OMB No. 0990-0115

Electronic Request for Proposal
SOLICITATION COVER PAGE

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Purchase Authority: Public Law 92-218, as amended.
NOTE: The issuance of this solicitation does not commit the government to an award.

RFP Number:	***Just In Time:***	***Small Bus. Set-Aside*** [√] Yes [ ] No ***8(a) Set-Aside*** [ ] Yes [√] No ***SIC Code:*** 7379 ***Size Standard:*** $18 Million	***Level of Effort:*** [ ] Yes [√] No ***Total Effort:*** n/a
NIH-NIAID-DMID- 01-10	[ ] Yes [√] No		

TITLE: *Bacteriology and Mycology Biostatistical and Operations Unit (BAMBU)*

Issue Date: May 1, 2000	***Due Date/Time:*** July 28, 2000 4:00pm EST	***Technical Proposal Page Limits:*** [√] Yes [NTE **300** pages] [ ] No **See: "How to Prepare & Submit an Electronic Proposal"**

ISSUED BY:

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

We reserve the right to make awards without discussion.

NO. OF AWARDS:

[√] Only 1 Award
[ ] Multiple Awards

PERIOD OF PERFORMANCE:

5 Years beginning on or about March 1, 2001.

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

The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. 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 PHS Clause 352.215-10 entitled "Late Proposals, Modifications of Proposals and Withdrawals of Proposals" located in this Solicitation.

POINT OF CONTACT -- Mrs. Dawn Caracci ***[COLLECT CALLS WILL NOT BE ACCEPTED.]***

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BACKGROUND/STATEMENT OF WORK

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BACKGROUND

Treatment of serious fungal and healthcare-associated resistant bacterial infections and chronic Lyme disease are high priorities of the NIAID. Through the BAMSG, CSCLD, and BAMBU, NIAID will continue to support research on interventions for fungal diseases and chronic Lyme disease and will initiate clinical studies of interventions for resistant bacterial infections.

Fungal Infections

Systemic fungal infections are an increasingly significant health problem in immunocompetent and immunocompromised hosts. They are recognized as important emerging infectious diseases, especially in nosocomial settings involving the management of neutropenic cancer patients, bone marrow and solid organ transplant recipients, and surgical, trauma and critical care patients. Fungi cause approximately ten percent of nosocomial bloodstream infections. Despite a reduction in the frequency of opportunistic fungal infections in HIV-infected and AIDS patients apparently due to "highly active anti-retroviral therapy" (HAART), these infections remain a major cause of morbidity and mortality. The frequency of opportunistic infections in AIDS patients can be expected to rebound as more and more patients fail HAART for controlling their HIV infection. Currently, treatment of some life-threatening fungal infections requires prolonged administration of relatively toxic agents. In the immunocompromised host, available treatment is frequently unsuccessful initially, or results in relapses when treatment is discontinued.

Since 1978, the NIAID has supported the NIAID Mycoses Study Group (MSG) through the contract mechanism to provide an infrastructure for the conduct of clinical trials and studies of antifungal interventions in collaboration with pharmaceutical industry sponsors (University of Alabama at Birmingham, contract number N01-AI-65296). The structure of the MSG has consisted of a Central Unit, a Data Management and Biostatistics Unit, and five disease subprojects organized by fungal diseases caused by specific groups of organisms: cryptococcosis, coccidioidomycosis, the endemic mycoses, aspergillosis, and candidiasis.

Resistant Bacterial Infections

Antimicrobial resistance is a major public health problem that is increasing at an alarming rate. At present, virtually all important human pathogens have become resistant to one or more antimicrobial drugs. Since the arsenal of antimicrobial agents is not growing rapidly, physicians are forced to consider the use of more expensive and toxic drugs. In order to safeguard our current arsenal of antimicrobial drugs, more information is needed on how best to maximize their efficacy to minimize the emergence of drug-resistant strains of bacteria. In addition, new diagnostic, preventive, and therapeutic approaches need to be developed and tested to monitor, as well as reduce, the incidence of multi-drug resistant infections.

The BAMSG will be established to evaluate interventions for preventing, rapidly diagnosing, and treating serious fungal and resistant bacterial infections (see RFP NIH-NIAID-DMID-01-11). The BAMSG will be structured to address serious fungal and healthcare-associated resistant bacterial infections occurring in the following risk groups:

1. Immunocompromised patients including those receiving chemotherapy as anticancer treatment or immunosuppression for cellular and/or solid organ transplantation;
2. Non-immunocompromised patients with or at risk for serious healthcare-associated or endemic fungal infections;
3. Patients with or at risk for opportunistic fungal infections secondary to HIV infection; and
4. Patients with or at risk for healthcare-associated resistant bacterial infections including those in intensive care settings.

Clinical Studies of Chronic Lyme Disease

Lyme disease (LD) is the most common tick-borne disease in the United States and is a classic example of an emerging infectious disease. The etiologic agent, *Borrelia burgdorferi*, is a spirochete and is transmitted to humans and other animals by *Ixodes* ticks. The natural reservoir for the etiologic agent is rodents; many other mammals and some birds may also become infected. As with many infectious diseases, the clinical manifestations of LD are variable and unpredictable. Early manifestations include a rash (erythema migrans), general malaise, and flu-like symptoms. Chronic manifestations include rheumatologic, cardiac and neurologic symptoms and signs which have been reported to spontaneously remit and recur even following antibiotic therapy. Chronic Lyme Disease (CLD) is a condition of chronic or intermittent symptoms that persist after treatment for acute LD. The cause of CLD is not known but at least two possibilities have been suggested. The first is that it is the result of a chronic active infection of *B. burgdorferi* that has escaped control or eradication with the use of conventional antibiotic regimens. A second possibility is that CLD may be due to damage caused by the original infectious process, including triggering of post-infectious immune phenomena despite the eradication of the living spirochete.

In 1994, a meeting was convened at the NIAID to review the current understanding of CLD and to examine a number of possible clinical approaches for studies of CLD. The NIAID has since provided support (CSCLD, contract no. N01-AI-65308) for randomized, double-blind, placebo-controlled, multicenter trials to study the therapeutic effects of antimicrobial agents in CLD. Summaries of the two ongoing studies (NIAID DMID 97-002 and NIAID DMID 97-003) are available through the NIAID Clinical Trials Database website which can be found at: http://www.niaid.nih.gov/clintrials/ntest.asp.

STATEMENT OF WORK

The Contractor shall, independently and not as an agent of the Government, furnish all necessary services, qualified personnel, materials, equipment and facilities not otherwise provided by the Government under the terms of this contract, as needed to establish the Bacteriology and Mycology Biostatistical and Operations Unit (BAMBU) a biostatistical and operations unit to support clinical trials conducted by the Bacteriology and Mycology Study Group (BAMSG) and Clinical Studies of Chronic Lyme Disease (CSCLD) (hereinafter referred to as the Study Groups).

