RFP NIH-NIAID-DAIT-01-08

"Clinical and Statistical Coordinating Center: Cooperative Clinical Trials in Pediatric Transplantation"

All Amendments to this RFP will be posted on the NIAID Contract Management Home Page: http://www.niaid.nih.gov/. All Offerors are responsible for routinely checking the NIAID Website for any possible solicitation Amendments that may be issued. No additional notification of any Amendments will be provided by this office.

Request for Proposal No.:	NIH-NIAID-DAIT-01-08
OMB #:	0990-0115
Issue Date:	February 10, 2000
Issued By:	Cyndie Cotter Contracting Officer Contract Management Branch, NIAID, NIH 6700-B Rockledge Drive MSC 7612, Room 2230 Bethesda, Maryland 20892-7612
Purchase Authority:	Public Law 92-218 as amended
Small Business Set-Aside:	Yes, SIC Code 7379, Size Standard $18M
Just In Time:	No
Offer Expiration Date:	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".
Proposal Due Date:	**May 5, 2000, 4:00 p.m. EST**

Ladies and Gentlemen:

You are invited to submit a proposal in accordance with the requirements of this RFP. The Government anticipates that one (1) cost reimbursement, completion type contract will be awarded for a period of five (5) years as a result of this RFP.

The Government reserves the right to make award without discussions. Accordingly Offerors are advised to submit their best offer and complete proposal information by the closing date of the RFP.

This RFP will utilize the National Institute of Allergy and Infectious Diseases' (NIAID) Contract Review On-line (CRON) system; therefore, Offerors must submit their proposals

ELECTRONICALLY. Please note that the electronic copy of your proposal will need to be submitted in Adobe Acrobat Portable Document Format (PDF). Adequate security for electronic transmission is provided by using a dedicated server with access restricted through passwords. HARDCOPIES OF BOTH THE TECHNICAL AND BUSINESS PROPOSALS MUST BE SUBMITTED IN ACCORDANCE WITH THE INSTRUCTIONS AND TO THE ADDRESS LISTED IN **ATTACHMENT F, PACKAGING AND DELIVERY OF THE PROPOSAL. An official authorized to bind your organization must sign the hardcopy of your proposal.**

Please note and adhere to the page limitations set forth in Attachment F. The Technical Approach portion of the Technical Proposal is limited to 35 pages. Pages in excess of this limitation will be deleted and will not be read or evaluated. See Attachment F for complete details on page limitations, proposal format, and instructions on how to prepare and submit a proposal. All pages of the technical proposal must be numbered sequentially and these numbers must be consistent with the information outlined in the technical proposal Table of Contents.

The Attachments included with this electronic RFP package are as follows:

A. Introduction, Background, and Work Statement, dated February 10, 2000
B. Reporting Requirements and Deliverables, dated February 10, 2000
C. Evaluation Factors for Award, dated February 10, 2000
D. Specific RFP Instructions and Provisions, dated February 10, 2000
E. Applicable RFP References, dated February 10, 2000 **[Note: This Attachment contains five (5) other referenced documents that must be retrieved, in whole or in part, in order to submit a proposal.]**
F. How to Prepare and Submit an Electronic Proposal, dated February 10, 2000

If you are unable to download any of the applicable documents, please contact Cyndie Cotter, Contracting Officer, by phone, fax or e-mail at the numbers/address listed below.

YOUR ATTENTION IS FURTHER DIRECTED TO THE "PROPOSAL INTENT RESPONSE SHEET" CONTAINED IN ATTACHMENT D OF THIS DOCUMENT. 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 FRIDAY, MARCH 31, 2000. THE RECEIPT OF THIS FORM IS CRITICAL AS IT CONTAINS INFORMATION ESSENTIAL FOR NIAID'S COORDINATION OF THE ELECTRONIC SUBMISSION AND REVIEW OF PROPOSALS.

If 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 the PHS Clause 352.215-10 entitled, "Late Proposals, Modifications of Proposals, and Withdrawals of Proposals."

Questions concerning the solicitation must be furnished in writing. Please contact the Contracting Officer, Cyndie Cotter, by telephone at (301) 402-0641, via fax at (301) 402-0972 or via the Internet address cc41w@nih.gov. Collect calls will NOT be accepted.

Sincerely,

Barbara Shadrick
Senior Contracting Officer
Contract Management Branch
National Institute of Allergy and Infectious Diseases, NIH

Attachments: A - F

ATTACHMENT A

RFP-NIH-NIAID-DAIT-01-08
February 10, 2000

INTRODUCTION, BACKGROUND AND WORK STATEMENT

INTRODUCTION

To address the present and anticipated future needs of the Government, the Division of Allergy, Immunology and Transplantation (DAIT), National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health, is requesting proposals to establish and manage a Clinical and Statistical Coordinating Center (CASCC) to provide support for a major research program: the NIAID Cooperative Clinical Trials in Pediatric Transplantation (CCTPT), originally established in FY 1994 and renewed in FY 1999. This research program will: (1) design and conduct clinical trials to evaluate the safety, toxicity and efficacy of tolerogenic and immunomodulatory approaches to promote kidney graft survival in pediatric recipients; and (2) design and conduct studies of the underlying mechanisms of therapeutic agents as an integral part of the clinical trials undertaken.

The purpose of this five (5)-year contract is to: provide the statistical, clinical, regulatory, technical and administrative expertise necessary to support clinical trials and mechanistic studies of therapies to prolong graft survival and effect standards of care in pediatric kidney transplantation, including: (1) statistical leadership in the design, implementation and analysis of clinical trials and studies of underlying mechanisms; (2) establishment and administration of systems for the collection, storage, management, quality assurance and reporting of study data; (3) clinical site monitoring and training; (4) regulatory and technical functions and requirements associated with Investigational New Drug Applications (INDs); (5) preparation and final analyses of study data (6) coordination and support of technical and administrative activities of the CCTPT Steering Committee and subcommittees and an independent Data and Safety Monitoring Board (DSMB); and (7) provide for the receipt, storage and distribution of study drugs or biologics being tested.

This solicitation is a re-competition of Contract N01-AI-25132 awarded to EMMES Corporation, with a reduction in scope to encompass only clinical trials conducted by the CCTPT.

BACKGROUND

NIAID COOPERATIVE CLINICAL TRIALS IN PEDIATRIC TRANSPLANTATION

In May 1998, the NIAID Division of Allergy, Immunology and Transplantation issued a Request for Applications RFA AI-98-012 to renew the Cooperative Clinical Trials in Pediatric Transplantation. The major goal of this cooperative research program is to support a program of prospective, multi-site cooperative clinical trials in pediatric kidney transplantation, including the components outlined below. All participating clinical sites will utilize uniform controlled study designs and standardized data collection procedures. Specifically, the CCTPT awardees have proposed:

o Clinical trials to evaluate the safety and efficacy of new and innovative therapeutic approaches to improve long-term graft and patient survival, including: pre-, peri-, and post-transplant tolerogenic and immunomodulatory interventions to induce donor-specific tolerance with and without temporary or permanent withdrawal of, or new combinations of, standard immunosuppression; new less toxic immunosuppressive agents to prevent rejection; and new approaches to reduce the number of immunosuppressive agents required to prevent rejection;

o Clinical trials of the safety and efficacy of modifications in standard therapeutic approaches both to improve short- and long-term graft/patient survival and to reduce the deleterious side effects of current immunosuppressive regimens, including withdrawal of one or more standard therapies, reduction in dosage, and modifications in timing and administration or new combinations of immunosuppressive agents;

o Adjunct studies of the underlying mechanisms of action of the therapeutic approaches being evaluated, including changes in immune response and function; and

o Adjunct studies to develop, evaluate and validate sensitive immune and/or surrogate markers of long-term graft survival and rejection, with particular emphasis on defining clinically relevant predictors of chronic rejection. The use of non-invasive approaches is also explored.

Overall scientific leadership and direction for the Cooperative Clinical Trials in Pediatric Transplantation will be carried out by a Steering Committee, composed of CCTPT basic and clinical investigators, NIAID scientific staff, and the Project Director for the Clinical and Statistical Coordinating Center. The Cooperative Clinical Trials in Pediatric Transplantation Steering Committee will be responsible for: (1) the establishment and implementation of procedures for the development, review and evaluation of proposed clinical trials and mechanistic studies; (2) monitoring and evaluating progress; (3) allocating resources; and (4) assessing the need for redirection in scientific focus and implementing necessary changes to redirect resources in order to accommodate new knowledge and changing opportunities.

Additional Information about the CCTPT relevant to CASCC functions:

1. **The NIAID Cooperative Clinical Trials in Pediatric Transplantation are supported through the Cooperative Agreement mechanism for a period of four (4) years, which began in late FY 1999. The Clinical and Statistical Coordinating Center shall provide support for the NIAID Cooperative Clinical Trials in Pediatric Transplantation for a total period of five (5) years. There are two CCTPT grantees with forty-four (44) participating centers in the United States, three (3) participating centers in Canada, and one participating center in Mexico. Current CCTPT grantees and participating centers are listed in Exhibit 1 to this Work Statement.**

2. **A broad range of statistical, technical, regulatory, clinical trial coordination and monitoring, and administrative expertise will be necessary to carry out the requirements of this solicitation. The Government recognizes that a single organization may not have the expertise and facilities necessary to perform all requirements and, therefore, that it may be necessary for the Prime Contractor to subcontract portions of**

the work to be performed. Offerors shall have flexibility in proposing a structure and organization capable of meeting the requirements of this work statement.

