OMB No. 0990-0115

Electronic Request for Proposal
SOLICITATION COVER PAGE

OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE CMB WEBSITE http://www.niaid.nih.gov/contract/default.htm FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.

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 [X] No ***8(a) Set-Aside*** [ ] Yes [X] No ***SIC Code:*** 8731 ***Size Standard:*** 500 employees	***Level of Effort:*** [ ] Yes [X] No ***Total Effort:*** N/A
NIH-NIAID-DMID-01-11	[ ] Yes [X] No		

TITLE: "The Bacteriology and Mycology Study Group (BAMSG)"

Issue Date: April 28, 2000	***Due Date/Time:*** ***July 28, 2000; 4:00 p.m., EST***	***Technical Proposal Page Limits:*** [X] Yes [ ] No

ISSUED BY:

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

[X] ***We reserve the right to make awards without discussion.***

NO. OF AWARDS:

[X] Only 1 Award
[ ] Multiple Awards

PERIOD OF PERFORMANCE:

5 Years beginning on or about March 15, 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 -- Brenda Brooks ***[COLLECT CALLS WILL NOT BE ACCEPTED.]***

Telephone **(301) 435-2765**	***Fax*** **(301) 480-5253**	***E-Mail*** bb76n@nih.gov

TABLE OF CONTENTS

INTRODUCTION/BACKGROUND/STATEMENT OF WORK

[Return to Table of Contents]

I. INTRODUCTION

This contract applies to one component of a multiple procurement to provide support for clinical studies of interventions for serious fungal and healthcare-associated resistant bacterial infections (Bacteriology and Mycology Studies Group or BAMSG), and chronic Lyme disease (Clinical Studies of Chronic Lyme Disease or CSCLD, New England Medical Center, contract no. N01-AI-65308). The Bacteriology and Mycology Biostatistical and Operations Unit (BAMBU) will provide statistical leadership, data management and analysis, site monitoring, and operations support for these components. These activities are administered through the Bacteriology and Mycology Branch, Division of Microbiology and Infectious Diseases (DMID), National Institute of Allergy and Infectious Diseases (NIAID). This solicitation is for the BAMSG which will be co-funded by the DMID and the Division of AIDS (DAIDS). BAMSG is being created to conduct ongoing and new clinical studies of interventions for addressing serious fungal and healthcare-associated resistant bacterial infections. The Requests for Proposals (RFP) for BAMBU and BAMSG are being released simultaneously. Offerors responding to the RFP for BAMSG should refer to the RFP for the BAMBU (RFP NIH-NIAID-DMID-01-10).

The objective of this Request for Proposal (RFP) is to solicit proposals to establish a clinical studies collaborative group with the expertise to construct and conduct clinical studies addressing the key management problems involving serious fungal and healthcare-associated resistant bacterial diseases occurring in appropriate at-risk populations. The group will have a Coordinating Unit and will collaborate closely with the BAMBU. It is expected that the BAMSG will:

1. Formulate a scientific agenda directed at the clinical studies of interventions for serious fungal and healthcare-associated resistant bacterial infections, prioritized according to public health need and scientific opportunities, for approval by NIAID;
2. For most studies, secure industrial support for clinical site, data management, and site monitoring costs;
3. Conduct innovative studies not having an industrial sponsor as the primary source of support;
4. Provide administrative support for the development of concepts, implementation, and completion of clinical studies;
5. Establish a multi-site clinical studies group for evaluating interventions for serious fungal and healthcare-associated bacterial infections.
6. Assess and report progress and results of all studies; and
7. Facilitate development and advancement of new clinical investigators for the evaluation of interventions for serious fungal and healthcare-associated resistant bacterial infections.

II. BACKGROUND

Research on serious fungal and healthcare-associated resistant bacterial infections is a high priority of the NIAID. Through the BAMSG and BAMBU, NIAID will continue to support research on interventions for serious fungal infections and will initiate clinical studies of interventions for healthcare-associated resistant bacterial infections.

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 to maximize their efficacy in order 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.