[NOTE (1) TO OFFEROR: The Offeror's role in the support of each study will be defined by the Project Officer. Offerors must have the flexibility to adjust the relative time commitments of their staff to meet the varying needs of the studies to be undertaken.]

[NOTE (2) TO OFFEROR: For purposes of budgeting, the Offeror should assume that approximately twelve (12) studies will be initiated during this contract period, approximately two thirds of these studies will be Phase III clinical trials.]

A. Statistical Leadership

1. Provide statistical leadership, scientific advice and judgment regarding research options, and clinical trial design expertise for the development and implementation of protocols to be conducted by the Study Groups. Advice shall address, but not be limited to, alternate design strategies, power, sample size, and impact of interim analyses, and NIH priorities and requirements for inclusion of women and minorities and children, when appropriate, in study populations.

2. Attend and participate at meetings and on teleconference calls of the Study Group Steering Committees, research committees, and annual meetings.

   [NOTE (3) TO OFFEROR: The Offeror should budget for at least three staff members, to include the PI or designee, to attend the annual scientific meetings of the Study Groups (one per group) in Bethesda, Maryland. These meetings will typically last two and one half days.]

3. Collaborate with Study Group investigators and NIAID staff to develop and refine other aspects of the experimental design of clinical studies, including but not limited to:

   a. Delineation of the research questions to be addressed.
   b. Consultation on concepts to be developed by the Study Groups.
   c. Selection of appropriate study populations and control or comparison groups.
   d. Development of inclusion and exclusion criteria.
   e. Definition of clinical endpoints and surrogate markers.
   f. Selection of randomization and stratification/blocking methods.
   g. Data collection forms.
   h. Interim and final analysis methods.
   i. Quality assurance methods.
   j. Development of recommendations for modifications in the design of ongoing clinical trials with respect to the above parameters, as determined by the Project Officer.

4. Develop innovative approaches for analyzing outcome data, including development of improved criteria for evaluating disease stages in conjunction with Study Group principal investigators, and development of new statistical methods or modification of existing methods for data analysis that will better address relevant clinical research questions.

B. Data Management and Systems Development

1. Establish and administer efficient, reliable, secure and responsive systems for the collection, management, quality assurance and reporting of study data, as well as a system for electronic communication linkages among Study Groups and their respective clinical study sites, the NIAID, and the Study Groups coordinating units, protocol teams, and steering committees.

2. Develop computer programs and related procedures for the collection, processing, editing, and analysis of all clinical and laboratory study data, including storage, tracking, and retrieval of study data at the central data management facility.

3. Produce and distribute standardized forms for collection of all data needed on study subjects, including eligibility, demographic and other baseline data, sequential clinical outcome assessments, serious adverse events and side effects, and laboratory results. Work with the Study Group investigators in the development and pretesting of forms and procedures; reproduce and distribute all forms and revise as directed by the Project Officer.

4. Provide centralized computerized registration, randomization, and stratification of all patients on Study Groups protocols, or alternative non-computerized methods as directed by the Project Officer, including built-in checks for breakdowns in the assignment process, and procedures for monitoring masking of randomized treatment assignment codes.

5. Collect study data from the study sites. Using the computerized data management system developed in response to item B2 above, verify, process, monitor, correct, update, file and store the data securely and in accordance with applicable FDA regulations. Contact study personnel to obtain clarifications or corrections for questionable data or to correct deficiencies.

6. Develop and implement quality assurance and quality control procedures to detect data deficiencies.

7. Evaluate and improve the accuracy, timeliness, and completeness of data submitted by the Study Group clinical sites at each stage through creation of final datasets, including verification of the clinical and laboratory data used to determine that study participants have reached protocol-defined endpoints.

8. Develop and implement a system for evaluating protocol adherence by the Study Group clinical sites, and performance and quality of the data from any central laboratories.

[NOTE (4) TO OFFEROR: The Offeror must submit standard operating procedures for quality control as part of their proposal.]

9. Prepare and provide study data (subject specific and/or summary data) and accompanying documentation to NIAID staff, study investigators or to industrial sponsors, as requested by the Project Officer, to be used for special investigations, selected data analyses, or other purposes. The data shall be provided in a format compatible with the systems and software used by the recipient (NIAID, Study Group investigators, and/or industrial sponsors) as directed by the Project Officer. Upon completion of each study, prepare a final, cleaned, edited, and documented data set containing all study data. Deliver an electronic copy of the data set to the Project Officer.

10. Provide the computer system used for data management with the potential for expedited processing of selected high-priority information (e.g., randomization assignment, monitoring progress of a particular study, tracking of serious adverse events) and for ready transferal of data and data documentation to NIAID or others at any point during a study. Also, the system shall provide sufficient flexibility and accessibility to answer any inquiries in a timely manner, typically no more than one business day.

11. Develop, implement, and maintain security requirements for the computer system used for data management to:

    a. Ensure patient confidentiality for all subject records (both hard copy and electronic).

    b. Provide security against anticipated risks, including loss of confidentiality of subject records and viral or catastrophic loss of study data or important software.

    [NOTE (5) TO OFFEROR: The Offeror must describe in detail the various components of the proposed systems and how they will function with respect to the Study Group clinical sites; also, predicted upper limits for time duration of the steps needed to accomplish the data management procedures described above must be provided.]

12. Establish reliable and secured electronic communication linkages with NIAID and Study Groups that facilitate sending mail and sharing word processor and data files.

    [NOTE (6) TO OFFEROR: Microsoft Office Suite 2000 includes the word processing and e-mail software currently used by NIAID.]

C. Operations and Support

[NOTE (7) TO OFFEROR: The Contractor will also function as an administrative, operations and regulatory support office to accomplish the CTBM research agendas.]

1. Provide administrative support to the Study Groups and the NIAID for the conduct of CTBM clinical trials, including but not limited to:

    a. Coordination of the activities of study teams and sites, central laboratories, Study Group coordinating units, NIAID, appropriate BAMBU staff, and other relevant entities (such as other collaborating groups and industrial sponsors) for study planning, implementation and analysis, training, and communications, including all necessary logistic and support activities. E-mail and word processing software shall be compatible with that used at NIAID.

b. Coordination of the development, preparation, review, and implementation of an overall set of Standard Operating Procedures (SOP) for each Study Group incorporating the relevant policies, procedures and requirements of the Study Groups, NIAID, Office for Protection from Research Risks (OPRR), and the Food and Drug Administration (FDA). The Contractor shall update these SOPs, as directed by the Project Officer, and distribute copies to study sites and NIAID staff.