3. **The Prime Contractor should demonstrate proven expertise in: (1) providing statistical leadership for the design of clinical trials and the analysis of study results; (2) designing and administering data collection, management, quality assurance and reporting systems; (3) supporting regulatory and technical functions and requirements associated with Investigational New Drug (IND) Applications; (4) coordinating, and technically and administratively supporting multi-center clinical trial steering committees and subcommittees and Data Safety and Monitoring Board activities, including the preparation of interim and final data reports and analyses; and (5) supporting the technical and administrative functions of governing bodies of multi-site cooperative clinical trial research programs. Expertise in receipt, storage and distribution of drugs or biologicals may be subcontracted.**

4. **Agents, molecules and reagents for the clinical trials to be conducted by the CCTPT Centers will be provided at no cost to the Contractor. Therefore, Business Proposals should not include any costs associated with the purchase of investigational agents.**

5. **The Contractor shall be processing data from research activities sponsored by grants, therefore data rights for the Cooperative Clinical Trials in Pediatric Transplantation are retained by the awardees of the cooperative agreements.**

WORK STATEMENT

This solicitation encompasses the establishment of the Clinical and Statistical Coordinating Center and the provision of statistical, clinical coordination, technical, regulatory, and administrative support for clinical trials and mechanistic studies in kidney transplantation undertaken by the NIAID Cooperative Clinical Trials in Pediatric Transplantation (CCTPT).

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 under the terms of this contract, as needed to perform the work set forth below.

The Contractor shall:

1. Establish and manage the Clinical and Statistical Coordinating Center (CASCC) for the CCTPT. The Contractor shall provide the statistical, clinical, technical, regulatory and administrative expertise necessary to carry out the tasks specified below, and other tasks as directed by the Project Officer:

    a) Develop, implement, refine, and monitor all phases of clinical trials and studies of underlying mechanisms of chronic rejection in Pediatric kidney transplant recipients;

    b) Design and conduct interim and final analyses of study data;

c) Conduct clinical site monitoring and training;

d) Establish and administer data collection, management, quality assurance and reporting systems;

e) Provide support for regulatory functions and requirements associated with Investigational New Drug (IND) applications;

f) Distribute and ensure quality control of study products;

g) Support the technical and administrative functions of the CCTPT Steering Committee and subcommittees; and

h) Coordinate, provide administrative support, and prepare reports and statistical analyses for the activities of the independent Data and Safety Monitoring Board (DSMB).

2. Provide statistical leadership and clinical trial design expertise for the development of protocols at all phases to be conducted by the CCTPT, including the development of clinical protocols with respect to:

a) Delineation of the research questions to be addressed;

b) Selection of appropriate study populations and control or comparison groups;

c) Development of inclusion and exclusion criteria;

d) Calculation of sample size requirements for statistical significance for Phase I, II and III clinical trials;

e) Definition of clinical end-points and immune/surrogate markers;

f) Selection of randomization and stratification methods;

g) Definition of the number and type of patient samples and proposed methods for the collection;

h) Assessment of the feasibility of recruiting and retaining adequate numbers of study participants;

i) Design and development of study forms in collaboration with CCTPT investigators;

j) Preparation and updating, as necessary, of a Manual of Operations for each clinical protocol delineating specific instructions, requirements and guidelines for the conduct of clinical trials by the clinical sites, including the clinical protocol, study forms, procedures

for the collection, testing, storage and shipping of patient samples, and procedures for data collection, entry, verification and storage;

k) Extensive participation in the writing of draft clinical protocols;

l) Arranging conference calls and meetings to review and modify, as necessary, proposed clinical protocols, including all costs associated with conference calls as well as travel expenses for CASCC staff and CCTPT Investigators to attend protocol development meetings;

[NOTE TO OFFEROR #1: For cost estimating purposes, assume there will be four (4) conference calls and two (2) meetings in Washington, D.C. each year. There will be nine (9) CCTPT Investigators attending each meeting and participating in each conference call.]

m) Distribution of proposed clinical protocols to members of the CCTPT Steering Committee and protocol specific subcommittee for evaluation; and

[NOTE TO OFFEROR #2: For cost estimating purposes, assume there will be nine (9) members of the CCTPT Steering Committee and protocol subcommittee.]

n) Preparation and distribution of final approved clinical protocols to the CCTPT Steering Committee and all participating clinical sites.

[NOTE TO OFFEROR #3: Best available current data indicate that Contractor support shall be provided for: (i) pilot and phase II/III clinical trials to be initiated by the CCTPT in FY 2000; (ii) the CCTPT will initiate one pilot clinical trial in kidney transplantation in FY 2000, involving a single CCTPT clinical site and approximately 30 total study participants; (iii) in FY 2000, the CCTPT will initiate one efficacy trial in kidney transplantation involving a total of 44 CCTPT sites and a total of 150 study participants per year for four years, (iv) in the second and subsequent years of the CCTPT, one new pilot clinical trial will be initiated, involving a total of 4 CCTPT clinical sites and approximately 150 total study participants for all the pilot studies.]

3. Provide statistical leadership and clinical trial design expertise for the development of studies of the underlying mechanisms of immunomodulatory and tolerogenic approaches conducted by the CCTPT, including the development of proposed mechanistic studies and the development of detailed research plans for all such studies, including but not limited to:

a) Delineation of the research questions to be addressed;

b) Development of statistical parameters associated with the techniques and methodologies to be used to assess underlying mechanisms;

c) Definition of the type, number and volume of patient samples required and specific instructions to clinical sites for the appropriate collection, testing, storage and shipping of patient samples;

d) Analysis of new techniques and methodologies in comparison with standard approaches to the measurement of disease stage, activity and clinical outcome;

e) Design and development of study forms in collaboration with CCTPT Investigators;

f) Extensive participation in the writing of proposed draft research designs;

g) Arranging conference calls and meetings to review and modify, as necessary, research designs, including the costs associated with conference calls as well as meeting travel expenses for CASCC staff and CCTPT investigators;

[NOTE TO OFFEROR #4: For cost estimating purposes, assume there will be four (4) conference calls and two (2) meetings in Washington, D.C. each year. There will be 9 CCTPT Investigators attending each meeting and participating in each conference call.]

h) Distribution of proposed research designs to members of the CCTPT Steering Committee, protocol and mechanistic studies subcommittee for evaluation; and

[NOTE TO OFFEROR #5: For cost estimating purposes, assume there will be nine (9) members of the CCTPT participating.]

i) Preparation and distribution of final approved research designs to the CCTPT Steering Committee and all participating clinical sites and mechanistic study sites.

[NOTE TO OFFEROR #6: It is anticipated that the CCTPT program will have at least three (3) sites involved in the design and conduct of mechanistic studies throughout the life of this research program. For cost estimating purposes, assume one (1) mechanistic study will be conducted in conjunction with CCTPT single-site pilot clinical trials, and two (2) mechanistic studies will be conducted in conjunction with CCTPT multi-site clinical trials using all aforementioned patients.]

4. As requested by the Project Officer, and in collaboration with CCTPT investigators, design and conduct interim and final statistical analyses of study data, prepare reports on the status of clinical trials and mechanistic studies, and participate in the preparation of scientific manuscripts and reports for publication and presentation at scientific meetings. This shall include, but not be limited to:

a) Preparing interim and final analyses of: the safety, toxicity and efficacy of tolerogenic and immunomodulatory treatments evaluated in CCTPT clinical trials; and the validity, reliability and specificity of techniques and methodologies used to assess underlying mechanisms;

b) Developing recommendations for modifications in the design of ongoing clinical trials and mechanistic studies with respect to statistical parameters such as sample size, control or comparison groups, clinical endpoints and immune/surrogate markers;

c) Preparing interim reports on accrual, retention, compliance, loss to follow-up and other statistical issues and problems relevant to the conduct of CCTPT clinical trials, and recommendations for improvements and modifications to resolve such issues and problems; and

d) Presenting all such reports, analyses and recommendations to the CCTPT Steering Committee, and assisting in implementing necessary modifications approved by this governing body, including revised clinical protocols and research designs for mechanistic studies.