Many factors are believed to contribute to the emergence of drug-resistance among nosocomial pathogens. They include: the over-use of broad-spectrum agents, both inside and outside intensive care units (ICU); the increased numbers of susceptible, immunocompromised patients; technologic progress (increased use of implants, indwelling catheters and intravenous lines) that result in increased exposure to resistant microorganisms; and the breakdown of hygiene and infection and disease control programs. Resistant bacteria have become endemic in many healthcare settings, particularly in ICUs.

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 due to “highly active anti-retroviral therapy” (HAART), these infections remain an important cause of morbidity and mortality. The frequency of opportunistic infections in AIDS patients can be expected to rebound as more patients fail HAART for controlling their HIV infection. Initial treatment for immunocompromised hosts is frequently unsuccessful or results in relapses when treatment is discontinued. Current treatment of some life-threatening fungal infections requires prolonged administration of relatively toxic agents.

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 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.

The BAMSG will be established to evaluate interventions for preventing, rapidly diagnosing, and treating serious fungal and resistant bacterial infections occurring in the risk groups identified in item 1 of the work statement below. The BAMBU will serve as the biostatistical, data management, and operations unit for the studies conducted by the BAMSG.

III. STATEMENT OF WORK

The Contractor shall, independently and not as an agent of the government, furnish all services, qualified personnel, materials, equipment and facilities not otherwise provided by the government under the terms of this contract, as needed to establish a clinical trials collaborative group, hereafter called the Bacteriology and Mycology Study Group (BAMSG), for the evaluation of interventions for serious fungal and healthcare-associated resistant bacterial infections. Specifically, the Contractor shall:

1. Identify key unanswered questions relating to interventions for serious fungal and healthcare-associated resistant bacterial infections and establish priorities based on public health need and scientific opportunities and advances.

    a. Within 60 days after the award, the contractor shall submit a prioritized scientific research agenda that 1) discusses the public health needs and opportunities and 2) proposes strategic plans and scientific rationale for studies to address these needs and opportunities for improving interventions for these infections occurring in the following patient risk groups:

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

    Immunocompromised patients including those receiving chemotherapy as anticancer treatment or immunosuppression for cellular and/or solid organ transplantation are also at risk for healthcare-associated resistant bacterial infections. Studies that address serious fungal and healthcare-associated resistant bacterial infections simultaneously in this risk group would be appropriate for inclusion in this agenda.

    The agenda shall be submitted for review by an NIAID-appointed independent Advisory Panel and subsequently for NIAID approval. The agenda shall emphasize innovative interventions and shall establish priorities among the studies, both across and within the four risk groups. The agenda shall provide for flexibility in redirecting resources to meet changing needs and priorities. The agenda shall be updated annually thereafter and submitted for review by the Advisory Panel and subsequently for NIAID approval. The Contractor shall travel to Bethesda, Maryland each year to discuss the agenda and the status of ongoing and proposed work with the Advisory Panel and NIAID staff. Public health needs and scientific opportunities may arise which will require revision of the research agenda before the annual submission. These revisions must be submitted for review by the Advisory Panel and approval by the NIAID.

    [Note (A) to Offeror: The offeror must submit with this proposal a draft research agenda including prioritized studies for each risk group. The draft research agenda at a minimum must include: identification of public health needs, the potential studies that would address these needs, a brief description of the study design, and primary outcome measures.

Substudies to evaluate pathogenesis of fungal infections, protective immune mechanisms, and new diagnostics and biomarkers for use in clinical trials of antifungal interventions are encouraged. Also encouraged are substudies to evaluate the impact of interventions, including behavioral interventions, on days of work/life lost, cost of infection/treatment, relapse, and other health outcomes of healthcare-associated resistant bacterial infections.]

