting the requirements for timely projects, especially those tasks requiring an expedited response.
- c) Specific plan for quality assurance and evaluation of services and documents under this contract.

- d) Plan for efficient and cost-effective adjustments to workload fluctuations.
- e) Plan for providing excellent communications and rapid response in interactions with DAIT staff and other involved parties, including any subcontractors.

3) Understanding of the activity: **(10 points)**

Overall understanding of the purpose, scope and complexity of the project, as discussed by the Offeror, and as evidenced by the appropriateness of the proposed plan and services to the needs of the DAIT Program.

b. Personnel 35 points

Qualifications, related experience and availability of:

1) Other Staff: **(25 points)**

- a) Demonstrated experience, qualifications and availability of all senior and mid-level professional staff to successfully carry out their proposed specific responsibilities. This includes:

- (1) Meeting Planner Executive(s): experience, competency, availability and flexibility to successfully perform all aspects of meeting planning.
- (2) Conference Call Coordinator: documented training and or experience in coordinating, scheduling and distributing all necessary information, and a sufficient time commitment to provide excellent telecommunication services linking the DAIT studies and Program.
- (3) All other Professional and Support Staff: documented knowledge, skills and abilities necessary for accomplishing the specific tasks for which they are proposed.
- (4) Staff Composition: The number and type of staff proposed appropriate to the needs of the activity.

2) Project Director: **(10 points)**

Professional training in the health science field, documented successful experience in managing and coordinating multiple projects of a similar scope and complexity, and effective communication skills. The time commitment must be sufficient to properly oversee all the required tasks.

c. Organizational Experience, Facilities and Resources 20 points

1) Corporate experience, facilities, commitment and organizational structure that will allow accomplishment of the tasks requested in an efficient and timely manner, evidenced in part by: **(10 points)**

- a) Expertise with respect to similar projects, including dates and sponsors, specific responsibilities with respect to these projects, the type of personnel allocated and evidence of meeting performance standards.
- b) Adequate facilities, equipment, and other resources necessary to manage the scope and complexity of the activities outlined in the Statement of Work.
- c) Evidence of corporate commitment to this activity as necessary to ensure a high level of responsiveness despite competing work priorities.

2) Ability to provide a rapid response to the changing research needs of DAIT staff and plans to carry out necessary day-to-day interactions and functions with DAIT if the contractor facility is not local to NIH. Ability to meet with DAIT staff in Bethesda, MD, with as little as one-days notice. **(10 points)**

TOTAL WEIGHT = 100 points