5. Establish and administer efficient, reliable and responsive systems for the collection, storage, management, quality assurance and reporting of study data, as well as a system for electronic communication linkages among CCTPT clinical and mechanistic study sites, the NIAID, the CCTPT Steering Committee, and the CASCC. The Contractor shall develop and manage systems that provide for:

a) The collection, computer processing, storage, tracking and retrieval of all clinical and laboratory study data at a central data management facility;

b) Central computerized registration and randomization, where appropriate, of all patients on CCTPT protocols, or alternative non-computerized methods when appropriate;

c) Computerized study forms and systems for the remote entry and transmission of patient data from clinical sites to the central data management facility, or alternative non-computerized methods when appropriate;

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

e) The development, implementation and maintenance of security requirements, including:

1) An Automated Information System (AIS) Security Profile, which at a minimum shall include: the System's Security Plan (SSP); the Risk Analysis (RA); and the Continuity of Operations Plan (COOP) (also known as the Contingency Plan);

2) A log or record of the results from testing the COOP, any existing plans and progress reports for implementing additional security safeguards and controls; and the system access authorization list. The profile shall be kept up-to-date for review and potential inspection upon demand by NIH/DHHS authorized agents. Upon request, copies of specified profile documents shall be presented to NIH/DHHS for its own system's security reporting purposes;

3) The preparation and submission, for Project Officer approval, of a RA following the guidance given in Chapter V of the DHHS Automated Information Systems Security Program (AISSP) Handbook. The RA is to be maintained and updated every three years, or in advance of implementing major system modifications or enhancements;

4) The preparation and submission of an annual SSP, following the instruction in OMB Bulletin 90-08, for review and approval by the Project Officer and the NIH Systems' Security Officer;

5) The development and maintenance of an up-to-date COOP following Chapter VI of the DHHS AISSP Handbook. At a minimum, the COOP shall cover emergency operations, backup operations, and recovery plans to assure continuous operations of the system's facility. COOP testing shall be conducted and the results recorded at least every six months;

6) Plans, procedures, and a recommended schedule and budget for implementation of security safeguards required to satisfy the anticipated conditions of acquiring data from clinical and mechanistic study sites. This includes data integrity and security during electronic transmission, or during transit from the sites to the CASCC if non-electronic data transmission is used. All patient identifiable data is subject to the Privacy Act and DHHS regulations; and

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

f) Electronic communication linkages among CCTPT clinical and mechanistic study sites, the CASCC, the NIAID, and the CCTPT Steering Committee and subcommittees. E-mail and/or Internet- based communications are required for data submission and intergroup "discussions" while telephone communication will be used for conference calls.

6. Conduct clinical site monitoring and training for all CCTPT clinical sites. The Contractor shall establish a system to monitor CCTPT clinical sites and to train clinical, technical, data management and administrative site staff, including development and implementation of a set of Standard Operating Procedures (SOP) delineating the policies, procedures and requirements of the CCTPT and the FDA. This system shall adhere to the NIH policy for data and safety monitoring, released in the NIH Guide to Grants and Contracts on June 10, 1998 (http://www.nih.gov/grants/guide/notice-files/not98-084.html). The clinical site monitoring and training system shall include, but not be limited to:

a) Site establishment visits in year 01 for all CCTPT clinical sites and, in the second and subsequent years, site establishment visits for all new clinical sites added to the CCTPT programs. These initial site visits shall encompass: an assessment of the adequacy of all site facilities to be used for clinical trials, e.g., pharmacy, clinical unit, and patient record storage areas; a thorough explanation to site personnel of Federal regulations governing informed consent, Institutional Review Boards, responsibilities of sponsors and investigators, and protection of human subjects from research risks; and a thorough explanation of CCTPT policies and procedures and good clinical research practices;

b) Interim site visits to: (i) assess site compliance with the requirements for CCTPT clinical protocols being conducted, including: adherence to inclusion and exclusion criteria; reporting of serious adverse events; the appropriate collection, storage and transport of patient samples; the accuracy, timeliness and completeness of data collection and entry; clinical records maintenance; and study product accountability; and (ii) assess the various components of the operation and management of the clinical sites, including: site management, organization and utilization of the site staff; communication among clinical, technical and administrative staff; and the adequacy of site facilities and study equipment;

[NOTE TO OFFEROR #7: For cost estimating purposes, assume that the Contractor will conduct: one-day (i) site establishment visits to CCTPT sites as they become active participants enrolling patients; (ii) interim site visits to all CCTPT sites biennially.]

c) Standardized training for clinical site staff for the initiation of all CCTPT protocols by a meeting to be conducted at the Contractor's site whenever a new protocol is initiated and interim conference calls with all coordinators yearly thereafter, as well as the development of a Manual of Operations (MOP) for each clinical protocol delineating specific instructions and requirements necessary for the appropriate implementation and monitoring of each clinical trial by site personnel, and the provision of travel expenses associated with group meetings of clinical site personnel, when necessary to ensure appropriate training;

d) Identification of site-specific problems and development of recommendations for the improvement of site performance with respect to: the overall management and coordination of the clinical site; adherence to CCTPT Standard Operating Procedures (SOP), protocol requirements as specified in MOP and Federal regulatory requirements; the quality, timeliness and accuracy of data collection storage, management and analyses. This shall include the preparation of written site visit reports on the findings resulting from clinical site visits, including delineation of specific problems and recommendations for improvements, when necessary, for presentation to the CCTPT Steering Committee; and,

e) An annual drug accountability audit on a sampling of active protocols at each CCTPT site.

7. Provide support for regulatory functions and requirements associated with Investigational New Drug (IND) Applications and the design, conduct, monitoring and analysis of clinical trials of experimental therapies. This shall include:

a) Establishing and maintaining a computerized tracking system for the receipt, follow-up, reporting, and disposition of adverse events for all CCTPT clinical trials to the Food and Drug Administration (FDA), the NIAID, appropriate CCTPT investigators, and the CCTPT Steering Committee when appropriate. All procedures and systems must meet the guidelines and regulations of the FDA as related to processing of Adverse Event Reporting and safety information. This shall include:

1) Establishing and maintaining a system for CASCC central receipt of AER information 24 hours/day. This shall be accomplished by providing appropriately trained health care professionals during normal working hours and utilizing an answering machine/service after normal working hours and on weekends;

2) Providing experienced clinical personnel as may be necessary to evaluate adverse event reports received from CCTPT clinical sites, and working with clinical site staff to clarify information, obtain follow-up information, and/or reconcile discrepancies between adverse event data reported versus adverse event data collected on study forms;

3) Abstract and enter adverse event data into the CCTPT central databases within 24 hours of receipt;

4) Preparing and distributing, by hard copy or electronic methods, Safety Reports or Information Reports on adverse events following the established FDA, NIAID, CCTPT guidelines and regulations;

5) Developing and distributing to participating clinical sites adverse event reporting forms, standard operating procedures for processing adverse event data, and appropriate instructions or manuals. The forms shall be developed in coordination with CCTPT investigators and shall conform to NIH, NIAID and FDA guidelines and regulations;

6) Developing, implementing and maintaining quality control/assurance procedures and ongoing training to ensure consistency, completeness and accuracy of adverse event reporting, coding and data entry; and

7) Generating and submitting reports to the Project Officer documenting site performance, as measured by accuracy and completeness of Adverse Event Reports,

time required for response to queries, and CASCC performance, as measured by timely adverse event report disposition (i.e., time from receipt to entry into central databases, time from receipt to FDA reporting where applicable, and other tracking parameters identified by the Project Officer). These reports shall be prepared and submitted monthly or more or less frequently as determined by the Project Officer.

b) Developing and maintaining a computerized clinical site registration system which includes, but is not limited to, the following:

1) Filing and tracking registration documentation submitted by CCTPT clinical sites;

2) Preparing and submitting to the FDA, required registration documentation, including copies of the FDA 1572 forms, Curricula Vitae, Institutional Review Board (IRB) approval of each protocol, and IRB-approved consent forms for each protocol;

3) Responding to queries on the status of site registration from the clinical sites, NIAID, and the CCTPT Steering Committee; and

4) Confirming completion of all procedures necessary for study registration, and notifying clinical sites that registration has been completed for a particular protocol so that study products may be ordered and distributed.

c) Carrying out all regulatory requirements for NIAID- and investigator-sponsored Investigational New Drug (IND) Applications. IND sponsors for CCTPT clinical trials may include the NIAID, individual CCTPT investigators, and/or pharmaceutical companies. In instances where the pharmaceutical company serves as the IND sponsor, the Contractor shall <u>not</u> be responsible for carrying out the regulatory functions outlined below unless agreed upon by the company and the Project Officer. Approximately 80 percent of the clinical trials conducted by the CCTPT will involve IND sponsorship by the NIAID or by individual CCTPT investigators. The Contractor shall prepare, distribute and track Investigational New Drug Applications (INDs) sponsored by NIAID, CCTPT investigators, and, when appropriate, pharmaceutical companies. This shall include:

1) Providing technical and administrative assistance in the preparation and assembly of original and subsequent IND submissions;

2) Gathering information for use in the preparation of IND submissions, including pre-clinical screening, animal toxicity, chemistry, pharmacology, literature research and clinical research, contacting appropriate Federal and private organizations, including pharmaceutical companies; and editing, indexing, assembling and duplicating acquired data for subsequent submission to the FDA;

3) Obtaining letters from pharmaceutical company sponsors, NIAID and/or individual investigators authorizing the cross-filing of information from other sources for agents studied in clinical protocols under separate INDs;

4) Preparing statistical and technical information and other materials for meetings with officials of the FDA regarding the design, implementation and monitoring of CCTPT clinical trials and IND approval; responding to specific inquiries from FDA officials concerning clinical protocol design and IND submissions; and, when necessary, making presentations to FDA officials to explain protocol design and supporting safety, toxicity and efficacy data, clarify questions, and address concerns associated with IND approval;

5) Preparing, distributing and tracking of IND modifications as required to meet FDA requirements; and

6) Maintaining files on all IND correspondence and submissions to the FDA for CCTPT sponsored clinical trials.

d) Assisting the CCTPT and NIAID in the preparation of FDA-required IND sponsor's interim and annual reports. These reports include narrative analysis and tabular summaries of all results of clinical trials. This includes retrieving and summarizing information to be included in FDA annual reports, drawn from, but not limited to: chronologies, pharmaceutical company information, the latest protocol versions, schema depicting the protocols, comparison charts of protocol requirements, statistical analyses, relevant abstracts, posters, papers and presentations, copies of adverse event summary reports, and lists of all submissions to the FDA. The Contractor shall provide copies of all interim and annual reports to the FDA, the Project Officer, the CCTPT Steering Committee, and individual CCTPT investigators as may be necessary.