[NOTE (B) TO OFFEROR: The Offeror must submit with this proposal three well-developed concepts for clinical studies evaluating interventions for fungal infections (one for each of the first three risk groups identified in item 1 above) and one evaluating interventions for resistant bacterial infections in the fourth group of patients. A study addressing both fungal and resistant bacterial infections simultaneously in the first risk group would be acceptable. The concepts for each study should be abbreviated descriptions of the proposed studies (not fully developed protocols) and should be approximately three to five pages in length. A suggested outline is provided as Attachment A.1. The concepts must neither be underway nor have been sponsored or reviewed previously by the NIAID. The concepts must include a plan to comply with the DHHS regulations and NIH guidelines on the inclusion of both genders, minorities and children and that the disease incidence in these populations is adequately considered. It is important for the Offeror to understand that award of a contract does not commit the Government to approve the proposed concepts or the research agenda outlined in the proposal. The Project Officer must approve all concepts before they are developed and implemented as BAMSG studies.]

[NOTE (C) TO OFFEROR: It is anticipated that a representative Phase II study would require 50 to 100 patients and a representative Phase III study would require 200 to 1,000 patients. For cost estimation, assume that approximately 12 trials may be initiated over the life of the contract, with approximately two thirds of them being Phase III trials. The research effort devoted to each of the four risk groups should be approximately equal; however, studies evaluating interventions for serious fungal infections in the first risk group in item 1 above may also evaluate interventions for healthcare-associated resistant bacterial infections.]

b. The Contractor shall submit within 60 days of the award of this contract a detailed plan describing how collaborations with industry, small business, other NIH grantees and contractors, and other governmental agencies will be pursued to support conduct of future clinical studies for serious fungal and, in particular, healthcare-associated resistant bacterial infections for review and approval by the Project Officer. This plan shall outline how collaborations with industrial sponsors willing to negotiate Cooperative Research and Development Agreements (CRADA), small business innovative research and technology transfer grantees, and other NIH grantees and contractors will be developed. The plan shall also address the prioritized research agenda indicating how implementation of the submitted concepts will be funded.

[NOTE (D) TO OFFEROR: The Offeror must submit with this proposal a draft of the plan for establishment of industry collaborations. This draft plan must also address provision for funding for implementation of the submitted concepts for both antibacterial and antifungal studies.]

c. All subsequently submitted concepts must have a plan describing how implementation will be funded.

2. Develop a plan for utilizing a reserve fund to conduct "Orphan Studies" for which an industry sponsor is not the primary source of such support. These funds shall be used ONLY for clinical site and laboratory costs and, when necessary, data management and site monitoring costs incurred by the Bacteriology and Mycology Biostatistical and Operations Unit (BAMBU) associated with conducting the special studies supported with the reserve funds. The Contractor shall propose uses of the reserve funds that address the changing needs and priorities of the research agenda. Expenditure of these funds will be made with the written approval of the Project Officer and with the advice of the independent Advisory Panel.

[NOTE (E) TO OFFEROR: The NIAID anticipates that any resulting award from this solicitation will include an Advance Understanding to reserve funds solely for the purpose of conducting Orphan Studies. These funds shall be used ONLY for clinical site and laboratory costs and, when necessary, data management and site monitoring costs incurred by the BAMBU contract. The Government may accumulate and supplement the reserve fund when needed or when additional funds become available. Supplemental funding for these studies from industry and/or other sources will be encouraged.

It is anticipated that Year 1 Orphan Studies funds will be $ 1,238,842 with approximately 50% reserved for studies of interventions for healthcare-associated resistant bacterial infections and approximately 50% reserved for antifungal studies. Two of the concepts submitted with the Offeror's proposal must be for studies that would require significant support from the reserve fund: one of these must address serious fungal infections and the other must address healthcare-associated resistant bacterial infections in an intensive care setting. It is anticipated that the Advance Understanding will read substantially as follows:

ARTICLE XX. ADVANCE UNDERSTANDINGS

Other provisions of this contract notwithstanding, the Government and the Contractor agree to the following items within the limits set forth:

a. Orphan Studies

This contract provides $1,238,842 in Year 1, which is reserved solely for the purpose of conducting Orphan Studies. Orphan Studies are defined as those clinical studies where an industry sponsor is not the primary source of support. These funds shall be used ONLY for clinical site and laboratory costs and, when necessary, data management and site monitoring costs incurred by the BAMBU contract. Expenditure of these funds will be authorized in writing by the Project Officer. It is estimated that additional funds will be reserved solely for Orphan Studies as follows:

Year 2	***$1,276,007***
Year 3	***$1,314,287***
Year 4	***$1,353,716***
Year 5	***$1,394,327***

Orphan Studies expenditures shall be separately recorded and reported to NIAID in

monthly invoices and/or quarterly financial reports.]