2. Coordinate and provide statistical, technical and administrative support for the activities of the independent Data and Safety Monitoring Boards (DSMB), internal monitoring boards (IMB) and external Advisory Panels for the Study Groups. Responsibilities shall include but not be limited to:

a. Survey membership of the DSMBs, IMBs, and Advisory Panels, NIAID staff, study chairs, industry representatives (if any), and Study Group coordinating unit staff for availability in order to schedule meetings and conference calls.

b. Prepare a roster of invitees for each study review, send letters of invitation, distribute agendas prepared by NIAID as well as relevant protocols, informed consent documents, case report forms, interim analysis reports, or other supporting documents to the DSMB, IMB, or Panel members, NIAID staff, Study Group coordinating unit staff, and other invited participants, as directed by the Project Officer.

c. Provide a staff member to handle meeting registration and other logistical matters during the meeting.

d. Schedule, arrange and pay for meeting room facilities, including audiovisual equipment, as necessary.

e. Assist non-Federal DSMB, IMB, and Panel members with scheduling, reserving transportation and lodging arrangements and provide reimbursement for their transportation, meals and lodging expenses associated with their participation at meetings of their respective groups.

f. Prepare and distribute copies of all review summaries to DSMB, IMB, and/or Panel members, protocol chairs, the Study Groups steering committees, study investigators, and industry sponsors (if any) if requested by the Project Officer.

g. Track implementation of action items and submission of DSMB reports by study investigators to their respective Institutional Review Boards (IRBs).

[NOTE (8) TO OFFEROR: Typically, IMBs oversee Phase I and small Phase II studies whereas DSMBs are used to monitor larger Phase II and Phase III clinical trials. The IMBs meet by teleconference call at least once during the study accrual period and are composed of approximately three (3) members consisting of a study investigator, the NIAID Medical Officer, and an investigator independent of the Study Group and the study. The BAMSG and CSCLD DSMBs will be composed of approximately five (5) members each and will be appointed by the NIAID. The DSMBs will meet at least annually in the Bethesda, Maryland and will typically convene by teleconference call once between these meetings. The BAMSG and CSCLD Advisory Panels will be composed of up to seven (7) members each and will be appointed by the NIAID to review the agenda for upcoming studies and overall progress of the Study Groups. Typically, the BAMSG Advisory Panel will meet annually and the CSCLD Advisory Panel will meet every other year. The Advisory Panels will meet in the Bethesda, Maryland area.]

3. Develop a standard protocol template and development process in collaboration with NIAID and the Study Groups coordinating units and submit to the Project Officer for review and approval within 60 days of award of contract.

   [NOTE (9) TO OFFEROR: The Offeror must include a model protocol template as an example with the proposal.]

4. Develop and maintain a tracking system (including expected completion timelines) in conjunction with the Study Group coordinating units for development and completion of protocols, informed consent documents, case report forms, and related documents.

5. Initiate, arrange, and participate in monthly (or more frequently, as needed) conference calls and meetings to develop protocols and address scientific and/or practical issues that may arise during the development and implementation of the studies, and, review progress of the studies. This shall include assembling and distributing necessary materials for these calls and meetings, and preparing minutes and action items as directed by the Project Officer.

   [NOTE (10) TO OFFEROR: The Offeror must propose a budget that includes all costs associated with conference calls and travel expenses to attend meetings related to protocol development and implementation.]

6. Track and distribute draft clinical protocols to the Study Groups, NIAID staff, steering committees, and external advisors.

7. Oversee the protocol development process in collaboration with the BAMSG Principal Investigator and coordinator, develop and prepare draft and final protocols and related documents, including informed consent and case report forms, as part of the protocol teams that will include the protocol chair, NIAID representatives, industrial sponsors (if any), and BAMBU representatives consisting of a statistician, clinical trials specialist, and data manager.

8. Provide a repository for current versions of protocols, informed consent documents, and case report forms and other documents (including conference call and meeting minutes) with the capacity to distribute copies to study sites, NIAID staff and others upon request by the Project Officer.

9. Conduct pretesting of case report forms and update, as directed by the Project Officer.

10. Prepare and update, as directed by the Project Officer, 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 procedures for the collection, testing, storage and shipping of patient samples, and procedures for data collection, entry, verification and storage.

11. Design, produce, and distribute labels for study materials, test articles, specimen containers, or data collection forms.

12. Prepare and distribute instructional materials regarding the study procedures and use these to conduct standardized training for study investigators and staff and clinical monitors using the Manual of Procedures and other materials.

13. Assist in drafting clinical trial agreements (CTA) or Cooperative Research and Development Agreements (CRADA) for each study involving an industrial sponsor(s) based on the List of Responsibilities (LOR) for that study. The draft CTAs or CRADAs shall address the cost to BAMBU associated with data management and site monitoring, as appropriate, as well as clinical site costs. Assigned CTA or CRADA shall be in place prior to the initiation of each study.

14. Prepare abstracts/protocol summaries for NIH clinical trials database, DMID and NIAID databases and other databases as specified by the Project Officer, and serve as a call-in center for the public regarding information on CTBM studies summarized in the clinical trials database and on the NIAID website.

15. Develop and maintain a tracking system (including expected timelines) in conjunction with the Study Groups for implementation and completion of the CTBM studies including study accrual and data analysis, manuscript and completion.

D. Regulatory

1. Assist in assuring that all CTBM sites are in compliance with all Federal regulations and NIH policies applying to the conduct of research involving human subjects including, but not limited to, Title 21 CFR 50, 56 and 312, and Title 45 CFR 46.

   [NOTE (11) TO THE OFFEROR: The Investigational New Drug (IND) sponsor for CTBM clinical trials may be the NIAID or an industrial sponsor. In instances where the industrial sponsor serves as the IND sponsor, the Offeror will <u>not</u> be responsible for carrying out the regulatory functions described in this section. In instances where NIAID holds the IND, the Offeror will assist and interact with the Clinical Regulatory Affairs Branch (CRAB), DMID in carrying out these regulatory functions. It is anticipated that the NIAID will hold the INDs for almost all new studies.]

2. Provide support for requirements associated with Investigational New Drug (IND) applications for clinical trials of experimental therapies including, but not limited to:

   a. Providing technical and administrative assistance in the preparation and assembly of original and subsequent IND submissions including interim and annual reports.

   b. Tracking of responses to specific inquiries from FDA officials related to clinical protocol design and IND submissions.

   c. Maintaining back-up files on all IND correspondence and submissions to the FDA for CTBM sponsored clinical trials.

   d. Compiling final study report and manuscripts.

3. Develop and maintain a computerized clinical site registration system including but not limited to:

   a. Assembling and tracking initial and subsequent modifications of registration documentation submitted by clinical sites participating in CTBM clinical trials including copies of the FDA Form 1572, Curricula Vitae, conflict of interest disclosure, IRB approval for each protocol, protocol amendment, consent form, and, study advertisements.

b. Assuring adherence to the informed consent forms submitted by each site to the NIAID-approved informed consent template for each study.

c. Confirming satisfactory completion of all procedures necessary for site registration to CRAB and the Project Officer and notifying clinical sites that registration has been completed for a particular protocol to allow initiation of study product shipment and enrollment of study participants.

d. Providing site registration status reports to the NIAID and the CTBM study group Executive and Steering Committees.

e. Confirming OPRR project assurance for each clinical site. No non-U.S. sites may participate in a CTBM study until documentation of compliance with these regulations has been submitted and prospectively approved by the Project Officer.

f. Maintaining site-specific back-up regulatory files for each study.