8. Establish and manage a system for the distribution and quality control of study products. For CCTPT clinical trials, study products shall be dispensed either directly to study participants or to the participating study center pharmacy by the CASCC drug distribution facility. The responsibilities of the Contractor with respect to the distribution and quality control of study products include:

a) Receipt and storage of study products, including, but not limited to, the following:

1) Receiving shipments of study products from a variety of sources, including domestic contract manufacturers or packagers, commercial pharmaceutical companies, and foreign pharmaceutical companies and suppliers; reconciling shipping lists; noting conditions of receipt; and notifying Project Officer of any discrepancies or problems;

2) Receiving and processing through U.S. Customs any shipments from foreign suppliers;

3) Storing products as indicated on the manufacturer's label;

4) Monitoring storage conditions to guarantee and document continuous proper storage; and

5) Ensuring that all applicable FDA current Good Manufacturing Practice regulations are met.

b) Labeling and packaging of study products, including, but not limited to, the following:

1) Labeling and packaging study products to provide supplies suitable for dispensing to individual patients at CCTPT clinical sites, using, where applicable, randomization schemes with patient numbers and corresponding treatment assignments;

2) Maintaining accurate records of all such labeled and packaged study products;

3) Providing the capability to affix auxiliary labels for use on certain products and on outer shipping cartons.

c) Inventory control/quality assurance, including performing a physical inventory of supplies for each protocol at least monthly, notifying the Project Officer of any discrepancies that cannot be reconciled with the current inventory, and monitoring use rate and notifying the Project Officer of low inventories or unusual increases in product requests from CCTPT clinical sites.

d) Shipping and distribution of study products, including, but not limited to, the following:

1) Processing Investigational Agent Request forms on a daily basis, confirming that the order is from an authorized CCTPT clinical site, filling the order and packaging the appropriate protocol-specific research product, dosage and quantity;

2) Supplying shipping cartons, cushioning materials, necessary labels (e.g., fragile), sealing tape, insulation materials, and all other supplies necessary to ensure safe and intact arrival of study products;

3) Supplying sufficient quantities of appropriate packaging (e.g., wet ice, dry ice, or cold packs) to ensure the safe and intact arrival of products requiring maintenance at low temperatures;

4) Shipping study agents to domestic and foreign CCTPT clinical sites so that shipments are received in a timely fashion. On a routine basis, shipments shall arrive within 24 hours.

5) Obtaining the appropriate licenses and permits required by local, state and Federal authorities for the safe import, storage and distribution of drugs, as well as the appropriate interstate, intrastate and foreign import/export shipping licenses and permits for transporting biologics and drugs;

6) Making shipments after hours or on weekends, as required;

7) Except for the above mentioned emergency shipments or other extraordinary tasks, the Contractor/subcontractor shall be open and accessible during regular business hours; and

8) Providing storage for and performing the packaging and shipping of reports and documents related to study products distributed. All original Investigational Agent Request forms shall be retained for the duration of the contract and shall be accessible for audit.

e) Pharmaceutical services, including, but not limited to, the following:

1) Reviewing CCTPT clinical protocols and providing the Project Officer with a written protocol evaluation, usually 1-2 pages in length, including estimates of the quantity of study products needed, comments regarding product handling concerns or packaging requirements;

2) Providing product information (e.g., special handling or shipping, study product preparation) to clinical site pharmacists or patients with every shipment;

3) Providing product ordering, transfer or return information to clinical site pharmacists or study participants;

4) Authorizing the transfer of products designated for one protocol to another, as permitted by FDA regulations and/or the pharmaceutical sponsor, and maintaining copies of Investigational Agent Transfer forms for the duration of the contract;

5) Providing evaluations of current study product usage and projections of anticipated requirements to manufacturers on a quarterly basis or as directed by the Project Officer. These evaluations will be reviewed and approved by the Project Officer before forwarding to manufacturers;

6) Preparing protocol-specific documents providing information regarding study product packaging, dosage strength and labeling for distribution to clinical site pharmacists; and

7) Establishing and maintaining a secured web site for clinical site pharmacists including but not limited to: protocol-specific information and requirements related to study

products; procedures and forms for ordering study products; procedures and requirements for the return of study products; and instructions to be provided to study participants.

f) Providing security/safety measures and procedures, including: 24-hour security to prevent theft, misuse or damage; an automated 24-hour temperature monitoring system to ensure maintenance of appropriate temperature storage conditions; programs or systems for fire protection; and training on safety, security and appropriate handling of investigational agents to all personnel with access to the drug storage facility. The Contractor shall also be required to meet the requirements of the Drug Enforcement Agency for the storage of controlled substances.

g) Processing and disposing of returned drugs, including: identifying and notifying affected investigators in the event that a lot of study product is recalled by the manufacturer or reaches the limit on its useful shelf life; receiving recalled, expired or unused study products returned from clinical sites and processing returns in conformance with local, state and Federal regulations; providing for the quarantine of returned products from other inventory; preparing computerized documentation of returns; and disposing of returned products in a manner prescribed by local, state and Federal regulations.

h) Maintaining a dedicated computerized data processing system to keep inventories and distribution records. All documentation shall be available for annual audits as required by Federal regulations.

9. Coordinate and provide statistical, technical, administrative and logistical support for the activities of the CCTPT Steering Committee, which is responsible for the overall scientific direction, management and implementation of the CCTPT clinical protocols and mechanistic studies, and all CCTPT subcommittees.

[NOTE TO OFFEROR #8: The CCTPT Steering Committee will be composed of approximately 6 non-Federal members. Meetings of the CCTPT Steering Committee will be held in the Bethesda, Maryland area.

The CCTPT Steering Committee will establish two (2) Subcommittees, one for clinical trials and the second for mechanistic studies, each composed of no more than two (2) members. These two CCTPT Subcommittees will meet twice annually for the 4-year period of the CCTPT awards in the Bethesda, Maryland area and will conduct quarterly, or more frequently as needed, conference calls. The CCTPT will also establish up to three (3) protocol development Subcommittees that will meet three (3) times per year via conference call. These committees will be composed of CCTPT Steering Committee and clinical trial and mechanistic studies subcommittee members. There will be no more than nine (9) total participants.]

Contractor support shall include:

a) Membership on the CCTPT Steering Committee by the CASCC Project Director, including participation in all meetings and conference calls convened by this governing body. Additional CASCC staff will attend these meetings as determined by the CASCC Project Director in consultation with the Project Officer.

b) Scheduling, arranging lodging and meeting room facilities, and arranging appropriate teleconferencing services for: three 2-day meetings of the CCTPT Steering Committee in the first year of the contract period, and semi-annual 2-day meetings thereafter; and monthly conference calls for the CCTPT Steering Committee. The Contractor shall provide for the transportation, meals and lodging expenses associated with participation in these meetings by the non-Federal members of the CCTPT Steering Committee;

c) Scheduling, arranging lodging and meeting room facilities, and arranging appropriate services for all meetings and conference calls of Subcommittees established by the CCTPT Steering Committee. The CASCC Project Director, or his/her designated representative, shall participate in all Subcommittee meetings and conference calls;

d) Preparing, assisting in the preparation of, and distributing in advance of CCTPT Steering Committee and Subcommittee meetings and conference calls a variety of materials, reports, analyses and recommendations for review. This shall include, but not be limited to:

    1) Proposed and approved protocols for clinical trials and research designs for proposed and approved mechanistic studies;

    2) Proposed modifications in the design of clinical trials and mechanistic studies;

    3) Status of and issues surrounding FDA approval of INDs;

    4) Status reports on the implementation of approved clinical trials and mechanistic studies, including accrual, retention, loss to follow-up, problems and issues with respect to data management and quality assurance, and recommendations for modifications/improvements where necessary;

    5) Interim and final analyses of the results of clinical trials and mechanistic studies, including recommendations for protocol and mechanistic study modifications to ensure the validity, reliability and feasibility of completing approved studies; and

    6) Preparing brief summaries of all decisions and recommendations of the CCTPT Steering Committee and its Subcommittees.

e) Assisting the NIAID and the CCTPT Steering Committee in the preparation of Standard Operations Procedures. This shall include, but not be limited to, policies and procedures governing:

1) The development, review, and modification of proposed protocols for clinical trials and detailed research designs for mechanistic studies, including the development of criteria for the evaluation of the scientific rationale, feasibility and potential success of clinical trials and mechanistic studies;

2) The monitoring of progress with respect to the implementation of clinical trials and mechanistic studies, including appropriate reporting requirements for ongoing progress reviews and criteria for expanding, curtailing or discontinuing approved studies;

3) The development and implementation of criteria and procedures for the evaluation of clinical and mechanistic site performance, as well as policies for correcting site deficiencies and/or curtailing or eliminating approved sites;

4) Requests for interim and final analyses of clinical and laboratory study results;

5) The addition of clinical and mechanistic study sites to accommodate new knowledge and scientific opportunities; and

6) The preparation and review of scientific reports, manuscripts, abstracts and presentations on CCTPT study results.