3. Establish a multicenter clinical studies group for evaluating interventions for serious fungal and healthcare-associated resistant bacterial infections consisting of a BAMSG Coordinating Unit, four BAMSG Research Subcommittees, the BAMSG Steering Committee and the network of BAMSG clinical sites and investigators. The Contractor shall conduct these activities and studies in collaboration with the Bacteriology and Mycology Biostatistical Unit (BAMBU), an independent entity to support multicenter clinical studies sponsored by the NIAID. The BAMBU will provide biostatistical leadership, data management, operational support, clinical site monitoring, and data analysis and reporting for these studies.

   a. The BAMSG Principal Investigator (PI) shall establish the BAMSG Coordinating Unit that will include a Co-PI, Coordinator, and other appropriate staff to support group functions and facilitate interactions among the components of the study group, BAMBU, industry sponsors, other collaborating groups, and NIAID. The responsibilities of the BAMSG Coordinating Unit are described in items 4 through 11 below.

   b. The Contractor shall establish and support the functions of the BAMSG Research Subcommittees (one addressing each of the four risk groups) that will be responsible for developing the research agenda and overseeing implementation of studies evaluating interventions for their respective risk group. Each Subcommittee shall consist of appropriate BAMSG investigators and each chair shall serve on the BAMSG Steering Committee. The BAMSG Co-PI will also serve as chairperson for the Research Subcommittee addressing interventions for patients with or at risk for serious healthcare-associated resistant bacterial infections.

   c. The Contractor shall organize and support the functions and conference calls of the BAMSG Steering Committee to develop and guide implementation of the overall group agenda and work to be accomplished under this contract, review progress, assess priorities, resolve problems, and redirect resources, as appropriate. The BAMSG Steering Committee shall include the BAMSG PI and Co-PI, the PI (or designate) of BAMBU, the BAMSG Research Subcommittee chairs, an investigator representing the BAMSG clinical investigators, representatives from other major collaborating groups (for example, from the transplantation and oncology communities) as appropriate, and NIAID staff. The BAMSG Steering Committee shall be responsible for reviewing and approving the study group research agenda for subsequent review by the independent Advisory Panel and approval by the NIAID, and all study concepts and protocols, including an assessment of the feasibility of each study. Rotation of membership representing the Research Subcommittees and the clinical site investigators will be required at least once during the contract period to provide for professional development of junior investigators.

   d. The Contractor shall identify and enlist services of sufficient participating medical institutions to serve as BAMSG-member clinical sites to perform evaluations of interventions for fungal and healthcare-associated resistant bacterial infections. These sites shall have recognized scientific, clinical and administrative expertise in the performance of multicenter clinical trials. The overall selection of sites must ensure availability of sufficient numbers of patients in each of the following at-risk groups: neutropenic cancer patients, and bone marrow and solid organ transplant recipients (1/4 of studies); immunocompetent patients with or at risk for serious healthcare-associated or endemic fungal infections (1/4 of studies); patients with or at risk for opportunistic fungal

infections secondary to HIV infection (1/4 of studies); and patients with or at risk for serious healthcare-associated resistant bacterial infections including those in intensive care settings (1/4 of studies). Participating BAMSG clinical sites shall include an adequate number of cancer and transplant centers to provide sufficient patients to meet goals set forth in the research agenda.