4. Establish and maintain a system for the receipt, follow-up, tracking, and disposition of serious adverse experience (SAE) reports for all CTBM clinical trials. Some examples of SAEs include events resulting in:

a. Death.
b. A life threatening experience.
c. Inpatient hospitalization or prolongation of existing hospitalization.
d. Congenital anomaly or birth defect.
e. Persistent or significant disability or incapacity.
f. Other important medical events that may not result in death, be life-threatening, or require hospitalization but may be considered an SAE when, based upon appropriate medical judgment, they may jeopardize the study participant and may require medical or surgical intervention to prevent one the outcomes listed above.

5. Satisfy FDA regulations and NIAID guidelines as related to processing of SAE reports and safety information by:

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

b. Establishing and maintaining a system for receiving faxes of SAE reports and related safety information 24 hours/day.

c. Providing personnel during normal working hours to assemble and distribute this information to appropriate BAMBU staff concerned with regulatory affairs (hereinafter referred to as the Regulatory Specialist or RS).

d. Working with clinical site staff, the RS will obtain follow-up information, and/or reconcile discrepancies between SAE data reported versus SAE data collected on study forms. The SAE will be assessed by the RS and relevant information for each SAE will be summarized, when appropriate, for submission to the NIAID, study chairs, and industrial sponsors, if any.

e. Abstracting and entering SAE data into the BAMBU database within 72 hours of receipt.

f. Preparing draft safety reports for submission to the NIAID following the established FDA regulations and NIAID guidelines.

g. Distributing final versions of SAE and safety reports to industrial sponsors (if any) and to study investigators and track submission to their IRBs.

h. Developing, implementing and maintaining quality control/assurance procedures and ongoing training of clinical site staff to ensure consistency, completeness, and accuracy of SAE reporting.

i. Generating line listings of all adverse events occurring in each specific CTBM study for which NIAID is the IND sponsor for annual and final reports to the FDA and as requested by the Project Officer.

j. The RS shall transmit SAE reports, as designated by CRAB, to site investigators to share with their respective IRBs.

[NOTE (12) TO THE OFFEROR: The Offeror must provide a proposed SOP for receipt, follow-up, tracking, and disposition of SAE reports.]

6. Distribute the investigator's brochure to the clinical sites when NIAID holds the IND for an investigational drug.

7. Attend and participate in a DMID regulatory workshops to discuss clinical trial coordination and regulatory issues related to clinical trials.

[NOTE (13) TO OFFEROR: The individuals serving as clinical trial and regulatory specialists should attend these 2-day meetings to be held in Bethesda, Maryland each year.]

8. Track distribution of study drugs to participating clinical sites and, ultimately, the disposition of study drug by those clinical sites as instructed by the Project Officer. The Contractor shall develop a plan for tracking the distribution and ultimate disposition of study drugs, in collaboration with the Project Officer, for selected trials where this function is needed.

E. Clinical Site Monitoring

1. Monitor Study Group clinical sites participating in CTBM studies to ensure completeness and accuracy of study data and adherence with good clinical practice standards, protocol specifications, regulatory requirements, and other relevant Federal policies where NIAID holds the IND, unless otherwise instructed. The Contractor shall be responsible for assuring that the monitors have sufficient clinical background and be trained to effectively perform the required tasks. The Contractor shall provide the monitors with protocol-specific orientation and assignments by the clinical trial specialists, data managers, the protocol chairs and/or other protocol team members, as appropriate, and NIAID.

2. Conduct initial site visits for all potential Study Group clinical sites not already participating in ongoing MSG or CSCLD studies before this contract is initiated. In conducting these initial site visits, the Contractor shall:

a. Assess the ability of all sites to perform CTBM studies including but not limited to:

1) Site management capabilities.
2) Organization and utilization of site staff.
3) Extent of site staff's clinical trial experience.
4) Communication among clinical, technical and administrative staff.
5) Adequacy of site facilities, pharmacy and study equipment including security measures in place to ensure patient confidentiality and standardization of methodologies.

b. Provide a thorough review 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. A thorough explanation of NIAID policies and procedures, good clinical research practices, as appropriate, will also be provided.

3. Conduct interim site monitoring visits to participating Study Group clinical sites to evaluate selected data elements, as designated by senior statistical staff with input from the study teams, to include verification of adherence to study requirements and procedures, for a subset of patients (usually a 10% sample and possibly a higher percentage when specified by the Project Officer). In conducting annual (or more often, as necessary) interim site monitoring visits, the Contractor shall:

a. Assess the operation and management of the Study Group clinical sites, including but not limited to:

1) Site management.
2) Organization and utilization of site staff.
3) Communication among clinical, technical and administrative staff.
4) Regulatory files.
5) Adequacy of site facilities, pharmacy and study equipment including security measures in place to ensure patient confidentiality and standardization of methodologies.

b. Assess site compliance with the requirements for the CTBM protocols being conducted, including but not limited to:

1) Compliance with the manual of operations.
2) Adherence to inclusion and exclusion criteria.
3) Reporting of SAEs.
4) Appropriate collection, storage and transport of patient samples.
5) Accuracy, timeliness and completeness of data collection and entry.
6) Documentation of study endpoints.
7) Clinical records maintenance.
8) Study product accountability.

[NOTE (14) TO THE OFFEROR: There are approximately forty (40) different clinical sites actively participating in the MSG and CSCLD studies. The number of new sites that may need initial site visits will depend upon the studies to be designed. Therefore, it is not possible to specify that number but for purposes of budget construction, the Offeror should assume that there will be ten (10) initial site visits per year.]

4. Provide more thorough monitoring of Study Group clinical sites that have significant deficiencies discovered until those deficiencies are corrected as determined by the Project Officer.

5. Submit reports on Study Group clinical site performance after each monitoring visit. Summaries of the findings for each site shall be provided to the Project Officer and the appropriate Study Group coordinator within two weeks of the site visit. In addition, if major concerns regarding site performance are noted, the monitor shall notify the Project Officer by telephone as soon as possible. The reports shall identify any site-specific operational issues or problems. In consultation with the Study Group and NIAID, the Contractor shall formulate actions to be taken to address them and track them until they are resolved.

6. Receive and participate in review of site monitoring reports prepared for studies where the industrial sponsor is conducting site monitoring. The Contractor shall also perform site visits to selected Study Group clinical sites when directed by the Project Officer.