10. Coordinate and provide statistical, technical, logistical and administrative support for the activities of the independent Data and Safety Monitoring Board (DSMB). The NIAID DSMB will be composed of scientific and clinical experts, bioethicists, and other representatives as may be necessary. The DSMB, composed of approximately five (5) members, will be appointed by the NIAID to oversee the clinical trials of the CCTPT. Contractor services shall include, but not be limited to, the following:

a) As requested by the Project Officer, develop and revise, as necessary, Conflict of Interest (COI) and disclosure forms for all permanent and ad hoc DSMB members; coordinate the distribution and receipt of completed forms; assess conflict of interest; provide assessments and all forms to the Project Officer; and re-assess potential conflict of interest for permanent DSMB members on an annual basis or more frequently as may be appropriate;

b) Schedule, arrange lodging and meeting room facilities, and arrange teleconference services for meetings and conference calls of the NIAID DSMB. The contractor shall provide for transportation, meals and lodging costs associated with the participation of non-Federal DSMB members;

[NOTE TO OFFEROR #9: The DSMB will meet at least annually in the Bethesda, Maryland area to review clinical and laboratory data on CCTPT studies. Meetings will be one-day, but may be longer if necessary. Conference calls of the DSMB shall be conducted as needed.]

c) Distribute copies of all protocols for clinical trials and mechanistic studies to the NIAID DSMB members for review, including forms and procedures for obtaining informed consent; prepare summaries of all comments received from NIAID DSMB members; provide summaries of DSMB comments to the NIAID Project Officer, the CCTPT Steering Committee and CCTPT subcommittees, as necessary; and participate in preparing responses to DSMB comments and designing modifications to CCTPT approved studies as necessary;

d) Prepare a variety of interim and final statistical analyses and reports for review by the NIAID DSMB, including, but not limited to:

1) Analyses of ongoing pilot and efficacy trials with respect to safety, toxicity and efficacy, including adverse event reports and assessments;

2) Study accrual and retention data, including issues and problems associated with the recruitment and retention of study participants; and

3) Recommendations for improvements and modifications in study protocols as may be necessary to enhance recruitment and retention, ensure the feasibility and scientific validity of inclusion and exclusion criteria and comparison and control groups, and assess the techniques and methodologies used to delineate underlying mechanisms.

e) Prepare summaries of the results of all NIAID DSMB meetings for review and approval by the Project Officer.

11. Ensure an orderly and timely transfer of all data, information and documentation from the EMMES Corporation necessary to proceed with the functions of the CASCC as detailed above.

12. Ensure an orderly transition of contract-related materials to a successor contractor or the Government. Six months prior to the completion date of this contract, a transition plan shall be submitted to the Project Officer for approval.

EXHIBIT 1 TO THE WORK STATEMENT
RFP-NIH-NIAID-DAIT-01-08
February 10, 2000

COOPERATIVE CLINICAL TRIAL IN PEDIATRIC TRANSPLANTATION

Active Institutions

Stanley C. Jordan, M.D.

Pediatric Nephrology & Transplant Immunology

Cedars-Sinai Medical Center

8700 Beverly Boulevard, Suite 4310

Los Angeles, California 90048

310/855-4747

Amir Tejani, M.D.

Westchester Medical Center

19 Bradhurst Avenue, Suite 10

Hawthorne, New York 10532

914/345-0414

William E. Harmon, M.D.

Division of Nephrology

Children's Hospital of Boston

300 Longwood Avenue

Boston, Massachusetts 02115

617/735-6129

Participating Centers

Terry B. Strom, M.D.
Division of Immunology
Beth Israel Hospital
Research East Room 319
330 Brookline Avenue
Boston, Massachusetts 02215
617/667-3550

Gary M. Lum, M.D.
Kidney Center - B328
Children's Hospital of Denver
1056 East 19th Avenue
Denver, Colorado 80218
303/861-6262

Oscar Salvatierra, M.D.
Pacific Transplant Institute
California Pacific Medical Center
2340 Clay Street - Suite A-417
San Francisco, California 94115
415/923-3450

Carl M. Grushkin, M.D.
Department of Pediatrics
Children's Hospital of Los Angeles
4650 Sunset Boulevard
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Los Angeles, California 90027
213/669-2102

Ruth McDonald, M.D.
Department of Pediatrics
Children's Hospital and Medical Center
CH-46
4800 Sand Point Way, NE
Seattle, Washington 98105
206/526-2524

Gary Lerner, M.D.
Division of Nephrology
Children's Hospital of Los Angeles
4650 Sunset Boulevard
Mailstop 40
Los Angeles, California 90027
213/669-2102

C. Frederic Strife, M.D.
Paul T. McEnery, M.D.
Division of Nephrology - TCHRF-5
Children's Hospital Medical Center of Cincinnati
3333 Burnet Avenue
Cincinnati, Ohio 45229-2899

Rudy Valentini, M.D.
Children's Hospital of Michigan
Wayne State University
3901 Beaubien Boulevard
Detroit, Michigan 48201
(313) 745-5604

Barbara Fivush, M.D.

Pediatric Nephrology

Johns Hopkins Children's Center

600 North Wolfe Street

Park 327

Baltimore, Maryland 21205

410/955-2467

H. Jorge Baluarte, M.D.

Department of Pediatrics

St. Christopher's Hospital for Children

Suite 3301 - 3rd Floor

Erie Avenue at Front Street

Philadelphia, Pennsylvania 91134

215/427-5195

Shobba Sahney-Long, M.D.

Pediatrics - Room A541

Loma Linda University Medical Center

11262 Campus/West Hall #173

Loma Linda, California 92354

714/824-0800, x2832

S. Paul Hmiel, M.D.

St. Louis Children's Hospital

Washington University Medical Center

One Children's Place

St. Louis, Missouri 63110

314/454-6043

Vivian Tellis, M.D.

Frederick J. Kaskel, M.D., Ph.D.

Montefiore Medical Center

Division of Transplantation Surgery

Division of Pediatric Nephrology

111 East 210th Street

Bronx, New York, 10467

718/655-1120

Richard N. Fine, M.D.

Department of Pediatrics

SUNY at Stony Brook

Stony Brook, New York 11794-8111

516/444-2716

Ira Davis, M.D.

Rainbow Babies and Children's Hospital

11100 Euclid Avenue

Cleveland, Ohio 44106-6003

216/844-1389

Anup Singh, M.D.

SUNY – HSC Brooklyn

Pediatric Nephrology

450 Clarkson Avenue

Box 49

Brooklyn, NY 11203

ATTACHMENT B

RFP-NIH-NIAID-DAIT-01-08
February 10, 2000

REPORTING REQUIREMENTS AND DELIVERABLES

The Contractor shall submit to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during each reporting period. These reports shall be brief and factual. The exact submission schedule will be negotiated and established in the contract document. Other reporting requirements may be established during negotiations.

In addition to those reports required by Section I and other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below:

A. MONTHLY ACCRUAL AND SITE REGISTRATION REPORT

The Contractor shall provide one copy of the Monthly Accrual and Site Registration Report to the NIAID Project Officer. Additionally, one copy of the report shall be provided to each member of the CCTPT Steering Committee and the protocol Principal Investigator, if not a member of the Steering Committee.

Every month, the Contractor shall submit a report for each open clinical protocol sponsored by the CCTPT, which includes:

1) For each clinical site enrolling study participants in open clinical protocols: projected overall accrual at each site; date of first enrollment; actual accrual to date; summary of all eligible patients per month and to date; and reasons for non-entry of eligible patients;

2) For each clinical site in the process of registering and obtaining approval to participate in open clinical protocols: outstanding requirements for approval; anticipated date of approval; projected accrual; and any anticipated problems with protocol approval/implementation;

3) Summary of the projected versus actual accrual to date for all approved clinical sites, and reasons for non-entry of eligible patients;

4) For each approved mechanistic study associated with an open clinical protocol: status of implementation; status of collection, shipping and receipt of patient samples; problems and/or issues associated with the collection, shipping or receipt of patient samples; and recommendations for resolving any such issues or problems; and

5) Recommendations for modifications in study design, clinical site monitoring, or clinical site training appropriate to improve overall or site-specific accrual, including recommendations for increasing the number of participating clinical sites.

B. MONTHLY ADVERSE EVENT REPORT

The Contractor shall submit a report on all adverse experiences for each CCTPT-sponsored open clinical protocol, including copies of adverse event report forms. The Contractor shall provide one copy to the NIAID Project Officer and to each member of the CCTPT Steering Committee.