e. Each participating BAMSG site shall accrue a minimum of five patients a year into group protocols in order to continue participation in the group. Each site must satisfactorily perform screening, entry and follow-up of patients in protocols designed to evaluate interventions for fungal and/or healthcare-associated resistant bacterial infections. Each site shall have an identified site-specific Principal Investigator and clinical research staff with experience in clinical research involving evaluation of antimicrobial interventions and capability to comply with all protocol specifications and data submission and regulatory requirements. The Contractor shall review each BAMSG site annually with respect to overall performance including patient accrual and retention on protocols, adherence to protocols, regulations, research standards, and timeliness and accuracy of completion and submission of case report forms. These site-specific assessments shall be submitted to the Project Officer in the required annual report along with a recommendation for continuance or discontinuance of each site as a "BAMSG site".

f. Participation of non-BAMSG clinical sites in any BAMSG studies will be permitted only with the approval of the Project Officer. The decision to allow participation of non-BAMSG sites will be based on the demonstration that such additional sites are required in order to assure timely completion of studies and that appropriate provisions can be made for monitoring and overseeing their performance. Decisions about allowing participation of individual non-BAMSG sites will be based on their qualifications and past performance in multicenter clinical trials and the ability to accrue sufficient numbers of study participants. The Contractor shall review each BAMSG site annually with respect to overall performance including patient accrual and retention on protocols, regulations, adherence to protocols and research standards, and timeliness and accuracy of completion of case report forms. These site-specific assessments shall be submitted to the Project Officer in the required annual report along with a recommendation for continuance or discontinuance of each site's participation in BAMSG studies.

g. The Contractor shall assure that minorities, both genders, and children shall be included in the clinical studies to comply with the current guidelines published in the NIH Guide, Vol. 23, No. 10, March 11, 1994 and that the disease incidence in these populations is adequately considered and reflected in the protocol.

h. The Contractor shall maintain administrative records of the BAMSG and documentation of group proceedings and activities.

4. Under the direction of the BAMSG Principal Investigator, a Coordinator and appropriate staff shall be responsible for facilitation and accomplishment of the following tasks:

a. Developing a concept receipt, development and review process to ensure that all approved concepts meet high scientific, medical and ethical standards. The concepts shall be prioritized both across and within the four risk groups. As a component of this process, the feasibility of the study concept shall be assessed and this shall include site surveys to document expected patient accrual based on proposed eligibility/exclusion criteria. All concepts must be reviewed and approved by the Steering Committee before submission to NIAID.

b. Distributing and tracking materials such as concepts and study progress reports for review and approval by the BAMSG Steering Committee and to investigators, industrial sponsors, other collaborating groups, and NIAID.

c. Working with the Clinical Regulatory Affairs Branch (CRAB), DMID and the BAMBU to facilitate the preparation and submission of Investigational New Drug (IND) applications, as required, for each study to the Food and Drug Administration (FDA).

d. Negotiating with industrial sponsors to provide financial support to the BAMBU for site monitoring and data management costs, as needed, in addition to clinical site costs.

[NOTE (F) TO OFFEROR: The IND sponsor for almost all new studies initiated by the BAMSG will be CRAB, DMID. Whenever the IND is held by CRAB, DMID, the associated site monitoring will be conducted by the BAMBU or another DMID contractor. When an industrial sponsor is permitted to hold the IND, they will be required to provide their site monitoring reports, information on adverse events, and copies of letters accompanying submissions to the FDA in a timely fashion to the BAMBU.]

e. Preparing, with assistance from BAMBU, a list of responsibilities (LOR) delineating the role of the BAMSG Coordinating Unit and investigators, industry sponsor(s) (if any), collaborative groups (if any), BAMBU, and NIAID in the implementation for each study. The LORs shall be submitted by the BAMSG Coordinating Unit for review and approval by the Project Officer at least 60 days before the expected initiation date of each study.

f. Assisting the Project Officer in the drafting of Clinical Trial Agreements (CTA) or a CRADA for each study involving an industrial sponsor(s) based on the LOR for that study. The draft CTAs and/or CRADAs shall address all support from the Industrial sponsors including the costs to the BAMBU associated with site monitoring and data management, as appropriate. A signed CTA or CRADA must be in place prior to the initiation of each new study.

g. Organizing and maintaining protocol teams for each study in collaboration with the BAMSG Steering Committee and investigators, BAMBU, collaborating groups (if appropriate), industry sponsors (if any). Each protocol team shall be led by a protocol chair and will be responsible for development of the study protocol and case report forms, guiding implementation of the protocol at the participating sites, monitoring study progress, addressing study issues as they arise, suggesting analyses and interpreting the results, and preparing and submitting manuscripts for publication in a timely manner.