F. Data Analyses and Reporting

1. Design and conduct interim and final statistical analyses of study data as directed by the Project Officer and in collaboration with Study Groups investigators, NIAID staff, and industry sponsors (if any) including but not be limited to:

   a. Conducting comprehensive statistical analyses, including relevant subgroup and exploratory analyses.

   b. Preparing interim analyses data on the safety, toxicity, and efficacy of interventions evaluated in studies for presentation to and review by the DSMBs, IMBs, and the NIAID that shall also include analyses of data on accrual, retention, loss to follow-up and other status indicators relevant to the conduct of the studies.

   c. Responding to requests for additional analyses from the Study Groups, DSMBs, IMBs, and NIAID.

2. Prepare study status and site-specific performance reports including, but not limited to, accrual and retention of study participants, timeliness of data submission, and adherence to protocol specifications at least quarterly for CTBM studies for review by the appropriate Study Group coordinator, the appropriate DSMB or IMB, and the NIAID with recommendations for improvements and modifications to resolve such study issues and problems.

3. Prepare reports based on the interim analyses data on the safety, toxicity, and efficacy of interventions evaluated in studies for presentation to and review by the DSMBs, IMBs, and the NIAID.

4. Participate in the preparation of scientific manuscripts and reports of the studies for publication in the peer-reviewed literature and presentation of the study results at relevant scientific meetings in collaboration with the protocol chairs, other Study Group investigators, NIAID staff, and others, as appropriate. (See Appendix I for guidelines.)

G. Responsibilities for Ongoing Studies from the MSG and CSCLD

Assume responsibility for the biostatistical support, data management, operations, site monitoring, and data analysis and reporting activities for ongoing studies being conducted by the NIAID Mycoses Study Group (MSG) and the Clinical Studies of Chronic Lyme Disease (CSCLD).

[NOTE (15) TO THE OFFEROR: At the initiation of the contract to support the BAMBU, it is anticipated that the following multicenter CTBM studies will be active:

MSG studies:

- **MSG #37: A Multicenter, Prospective, Randomized, Double-Blind Clinical Trial Comparing Oral Itraconazole (Cyclodextrin Solution) Versus Placebo in the Treatment of Aspergilloma**

- **MSG #43: Phase I Evaluation of the Safety and Pharmacodynamic Activity of a Murine-derived Anticryptococcal Antibody in Patients Who Have Recovered from AIDS-associated Cryptococcal Meningitis**

- **MSG #44: Invasive Fungal Infection in Liver Transplant Recipients: A Randomized Double-Blind Trial Comparing AmBisome and Fluconazole in the High-Risk Group and an Observational Cohort Study in the Low Risk Group**

- **MSG #46: A Phase III Randomized, Double-Blind Comparative Trial of FK 463 Versus Fluconazole for Prophylais of Fungal Infections in Patients Undergoing Hematopoietic Stem Cell Transplant**

CSCLD studies:

- **A Phase III randomized, double-blind, placebo-controlled, multicenter trial of the safety and efficacy of ceftriaxone and doxycycline in the treatment of seropositive chronic Lyme disease**

- **A Phase III randomized, double-blind, placebo-controlled, multicenter trial of the safety and efficacy of ceftriaxone and doxycycline in the treatment of seronegative chronic Lyme disease**

The table below provides information on the status of the MSG and CSCLD studies that are expected to be active at the initiation of this contract:

Study	Phase	No. of centers	Sample size	Biostatis-tical support	Data manage-ment	Operations support	DSMB reports	Site monitor-ing	Projected study end
MSG #37	II	12	96	√	√	√	√	X *	2002
MSG #43	I	6	30	√	√	√	NA	√	2002
MSG #44 High Risk	III	20	300	√	√	√	√	√	2003
MSG #44 Low Risk	Observa-tional	20	200	√	√	√	NA	√	2002
MSG #46	III	30	800	√	X	+/-	√	X	2003
CSCLD seropos.	III	3	194	√	√	√	√	√	2005
CSCLD seroneg.	II	3	66	√	√	√	√	√	2005

√ BAMBU responsibility
X Not BAMBU responsibility
+/- Shared with industrial sponsor
*** BAMBU will receive and evaluate site-monitoring reports provided by the industrial sponsor.]**

H. Contract Transition

1. Prepare for an orderly transition to a subsequent Contractor by developing and submitting to the Project Officer at least 120 days prior to Contract expiration a written transition plan outlining the secure and orderly transfer of this project to a designated Contractor, if other than the incumbent that includes but is not limited to provision for transferring files, computer programs, and all written documentation for any studies and for general BAMBU operating procedures. The Contractor shall carry out the plan as approved by the Project Officer by providing detailed instructions for employees of the new Contractor on the operation of the data management system as well as on particular study records and data sets.

2. Upon completion of this contract all data (including all source codes) collected and/or analyzed under this contract shall be delivered to the Government and/or subsequent contractors, if any.

GUIDELINES FOR MANUSCRIPT WRITING

1. For publication of the primary results from each official study, a writing committee will be appointed. This committee will typically consist of:

   a. The study protocol chair;
   b. The study biostatistician; and,
   c. Other appropriate individuals may include study investigators, BAMBU, BAMSG or CSCLD Coordinating Unit and NIAID staff, and others who have contributed substantially to the study as determined by the study protocol chair.

2. The chair of the writing committee will be the study protocol chair.

3. For joint studies with the AIDS Clinical Trials Group (ACTG) or other collaborative groups, the writing committee will be merged with a similarly constituted writing committee from the appropriate collaborative group.

4. The writing committee will prepare drafts of a manuscript. Before submission of the final draft to a peer-reviewed journal, the draft will be circulated to all participating investigators, BAMBU, the BAMSG or CSCLD Principal Investigator (as appropriate) and representatives of industry (where appropriate) for comments and suggestions, and to the NIAID for approval by the BAMBU and BAMSG or CSCLD (as appropriate) Project Officers.

5. If additional manuscripts result from a BAMSG or CSCLD study, additional writing committees can be constituted. The same general guidelines will apply.

6. Authorship and its order for a given manuscript should reflect workload, intellectual contribution, and patient contribution. The composition of authorship will differ depending on the number of institutions involved, the number of patients, and the nature of any special assessments, such as laboratory studies. The first author of the manuscript will usually be the study protocol chair. The ultimate order of names on the masthead will be determined by the study protocol chair. If there is any appeal about the order of authors, the final decision will be made by the BAMSG or CSCLD Principal Investigator, as appropriate.

7. The NIAID contract numbers for BAMBU and BAMSG or CSCLD, as appropriate, must be acknowledged. Manuscripts should also acknowledge all participating institutions (sites) enrolling evaluable patients, industry sponsors (if any), and other collaborating groups (if any). The listing of institutions should be in order of evaluable patients.

8. The selection of the journal will be at the discretion of the study protocol chair.

9. Copies of the final draft submitted for publication should be sent to each of the authors, the BAMSG or CSCLD Coordinating Unit, as appropriate, industry sponsors (if any), collaborating groups (if any), and the BAMBU and BAMSG or CSCLD (as appropriate) Project Officers.