C. QUARTERLY STATUS, STATISTICAL AND CASCC WORK REPORT ON CLINICAL PROTOCOL AND MECHANISTIC STUDIES

On a quarterly basis, the Contractor shall submit two copies of the Quarterly Status, Statistical and CASCC Work Report, comprising one to the P.O. and one to the C.O. This Report shall summarize the status of the following for CCTPT activities:

1) Clinical protocols and mechanistic studies under development, including: lead investigator(s); stage of development; actions required for final modification or implementation, including unresolved issues, questions or problems; and timeframe for completion;

2) Clinical protocols and mechanistic studies open to enrollment, including: lead investigator(s); stage of patient enrollment; actions required to meet enrollment projections, including any protocol modification(s) and unresolved issues, questions or problems; and timeframe for completion;

3) Proposed or ongoing interim and final analyses of the results of clinical trials and mechanistic studies sponsored by CCTPT. This shall include:

   a) Title, author(s), brief description and status of approved analyses, including any pending issues, problems or modifications; and

   b) Recommendations for additional interim and final analyses for clinical trials and mechanistic studies.

4) CASCC work performed. This report shall be in sufficient detail to explain comprehensively the tasks accomplished and the results achieved, and shall summarize data analyses performed in text, tabular and graphical form. This report shall include, but not be limited to, the following:

   a) A summary of all relevant descriptive information for all clinical sites combined, as well as for each site individually, to include patient accrual data, attrition (i.e.-patient drop-outs), number of forms received and number of forms delinquent, number of data edits, clinical site monitoring reports, adverse events, safety information, and any other relevant information that the CASCC considers

important.

5) Any other information the CASCC determines that the Project Officer should be advised about.

D. ANNUAL REPORT

On an annual basis, the Contractor shall submit a report summarizing the results of the contract work for the period covered. These Annual Reports shall be in sufficient detail to explain comprehensively the results achieved. Two copies of this report shall be provided, comprising one to the Contracting Officer and one to the Project Officer. The Annual Report shall address each of these items:

1) STATISTICAL DESIGN CONSIDERATIONS

a) The advantages and disadvantages of the various approaches to the statistical design of ongoing and completed CCTPT clinical trials and mechanistic studies relevant for the assessment of the safety, toxicity and efficacy of drug and immunomodulatory treatments for pediatric kidney transplantation, including: control and comparison groups, inclusion and exclusion criteria, sample size; research questions addressed; clinical end-points and immune/surrogate markers, number and type of patient samples, and other information the CASCC determines is important to Project Officer decisions regarding CCTPT operations; and

b) Recommendations for improved statistical approaches and methods to enhance the ability to assess disease stage and activity, therapeutic effect and underlying mechanisms.

2) STANDARD OPERATING PROCEDURES, including:

a) Development, review and implementation of approved protocols and mechanistic studies, including criteria for evaluation and prioritization;

b) Clinical site monitoring and training with respect to adherence to protocol requirements, data collection and quality assurance, adherence to regulatory requirements;

c) Preparation, review and approval of requests for statistical analyses;

d) Review and approval of publications, abstracts, reports and presentations;

e) Monitoring and evaluating the performance of clinical and mechanistic study sites and procedures for addressing performance problems; and

f) Other policies and procedures as may be developed by the CCTPT Steering Committee.

3) CLINICAL SITE MONITORING AND TRAINING, including:

a) Clinical site training activities conducted, including written materials on CCTPT-specific standard operating procedures and protocol-specific requirements;

b) Issues and problems encountered in the training and monitoring of CCTPT clinical sites;

c) Recommendations for modifications/improvements in training materials and/or standard operating procedures to ensure adherence to protocol requirements, standard operating procedures and regulatory requirements; and,

d) All reports from clinical site establishment and interim site visits, including documentation of site capabilities and deficiencies and remedies implemented to assure the sites are in compliance with all appropriate Federal regulations and CCTPT procedures.

4) DISTRIBUTION AND QUALITY CONTROL OF STUDY PRODUCTS, including: receipt, labeling, storage, distribution, security, inventory quality assurance, shipping, evaluations of usage, and disposition of returned investigational agents.

5) REGULATORY FUNCTIONS AND REQUIRMENTS, including the status of INDs, issues and problems in the development, FDA review and approval of INDs, and recommendations for improvements/modifications in CASCC and CCTPT regulatory procedures. Copies of all interim and final reports submitted to the FDA by the CASCC shall also be provided.

6) DMSB RESPONSIBILITIES AND PROCEDURES, including: procedures for the review of interim and final analyses of study data and recommendations for improvements in the analyses prepared for DSMB review and the nature and type of study data generated by CCTPT sites;

7) MONITORING PROGRESS AND EVALUATING PERFORMANCE, including an assessment of policies and procedures used by the CCTPT and recommendations for improvements.

8) ANNUAL AUTOMATED INFORMATION SYSTEM SECURITY REPORT, including the Automated Information System (AIS) Security Profile, which at a minimum shall include: the System's Security Plan (SSP); the Risk Analysis (RA); the Continuity of Operations Plan (COOP) (also known as the Contingency Plan).

E. FINAL REPORT

The Contractor shall prepare a Final Report summarizing all CASCC activities for the entire contract period and all final study results and interim results from unfinished clinical trials or mechanistic studies. All study results shall include the Principal Investigator; all study sites and participating investigators; enrollment statistics by clinical site (including demographic information on all enrollees) and results of the studies in textual, tabular and graphical format. Included in this Final Report, the Contractor shall provide a 200 word "Summary of Salient Results" detailing the important results from the CCTPT studies accomplished during the performance of the contract. The Contractor shall submit two copies of this Final Report, comprising one to the C.O. and one to the P.O.

F. FINAL DELIVERABLE: At the completion of the contract, the Contractor shall deliver to the Government a cleaned and edited public use data set, on media to be determined at the time of delivery, as specified by the Project Officer, and copies of all data management tools, including, but not limited to, data documentation and data dictionaries, data entry software and editing programs to allow reading and analysis of the data. The Contractor shall provide to the Government appropriate computer programs capable of: (1) reading and manipulating all data, and (2) creating SAS compatible databases. Additionally, at the completion of the contractor, the Contractor shall deliver to the Project Officer an audit trail of all raw data corrections, hard copies of the original data collected from study participants from all studies supported by this contract, and all logs and other records related to data collection, entry, editing, analysis and transfer.

G. If the Contractor is unable to deliver the items specified above within the period of performance, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of anticipated delays with reasons therefore.

ATTACHMENT C

RFP-NIH-NIAID-DAIT-01-08
February 10, 2000

EVALUATION FACTORS FOR AWARD

A. 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: (1) technical and (2) cost/price. Although technical factors are of paramount consideration in the award of the contract, cost/price is also important to the overall contract award decision. Technical factors are significantly more important than cost/price. However, cost/price may become a critical factor in source selection in the event that two or more Offerors are determined to be essentially equal following the evaluation of all technical evaluation factors.

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

B. TECHNICAL EVALUTION 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 Offerors. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

CRITERIA **(POINTS)**

1. TECHNICAL APPROACH **(40 points)**

   a) Soundness and practicality of the technical approach for executing the requirements specified in the Work Statement, with adequate explanation, substantiation and justification for recommended methods for handling the projected needs of the CCTPT, including alternative strategies, for: (25 points)

      - providing statistical leadership for the design, implementation, monitoring, modification and analysis of clinical trials and mechanistic studies conducted by the CCTPT;

      - establishing and administering reliable, efficient and responsive data management and quality assurance systems;

- designing and implementing clinical site monitoring and training requirements;
- providing support for regulatory functions and requirements associated with Investigational New Drug (IND) Applications and clinical trials of experimental therapies;
- establishing and managing systems for the distribution and quality control of study products;
- providing statistical, technical, administrative and logistical support for the activities of the CCTPT and the Data and Safety Monitoring Board (DSMB).

b) Understanding of the scope and objectives of the contract, recognition of potential difficulties that may arise in performing the work required, presentation of adequate solutions and understanding of the close coordination necessary between the NIAID, the CCTPT Steering Committee, the clinical sites and other site personnel. (15 points)

2. QUALIFICATIONS, EXPERIENCE AND AVAILABILITY OF PERSONNEL **(30 points)**

a) Project Director/Co-Investigators

Proposed scientific, clinical, regulatory, technical and administrative leadership of the CASCC. This shall include the documented training, expertise, experience, leadership/management skills and availability of the Project Director and the surrounding leadership of the CASCC to successfully plan and manage the project.

Managerial ability to achieve delivery or performance requirements as demonstrated by the proposed use of management and other personnel resources and to successfully manage the project, including subcontractor and/or consultant efforts, if applicable, as evidenced by the management plan and demonstrated by previous experience.

b) Other Personnel

Documented availability, training, qualifications, expertise, experience, education and competence of the scientific, clinical, technical and administrative staff and any other proposed personnel [to include proposed subcontractors and consultants] to perform the requirements of the work statement as evidenced by resumes, endorsements and explanations of previous efforts.

Staffing plan for the conduct of the project, including the appropriateness of the time commitments of all staff, the clarity and appropriateness of

assigned roles, lines of authority, back-up staffing and the evidence that they will be able to function as a team.

3. EXPERIENCE AND CAPABILITIES OF THE ORGANIZATION **(20 points)**

- Documented experience of the organization in managing projects of similar complexity and scope.
- Clarity and appropriateness of lines of communication and authority for coordination and management of the project. Adequacy and feasibility of plans to ensure successful coordination of a multi-organizational collaboration.
- Adequacy and feasibility of provisions for transitions involving predecessor and successor contractors.

4. FACILITIES AND RESOURCES **(10 points)**

Documented availability and adequacy of facilities, equipment and resources necessary to carry out the work statement.

Total 100 points

ATTACHMENT D

RFP-NIH-NIAID-DAIT-01-08
February 10, 2000

SPECIFIC RFP INSTRUCTIONS AND PROVISIONS

NOTICE TO OFFERORS: This attachment contains proposal instructions and information that are specifically related to this acquisition. The information provided below is only a portion of the instructions and notices required for the submission of a proposal. References to additional, more general information, and forms regarding proposal preparation are contained in Attachment E, "Applicable RFP References".

1. NUMBER AND TYPE OF AWARD(S)

It is anticipated that one (1) award will be made from this solicitation on/about January 18, 2001.

It is anticipated that the award from this solicitation will be a cost reimbursement, completion type contract with a five (5) year performance period, and that incremental funding will be used.

2. ESTIMATE OF EFFORT

To assist you in the preparation of your proposal, the Government considers the five-year total effort to be approximately 1,650%, (330% per year). This estimate is furnished for the Offeror's information only and is not to be considered restrictive for proposal purposes.

As further assistance, it is estimated that the above total labor effort is constituted as follows:

Labor Category	**Annual Effort**	**5-Year Total**
Principal Investigator	30%	150%
Other Professional	210%	1,050%
Support Staff	90%	450%
TOTAL	**330%**	**1,650%**

These percentages are based on a 12 month calendar year.

3. SIC CODE AND SIZE STANDARD

Note: The following information is to be used by the Offeror in preparing its Representations and Certifications, specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATIONS, FAR 52.219-1:

(a) The standard industrial classification (SIC) code for this acquisition is 7379.

(b) The small business size standard is $18,000,000.

4. NOTICE OF SMALL BUSINESS SET-ASIDE

(1) **General**. Bids or proposals under this procurement are solicited only from small business concerns. The procurement is to be awarded only to one or more such concerns, organizations, or individuals. This action is based on a determination by the Contracting Officer, alone or in conjunction with a representative of the Small Business Administration, that it is in the interest of maintaining or mobilizing the Nation's full productive capacity, or in the interest of war or national defense programs, or in the interest of assuring that a fair proportion of Government procurement is placed with small business concerns. Bids or proposals received from others will be considered non-responsive.

(2) **Definitions**. The term "small business concern" means a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts, and can further qualify under the criteria set forth in the regulations of the Small Business Administration (13 CFR 121.3-8). In addition to meeting these criteria, a manufacturer or a regular dealer submitting bids or proposals in his own name must agree to furnish in the performance of the contract end items manufactured or produced in the United States, its territories and possessions, Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia, by small business concerns. Provided, that this additional requirement does not apply in connection with construction or service contracts.

5. SERVICE OF PROTEST (AUG 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:

Hand-Carried Address:

Brenda J. Velez, Chief

Contract Management Branch
DEA, NIAID, NIH
6700-B Rockledge Drive
Room 2230
Bethesda, MD 20817

Mailing address (U.S.) Postal Service:

Brenda J. Velez, Chief

Contract Management Branch
DEA, NIAID, NIH
6700-B Rockledge Drive
MSC 7612, Room 2230
Bethesda, MD 20892-7612

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

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

6. GOVERNMENT NOTICE FOR HANDLING PROPOSALS

AN OFFEROR SHALL PLACE THIS NOTICE ON TOP OF EACH COPY OF ITS TECHNICAL PROPOSAL.

> "This proposal shall be used and disclosed for evaluation purposes only, and a copy of this Government notice shall be applied to any reproduction or abstract thereof. Any authorized restrictive notices that the submitter places on this proposal shall also be strictly complied with. Disclosure of this proposal outside the Government for evaluation purposes shall be made only to the extent authorized by, and in accordance with, the procedures in HHSAR paragraph 315.608-72."

(For information regarding authorized restrictive notices, Offerors should refer to the "Confidentiality of Proposals" section, Item F.6, of the STANDARD RFP INSTRUCTIONS AND PROVISIONS, General Instructions.)

7. PRIVACY ACT SYSTEMS OF RECORDS NO. 09-25-0200, "Clinical, Epidemiologic and Biometric Studies of the National Institutes of Health (NIH), HHS/NIH/OD"

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

The Privacy Act System of Records Notice that applies to this RFP was published in the Federal Register dated April 7, 1997, Vol. 62, No. 66, Pages 16596-16602. This notice will be incorporated into any contract resulting from this RFP. If you would like a copy, please contact the Contracting Officer identified in the cover letter to this RFP.

8. SAFETY AND HEALTH DEVIATION PHS 352.223-70 (AUG 1997)

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State, and local laws and regulations applicable to the work being performed under the contract. These laws are implemented and/or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration, and other agencies at the Federal, State, and local levels (Federal, State and local regulatory/enforcement agencies.)

(b) Further, the Contractor shall take or cause to be taken such additional safety measures as the Contracting Officer, in conjunction with the project or other appropriate officers, determines to be reasonably necessary. If compliance with such additional safety measures results in an increase or decrease in the cost or time required of performance of any part of work under this contract, an equitable adjustment will be made in accordance with the applicable "Changes" Clause as set forth in the contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; and/or damage to property incidental to work performed under the contact and all violations for which the Contractor has been cited by any Federal, State, or local regulatory/enforcement agency. The report shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State, or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply promptly with the Federal, State, or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State, or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any such stop work order shall be subject to a claim for extension of time or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or hazardous operations. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor.

9. PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DAIT-01-08

RFP Title: *"Clinical and Statistical Coordinating Center: Cooperative Clinical Trials in Pediatric Transplantation"*

Please review the attached Request for Proposals. Furnish the information requested below and return this page by **Friday, March 31, 2000**. **Your expression of intent is not binding;**

however, the below information is required by the NIAID in order to coordinate the electronic submission and review of proposals.

[ ] DO INTEND TO SUBMIT A PROPOSAL

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

Company/Institution Name: _____

Address: _____
_____
_____
_____

Principal Investigator's Name: _____

Title: _____

Signature/Date: _____

Telephone Number and E-mail Address: _____

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

_____
_____
_____
_____

(Continue list on a separate page if necessary)

RETURN TO:

CMB, NIAID, NIH
6700-B Rockledge Drive
MSC 7612, Room 2230
Bethesda, MD 20892-7612
Attn: Cyndie Cotter, Contracting Officer
RFP-NIH-NIAID-DAIT-01-08
FAX# (301) 402-0972

Email cc41w@nih.gov

RFP-NIH-NIAID-DAIT-01-08
February 10, 2000

APPLICABLE RFP REFERENCES

This section identifies the items found in the RFP Web directory entitled RFP REFERENCES that are applicable to this RFP.

1. The entire file entitled "STANDARD RFP INSTRUCTIONS AND PROVISIONS" is applicable to this RFP, except as otherwise may be modified by the inclusion of an item from the "OPTIONAL RFP INSTRUCTIONS AND PROVISIONS".

2. The following items are applicable from the file entitled "OPTIONAL RFP INSTRUCTIONS AND PROVISIONS":

    - NOTICE OF SMALL BUSINESS SET-ASIDE
    - LATE PROPOSALS, MODIFICATIONS OF PROPOSAL, AND WITHDRAWALS OF PROPOSALS, PHS 352.215-10
    - HUMAN SUBJECTS
    - FACILITIES CAPITAL COST OF MONEY (for commercial organizations)
    - IT SYSTEMS SECURITY

3. The following items/files are applicable from the subdirectory entitled "FORMS, FORMATS, AND ATTACHMENTS":

    Applicable to Technical Proposal

    - Technical Proposal Cover Sheet
    - Technical Proposal Cost Information
    - Summary of Related and Proposed Activities

    Applicable to Business Proposal

    - Proposal Summary and Data Record, NIH-2043
    - Business Proposal Cost Information
    - Disclosure of Lobbying Activities, OMB Form SF-LLL
    - Excel cost spreadsheet (Template provided)

To Become Contract Attachments

- Invoice Instructions for NIH Cost-Reimbursement Type Contracts, NIH(RC)-4
- Procurement of Certain Equipment, NIH(RC)-7 (OMB Bulletin 81-16)
- Protection of Human Subjects Assurance/Identification/Certification/Declaration, OF 310
- Safety and Health Clause

Other-to be submitted as directed by Contracting Officer

- Certificate of Current Cost or Pricing Data, NIH-1397

4. The "Representations and Certifications" are applicable.
5. The "Sample Contract Format-General" is applicable.

ATTACHMENT F

RFP-NIH-NIAID-DAIT-01-08
February 10, 2000

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

1. ELECTRONIC SUBMISSION INSTRUCTIONS

GENERAL --- To submit a proposal electronically under this RFP, Offerors will need to prepare the proposal on a word processor or spreadsheet program (for the cost portions) and convert them to Adobe Acrobat Portable Document Format (PDF). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON SEPARATE FILES. Further, to expedite the file transferring process, the two files must be named using the following DOS naming convention:

- Technical Proposal: c:\rfp____\techprop.pdf
- Business Proposal: c:\rfp____\busiprop.pdf

If your organization does not have the capability to submit electronically, or unforeseen difficulties occur during transmission, you may submit the electronic copy of your proposal with the original proposal on a diskette, CD-Rom or ZipDisk, in lieu of the Internet. The Contract Specialist/Contracting Officer must be notified in advance of using these optional methods.