10. After journal review of a manuscript has been completed, the dialogue between editors, reviewers, and the writing committee should be handled at the writing committee level. Correspondence from the editors, including the reviews, should be distributed to each of the authors listed in the masthead, BAMBU, the BAMSG or CSCLD Coordinating Unit (as appropriate), industry sponsors (if any), collaborating groups (if any), and the BAMBU and BAMSG or CSCLD (as appropriate) Project Officers.

11. A copy of the final revised manuscript should be sent to each of the authors, BAMBU, the BAMSG or CSCLD Coordinating Unit (as appropriate), industry sponsors (if any), collaborating groups (if any), and the BAMBU and BAMSG or CSCLD (as appropriate) Project Officers.

GUIDELINES FOR ABSTRACTS

1. These guidelines (listed above) would apply, where appropriate, to abstracts.

2. No abstract shall be submitted nor presentation made regarding primary results from any study without the approval of the study protocol chair, the BAMSG or CSCLD Principal Investigator (as appropriate), study biostatistician from BAMBU, and the BAMBU and BAMSG or CSCLD (as appropriate) Project Officers.

3. A copy of all abstracts, based on BAMSG or CSCLD studies, must be submitted to BAMBU, the BAMSG or CSCLD Coordinating Unit (as appropriate), industry sponsors (if any), collaborating groups (if any), and the BAMBU and BAMSG or CSCLD (as appropriate) Project Officers simultaneously with submission for presentation.

REPORTING REQUIREMENTS AND DELIVERABLES

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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 and prepared in accordance with the format specified below.

A. Accrual And Site Registration Report

At specified time points to be determined by the Study Groups and approved by the Project Officer, the Contractor shall submit a report for each open clinical protocol sponsored by the Study Group summarizing:

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. 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.

Three copies of the Accrual and Site Registration Reports shall be provided to the NIAID Project Officer; additionally, one copy of the report on CTBM-sponsored open clinical protocols shall be provided to the Principal Investigator of the BAMSG or CSCLD Study Group, as appropriate.

B. Quarterly Technical Progress Report

The Contractor shall submit a report summarizing the activities undertaken during the reporting period, as follows:

1. Status of Protocol Development

a. Pending protocols for proposed clinical trials, including: lead investigator(s); stage of development; step within the NIAID and the Study Groups review process; actions required for final approval, modification or disapproval, including unresolved issues, questions or problems; and, time frame for completion of review, approval, modification or disapproval.

b. A summary of issues or problems encountered with respect to the NIAID and/or the Study Groups review and decision-making process, including recommendations for modifications and improvements to enhance the timeliness, efficiency or thoroughness of the review processes.

2. Statistical Reports

The Contractor shall submit separate reports summarizing the status of proposed, interim, and final analyses of the results of clinical trials sponsored by the Study Groups. This shall include:

a. Title, author(s), brief description, status of review/approval of proposed analyses, including any pending issues, problems or modifications.
b. Title, author(s), brief description and status of approved analyses, including any pending issues, problems or modifications.
c. Recommendations for additional interim and final analyses for clinical trials.

3. Study Report

Quarterly and at the completion of each study, the Contractor shall submit a summation of the work performed and the results obtained. 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, a summary of all relevant descriptive information for all clinical sites combined, as well as for each site individually (e.g., accrual data, attrition, number of forms received, number of data edits, clinical site monitoring reports, adverse events, and safety information).

Each quarterly report shall be due on or before 30 days following the end of each 3-month period beginning with the start of the contract. Three (3) copies of all reports shall be provided to the NIAID Project Officer and one (1) copy to the Contracting Officer.

C. Annual Technical Progress Report

On an annual basis, the Contractor shall submit a report summarizing the results of the entire contract work for the period covered, with separate reports prepared for each Study Group for the components as specified below. These Annual Reports shall be in sufficient detail to explain comprehensively the status of these activities and results achieved, if applicable. Annual Reports shall be submitted thirty (30) days after the anniversary date. Three (3) copies of these reports shall be provided to the Project Officer and one (1) copy to the Contracting Officer.

1. Statistical Design Considerations

a. The advantages and disadvantages of the various approaches to the statistical design of ongoing and completed Study Groups clinical trials for the assessment of the safety, toxicity and efficacy of treatments under study, including: control and comparison groups, inclusion and exclusion criteria, sample size; research questions addressed; clinical endpoints, number and type of patient samples, etc.

b. Recommendations for improved statistical approaches and methods to improve criteria for evaluating the diseases being studied.

2. *Standard Operating Procedures*, including:

   a. Development, review and implementation of approved protocols, including criteria for evaluation and prioritization.
   b. Clinical site monitoring and training with respect to adherence to protocol requirements, data collection and quality assurance, and 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 study sites and procedures for addressing performance problems.

3. *Clinical Site Monitoring And Training*, including:

   a. Clinical site training activities conducted, including written materials on Study Groups standard operating procedures and protocol-specific requirements;
   b. Issues and problems encountered in the training and monitoring of Study Groups 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.

4. *Regulatory Functions and Requirements*, including:

   a. Compilation of information for IND annual reports in response to DMID regulatory requests.
   b. Issues and problems in the coordination and assembly of IND documents when DMID is the IND holder.
   c. Recommendations for improvements/modifications in BAMBU and Study Groups regulatory procedures.
   d. Provide final study reports for submission to the FDA.

5. *Monitoring Progress And Evaluating Performance*, including:

   a. Assessment of policies and procedures used by the Study Groups.
   b. Recommendations for improvements.

D. Final Report And Deliverables

At the completion of the contract, the Contractor shall deliver to the Contracting Officer a cleaned, edited, documented public use data set containing all study data, 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 contract, 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, other records, and source codes related to data collection, entry, editing, analysis and transfer.

E. Other Deliverables

Provide the Project Officer and/or clinical investigators with information or reports as requested regarding any project. Such information may include, but not be limited to, current enrollment figures, breakdowns of participants by race and gender, and projected completion dates. These include:

a. Presentation of all reports, analyses and recommendations to the Study Groups Steering Committees and assistance in implementing necessary modifications approved by these governing bodies, including revised clinical protocols. These will include periodic reports on performance of clinical sites, central laboratories, and other units, if any.

b. Preparation of materials such as tables, text, graphs, and diagrams as needed in collaboration with investigators and NIAID staff for presentation at study meetings or professional meetings and other special reports concerning study findings.

c. Preparation of reports with custom formats and selection groups summarizing data for monitoring study progress or product safety or for use by the separate site monitoring Contractor.

d. Preparation of abstracts/protocol summaries for NIH clinical trials database and other databases specified by the Project Officer.

Deliverable	No. of Copies	Addressee/Distribution	Due Dates
Quarterly Report	3 1	Project Officer, BMB, DMID Contracting Officer, RR, CMB	Within 30 calendar days after each 3 month period from the time of contract award
Annual Report	3 1	Project Officer, BMB, DMID Contracting Officer, RR, CMB	Within 30 calendar days after anniversary date of contract award

TECHNICAL EVALUATION FACTORS FOR AWARD

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1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against two factors. The factors in order of importance are: technical and cost/price. Although technical factors are of paramount consideration in the award of the contract, cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price.