Approximately TWO weeks prior to the due date of proposals, all Offerors will be provided with specific electronic access information and electronic proposal transmission instructions. For this reason, it is imperative that all Offerors who are intending to submit a proposal in response to this RFP contact the Contracting Officer identified in this RFP and **complete and submit the attached Proposal Intent Form by FRIDAY, MARCH 31, 2000**.

NOTE: There is no limit to the size (MB) of the two electronic PDF files to be submitted; however, the size of the technical proposal is limited to the page limitation language outlined below. For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 3.0.

ADDITIONAL SUGGESTIONS --- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system will not incorporate a capability to read these files. Graphics which are embedded into documents should be kept as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly. Suggestions include:

- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.

- Be aware of how large these graphics files become. Large files are discouraged.
- Limit scanned images as much as possible.

PAGE LIMITS -- The Technical Approach portion of the Technical Proposal (see paragraph 2.b.4)b), Approach, below) is limited to thirty five (35) pages. Pages in excess of this will be removed from the proposal and will not be read or evaluated. EACH PAGE OF THE TECHNICAL PROPOSAL MUST BE NUMBERED SEQUENTIALLY. Offerors are encouraged to limit the overall size of the Technical Proposal, inclusive of appendices, attachments, etc. Please note that although no page limit has been placed on the Business Proposal, Offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi (characters per inch), whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.

Technical Proposal and Business Proposal preparation instructions along with proposal table of contents are detailed below.

2. TECHNICAL PROPOSAL INSTRUCTIONS

a. **GENERAL** --- The entire technical proposal, except as noted below in the "Technical Proposal Table of Contents", is to be submitted electronically. The STANDARD RFP INSTRUCTIONS AND PROVISIONS provide more detail on the TECHNICAL PROPOSAL requirements.

b. **TECHNICAL PROPOSAL TABLE OF CONTENTS/FORMAT**

(NOTE: Instructions to Offerors are indicated in parentheses or as footnotes.)

1) TECHNICAL PROPOSAL COVER SHEET ..... Page 1

2) TECHNICAL PROPOSAL TABLE OF CONTENTS ..... Page 2

3) SUMMARY OF OBJECTIVES AND METHODS (Abstract)*... Page 3

4) TECHNICAL PLAN (Refer to Technical Proposal Instructions located in the Standard RFP Instructions and Provisions.)

STATEMENT OF WORK

a) Objectives ..... Page 4
b) Approach ..... _____
c) Methods ..... _____
d) Schedule ..... _____

5) PERSONNEL (List by name, title, department and organization, and detail each

person's qualifications and role in the Project.)

Provide narrative for:

a. Principal Investigator/Project Director
b. Other Investigators
c. Additional Personnel, (e.g., technical support, subcontractors, consultants)

(Note: For key personnel, include 2 page biosketch/resume and the form entitled "Summary of Related and Proposed Activities.") -- . . . . . Page ____

6) FACILITIES/RESOURCES AND DIRECT COSTS (List/describe all equipment, facilities and other resources available for this project; include marked laboratory/clinical space floor plan)-- . . . . . Page ____

7) "Technical Proposal Cost Information" summary spreadsheet -- . . . . . Page ____

8) OTHER CONSIDERATIONS (Provide brief narrative of any unique arrangements, safety procedures in place, animal welfare issues, human subject and minority and gender issues, etc.)-- . . . . . .Page ____

9) HUMAN SUBJECTS, PARTICIPATION OF CHILDREN AND MINORITY AND GENDER ISSUES NOT OTHERWISE ADDRESSED (IF APPLICABLE) -- Page ____

10) VERTEBRATE ANIMALS (IF APPLICABLE) -- . . . . . Page ____

11) LITERATURE CITED -- . . . . . Page ____

12) APPENDICES** (Protocols, policy manuals, etc. for above Technical Plan; list each Appendix; Appendices must be clear and legible, and easily located.)

* *State the proposal's broad, long-term objectives and specific aims. Describe concisely the research design and methods for achieving these goals. DO NOT EXCEED ONE PAGE in providing the abstract. Identify the RFP number, institution, and Principal Investigator on the abstract.*

*** HARDCOPY SUBMISSION OF APPENDICES: The following items are excluded from our electronic submission requirement and will not be subject to page limitations. Offerors may provide appendices electronically or may instead submit ten (10) paper copies of the information.*

- *Complete SOPs; any other pertinent policy manuals; any letters of collaboration from other investigators; non-scannable figures or data.*

3. BUSINESS PROPOSAL INSTRUCTIONS

a. **GENERAL** --- THE ENTIRE BUSINESS PROPOSAL IS TO BE SUBMITTED ELECTRONICALLY. There are no page limits with the business proposal. The

STANDARD RFP INSTRUCTIONS AND PROVISIONS provide more detail on the BUSINESS PROPOSAL requirements.

Following proposal submission and review, additional information will be requested by the Contracting Officer from all Offerors that comprise the competitive range. The format of your BUSINESS PROPOSAL is detailed in the "Business Proposal Table of Contents", below.

With the Business Proposal, please submit Form NIH-2043, "Proposal Summary and Data Record." Note that in addition to telephone and fax numbers, the INTERNET addresses of both the Principal Investigator and the responsible business representative are to be included on the form.

b. **ESCALATION.** Due to the National Institute of Allergy and Infectious Diseases' current budget restrictions, it is recommended that any proposed annual increase in costs for inflation be limited to no more than 3% of total costs per year. Final inflation increases will be subject to the negotiation process taking into consideration the most current consumer price index (cpi).

c. BUSINESS PROPOSAL TABLE OF CONTENTS

Please use the following format to organize and present your Business Proposal:

SECTIONS/FORMAT

1. Proposal Summary and Data Record, NIH-2043

2. Business Proposal Cost Information and cost spreadsheets which include an itemized cost element breakdown for each year of the contract. Cost elements on these spreadsheets include (as applicable): Direct Labor, Fringe Benefits, Materials, Subcontracts, Travel, Equipment, ODC, Raw Materials, Purchased Parts, Indirect Costs, Fee/Profit.

   [Note: We have included a template cost spreadsheet in Microsoft Excel. Offerors are requested to complete this spreadsheet and include it with their business proposal. This spreadsheet can replace the cost sheets that you ordinarily provide. It is our hope that this spreadsheet will provide you with a useful tool, allow us to more easily understand your cost proposal, and eliminate our need to recreate your spreadsheets. This spreadsheet template is a new approach, and we would appreciate any feedback you could give us about it.]

3. Business Plan - the business plan has the following components:

   - A narrative of the BASIS of costs proposed; do not provide documentation with initial proposal
   - Qualification of the Offeror - This includes: General Experience, Organizational Experience Related to the RFP, Performance History, Pertinent Contracts and

Grants
- Property, Equipment, Facilities to be dedicated to this work
- Royalties, Financial Capacity, Subcontractors

4. Representations and Certifications

5. Other Forms/Information:

   - Disclosure of Lobbying Activities, OMB Form SF-LLL

4. PACKAGING AND DELIVERY OF THE PROPOSAL

[Note: Listed below are delivery instructions for the submission of the PAPER copies of your proposal. Instructions for your electronic submission are described above in Electronic Submission Instructions.]

Shipment and marking shall be as indicated below:

A. EXTERNAL PACKAGE MARKING

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

"RFP-NIH-NIAID-DAIT-01-08
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. NUMBER OF COPIES

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

Technical Proposal: One (1) unbound signed original **AND** five (5) unbound copies, with ten (10) copies of items excluded from electronic submission requirements that you choose to provide in paper format (SOPs, pertinent manuals, non-scannable figures or data, and letters of collaboration/intent).

Business Proposal: One (1) unbound signed original **AND** five (5) unbound copies.

C. PAPER COPIES TO:

If hand delivered or via delivery service:

Cyndie Cotter, Contracting Officer
Contract Management Branch
NIAID, NIH
6700-B Rockledge Drive
Room 2230
Bethesda, Maryland 20817

If using U.S. Postal Service:

Cyndie Cotter, Contracting Officer

Contract Management Branch
NIAID, NIH
6700-B Rockledge Drive
MSC 7612, Room 2230
Bethesda, Maryland 20892-7612

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

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with PHSAR 352.215-10, Late Proposals, Modifications of Proposals and Withdrawals of Proposals (NOV 1986).

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