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

2. TECHNICAL EVALUATION CRITERIA

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

CRITERIA	WEIGHT
1. TECHNICAL APPROACH	**60 points**

Soundness and practicality of the technical approach for each of the requirements specified in the Statement of Work, with adequate explanation, substantiation, and justification for the recommended methods for handling the projected needs of the Study Groups. Also, demonstration of the Offeror's understanding of the scope and purpose of this work, including discussion of potential difficulties which may arise in the performance of this work. This evaluation will assess:

- Technical approach for establishing and operating a reliable, well-monitored, efficient and responsive study and data management system including the design and development of a reliable computer-based system for data management; implementation of procedures to handle data typically from multicenter clinical studies; and, interfacing with NIAID and study sites.

- Technical approach for providing statistical leadership for the design, implementation, monitoring, modification, and analysis of clinical trials conducted by the CTBM Study Groups.

- Technical approach for designing and implementing clinical site monitoring and training requirements.

- Technical approach for the understanding of the scope and objectives of the contract, recognition of potential difficulties that may arise in performing the work required, and understanding of the close coordination necessary between the NIAID, the Executive and Steering Committees, the clinical sites and other study personnel, Data and Safety Monitoring Boards, Internal Monitoring Boards, and Advisory Panels.

- Adequacy of the administrative and organizational framework, with lines of authority and responsibility clearly demonstrated, and adequacy of the work plan, with proposed time schedule for achieving contract objectives and maintaining quality control over the implementation and operation of the project.

2. PERSONNEL **25 points**

All Staff:

- Demonstrated expertise, appropriate training, experience, and availability of the statistical, clinical, regulatory, technical, and administrative staff, as well as subcontractors, required to plan and implement the requirements of this project as described in the Statement of Work.

- Documented credentials, training, expertise, experience, leadership/management skills and availability of the Project Director and the surrounding leadership of the BAMBU to successfully plan and manage the project.

- It is highly desirable that the advice and leadership be provided by senior, Ph.D. level staff with documented biostatistical and clinical trials expertise.

- Evidence of interactive collaboration with clinicians in the design, conduct, and analysis of clinical research studies is also highly desirable.

Professional Staff:

- Documented composite expertise in biostatistics, multicenter clinical trials, computer systems design and proficiency in statistical software, and data management.

- Regulatory Specialist with an R.N. degree and sufficient clinical experience to perform the required duties.

Administrative Staff:

- Demonstrated experience in management of research budgets and subcontract administration.

3. FACILITIES AND RESOURCES **15 points**

Documented availability and adequacy of facilities, equipment and resources necessary to carry out all phases of this project.

TOTAL 100 points

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

SECTION I. GENERAL CLAUSES

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

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

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

FAR CLAUSE	DATE	TITLE
52.202-1	Oct 1995	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures(Over $100,000)
52.203-8	Jan 1997	Cancellation, Recission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Jun 1996	Printing/Copying Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data – Modifications

52.216-7	Mar 2000	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	Oct 1999	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Oct 1999	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Feb 1999	Equal Opportunity
52.222-35	Apr 1998	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Jan 1999	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era
52.223-6	Jan 1997	Drug-Free Workplace
52.223-14	Oct 1996	Toxic Chemical Release Reporting
52.225-1	Feb 2000	Buy American Act - Balance of Payments Program – Supplies
52.225-13	Feb 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data – General
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Jun 1997	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	Dec 1998	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	Oct 1995	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)

52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

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

HHSAR CLAUSE	DATE	TITLE
352.202-1	Apr 1984	Definitions
352.232-9	Apr 1984	Withholding of Contract Payments
352.270-4	Apr 1984	Pricing of Adjustments
352.270-6	Jul 1991	Publication and Publicity
352.270-7	Apr 1984	Paperwork Reduction Act

[End of GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT - Rev. 3/2000].

SECTON J
LIST OF ATTACHMENTS

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

- Packaging and Delivery of Proposals
- Proposal Intent Response Sheet ***Submit on/before June 28, 2000:***

  Your attention is directed to the "proposal intent response sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMB's coordination of the electronic submission and review of proposals.

- How to Prepare and Submit an Electronic Proposal

The RFP Forms/Attachments listed below are available in a variety of formats and may be viewed or downloaded directly from this site. http://www.niaid.nih.gov/contract/ref.htm

Applicable to Technical Proposal

- **Technical Proposal Cost Information**
- **Summary of Current and Proposed Activities**
- **Government Notice for Handling Proposals**

Applicable to Business Proposal

- **Disclosure of Lobbying Activities, OMB Form SF-LLL**
- **NIH-2043, Proposal Summary and Data Record**
- **Contact Points**
- **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours (includes an Excel cost spreadsheet template)**

To become Contract Attachments

- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **Procurement of Certain Equipment, NIH(RC)-7 (OMB Bulletin 81-16)**

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

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ELECTRONIC SUBMISSION INSTRUCTIONS

PAGE LIMITS -- THE NARRATIVE PORTION OF THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 100 PAGES. APPENDICES, ATTACHMENTS, OPERATING MANUALS, NON-SCANNABLE FIGURES OR DATA, LETTERS OF INENT, ETC. SHALL NOT EXCEED 200 PAGES.

Pages in excess of the above limitations will be removed from the proposal and will not be read or evaluated. 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, 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.

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 the date provided on the face page of the RFP.**.

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.
- Limit Appendices and Attachments to relevant technical proposal information (e.g. SOPs, pertinent manuals, non-scannable figures or data, resumes, letter of commitment/intent).

PROPOSAL INTENT RESPONSE SHEET

[Return to Table of Contents] or [Return to List of Attachments]

RFP No.: NIH-NIAID-DMID- 01-10
RFP Title: Bacteriology and Mycology Biostatistical and Operations Unit (BAMBU)

Please review the attached Request for Proposals. Furnish the information requested below and return this page by June 28, 2000 . Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

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

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

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

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

RETURN VIA FAX OR E-MAIL TO:
CMB, NIAID, NIH
Room 2230
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Dawn Caracci
RFP-NIH-NIAID- DMID- 01-10
FAX# (301) 402-0972
Email : dk28a@nih.gov

PACKAGING AND DELIVERY OF THE PROPOSAL

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[Note to Offeror: 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 NO. NIH-NIAID-DMID- 01-10
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. NUMBER OF COPIES:

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

Technical Proposal: One (1) unbound signed original and 5 unbound copies, with 10 copies of items excluded from electronic submission requirement that you choose to provide in paper format (SOPs, PERTINENT MANUALS, NONSCANNABLE FIGURES OR DATA, AND LETTERS OF COLLABORATION/INTENT.)

Business Proposal: One (1) unbound signed original and 5 unbound copies.

C. PAPER COPIES TO:

If hand delivery or express service	*If using U.S. Postal Service*
Dawn Caracci Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Dawn Caracci Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, Maryland 20892-7612

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

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

SECTION K

REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

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

1. REPRESENTATIONS AND CERTIFICATIONS

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

http://www4.od.nih.gov/ocm/contracts/rfps/REPCERT.htm

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

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L
INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

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1. GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Clause 52.215-1 (February 2000)]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(*3*) It is the only proposal received.

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

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

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

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

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

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

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

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

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

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

(e) Restriction on disclosure and use of data. Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall--

(1) Mark the title page with the following legend:

This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed--in whole or in part--for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of--or in connection with--the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [*insert numbers or other identification of sheets*]; and

(2) Mark each sheet of data it wishes to restrict with the following legend:

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

(f) Contract award.

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

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

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

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

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

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

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

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

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

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

(11) The Government may disclose the following information in postaward debriefings to other offerors:

(i) The overall evaluated cost or price and technical rating of the successful offeror;
(ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iii) A summary of the rationale for award; and
(iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

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

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

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

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

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

c. **SIC CODE AND SIZE STANDARD**

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

(1) The standard industrial classification (SIC) code for this acquisition is 7379.
(2) The small business size standard is $18 million.

d. **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

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

It is anticipated that the award from this solicitation will be a multiple-year cost reimbursement, completion type, contract with a term of five (5) years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the total five -year effort to be approximately 28,808 total labor hours. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

f. **COMMITMENT OF PUBLIC FUNDS**

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

g. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

h. **RELEASE OF INFORMATION**

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

i. **COMPARATIVE IMPORTANCE OF PROPOSALS**

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

j. **PREPARATION COSTS**

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

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

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

Brenda J. Velez
Chief, Contract Management Branch
National Institutes of Allergies and Infectious Diseases
6700 B Rockledge Dr., Room 2230 MSC 7612
BETHESDA MD 20892-7612

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

(End of Provision)

l. **LATE PROPOSALS, MODIFICATIONS OF PROPOSAL, AND WITHDRAWALS OF PROPOSALS**, PHS 352.215-10

Notwithstanding the procedures contained in the provision of this solicitation entitled Late Submissions, Modifications, and Withdrawals of Proposals, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government, and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

2. INSTRUCTIONS TO OFFERORS

a. **GENERAL INSTRUCTIONS**

INTRODUCTION

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

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

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

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

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

I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

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

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

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

(5) **Alternate Proposals**

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

(6) **Confidentiality of Proposals --HHSAR 352.215-12, Restriction on Disclosure and Use of Data (April 1984)**

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

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

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

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

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act.

The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification)

In addition, the offeror should mark each page of data it wishes to restrict with the following legend:

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

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

(7) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in the Technical Evaluation Factors for Award.

(8) **Potential Award Without Discussions**

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

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

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

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

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

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

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

(10) **Privacy Act**

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

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

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

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

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

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

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

- to the cognizant audit agency and the General Accounting Office for auditing.

- to the Department of Justice as required for litigation.

- to respond to congressional inquiries.

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

(11) **Selection of Offerors**

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

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

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

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

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

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

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

While it is NCI's policy to conduct discussions with all offerors in the competitive range, NCI reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct limited negotiations after Final Proposal Revisions (FPRs) in accordance with HHSAR 315.670.

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

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

(12) **HUBZone Small Business Concerns**

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

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

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

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

(14) **Salary Rate Limitation in Fiscal Year 2000**

Offerors are advised that pursuant to P.L. 106-113, no NIH Fiscal Year 2000 (October 1, 1999 - September 30, 2000) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level II* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses). This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level II*. The salary rate limitation set by P.L. 106-113 applies only to Fiscal Year 2000 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level II* annual salary rate limit also applies to individuals proposed under subcontracts. P.L. 106-113 states in pertinent part:

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

***This rate may change periodically. For your information, the rate can be found at: http://www.opm.gov/oca/2000tbls/Execses/html/execschd.htm**

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

EACH INSTITUTION MUST:

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

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

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

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

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

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

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

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

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

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

4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

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

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

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

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

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

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

b. TECHNICAL PROPOSAL INSTRUCTIONS

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

(1) **Technical Discussions**

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

a) **Statement of Work**

(1) Objectives

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

(2) Approach

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

(3) Methods

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

(4) Schedule

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

b) **Personnel**

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

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

(1) Principal Investigator/Project Director

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

(2) Other Investigators

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

(3) Additional Personnel

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

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

(4) Resumes

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

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the TECHNICAL EVALUATION FACTORS FOR AWARD.

(3) **Additional Technical Proposal Information**

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

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

(4) **Other Considerations**

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

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

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

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

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

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

c. BUSINESS PROPOSAL INSTRUCTIONS

(1) **Basic Cost/Price Information**

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

(2) **Proposal Cover Sheet**

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

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

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

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

1. **Direct Labor**

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

2. **Materials**

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

3. **Subcontracted Items**

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $500,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.806.

4. **Raw Materials**

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

5. **Purchased Parts**

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

6. **Fringe Benefits**

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

7. **Indirect Costs**

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

8. **Special Equipment**

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

9. **Travel**

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

10. **Other Costs**

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

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at: http://amb.nci.nih.gov/cpi.htm

(3) **Qualifications of the Offeror**

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

(1) **General Experience**

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

(2) **Organizational Experience Related to the RFP**

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

(3) **Performance History**

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

(4) **Pertinent Contracts**

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

(5) **Pertinent Grants**

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

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and while not an evaluation factor they are considered in the source selection process.

(4) **Other Administrative Data**

a) **Property**

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

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

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

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

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

b) **Royalties**

The offeror shall furnish information concerning royalties which are anticipated to be paid in connection with performance of work under the proposed contract.

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

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

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

d) **Financial Capacity**

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

e) **Incremental Funding**

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

> Sufficient funds are not presently available to cover the total cost of the complete multiple year project described in this solicitation. However, it is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled "Limitation of Funds." Under that clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover an initial period of performance. Additional funds are intended to be allotted from time to time, to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

The "Limitation of Funds" clause to be included in the resultant contract shall supersede the "Limitation of Cost" clause found in the General Clauses.

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

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

(a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

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

(End of Provision)

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

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

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

(5) **Subcontractors**

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

a) Willingness to perform as a subcontractor for specific duties (list duties).

b) What priority the work will be given and how it will relate to other work.

c) The amount of time and facilities available to this project.

d) Information on their cognizant field audit offices.

e) How rights to publications and patents are to be handled.

f) A complete cost proposal in the same format as the offeror's cost proposal.

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

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

(7) **Representations and Certifications**

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

(8) Travel Costs/Travel Policy

a) **Travel Costs - Commercial**

In accordance with Title II, section 201 of the Federal Civilian Employee and Contractor Travel Expense Act of 1985 (Public Law 99-234), costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b) **Travel Policy**

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