The BAMBU will provide logistical support for the protocol teams and will be responsible for the operational aspects of generating and disseminating the protocols, prototypic informed consent documents, case report forms, manuals of operations, and other study related materials, as well as the data management and analysis functions. Whenever possible and practical, the Contractor shall encourage the selection and nurturing of junior investigators to assume the responsibilities associated with being designated a protocol chair.

h. In collaboration with BAMBU, developing and implementing a process for review before implementation of all protocols, informed consent documents, case report forms and related study documents by the BAMSG Steering Committee, BAMBU, collaborating group(s) (if any), industrial sponsor(s) (if any), an NIAID-appointed external Data and Safety Monitoring Board (DSMB), and NIAID with respect to scientific, medical and statistical soundness and feasibility. The NIAID Project Officer will ultimately determine whether contract resources will be used for the implementation of a study.

i. In collaboration with BAMBU, developing and implementing a process for administrative review by the BAMSG Steering Committee of each study's progress at least annually, including attention to accrual and retention of study patients, to determine which studies should be continued, modified, or terminated, as appropriate. In addition, data from Phase III and larger Phase II trials will be monitored by the DSMB. Smaller Phase II studies will typically be monitored by Internal Monitoring Boards.

[NOTE (G) TO OFFEROR: The Internal Monitoring Boards will convene 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 DSMB will be composed of approximately five (5) members and will be appointed by the NIAID. The DSMB will meet at least annually in Bethesda, Maryland.]

j. With the assistance of BAMBU and NIAID, developing group policies and procedures including site evaluation criteria and publication policies.

k. Assisting BAMBU in obtaining necessary documents to ensure that all BAMSG sites are in compliance with all Federal regulations and NIH policies applying to the conduct of research involving human subjects. These include, but are not limited to, Title 21 CFR 50, 56 and 312, and Title 45 CFR 46. No non-member sites may participate in a BAMSG study until documentation of compliance with these regulations has been submitted and prospectively approved by the Project Officer.

l. Making recommendations to the Project Officer for communication to BAMBU regarding participating clinical site monitoring assignments to help determine the frequency and intensity of visits and areas of particular concern. These recommendations shall be study- and/or site-specific, as appropriate. The Contractor shall review the site monitoring reports and make assessments and recommendations to the Project Officer based on the site visit reports.

m. Developing and implementing a policy and related procedures for divulgence of real and potential conflicts of interest (COI) on the part of the investigators participating in the studies supported by this contract. This policy must be acceptable to the NIAID and compatible with FDA regulations on financial disclosure by clinical investigators. The policy must address any COI that may occur through financial interest or other associations between the BAMSG membership (including all participating investigators) and the private sector.

n. Organizing and conducting an annual BAMSG Investigators' Meeting in the Washington, D.C. area. The annual BAMSG Investigators' Meeting shall include presentation and review of data, updates on the progress of all studies, discussion of proposed protocols and the group's standard procedures, and active solicitation of ideas from the investigators for new concepts and research priorities for each research subcommittee to update the proposed overall group scientific agenda. At least one investigator from each BAMSG site shall receive support to attend this meeting. The Annual Investigators' Meeting shall provide for interaction with the Program Directors of the Mycology Research Units (MRU) program project grants and the Network on Antimicrobial Resistance in Staphylococcus Aureus (NARSA) and be used to facilitate collaborative efforts with other clinical trial groups.

The Offeror shall include the three MRU Program Directors, four members of the NARSA Executive Committee, and two or more other representatives from collaborating groups in the Annual Investigators' Meeting. The recommended level of participation of these individuals in the meeting is attendance at all sessions and an opportunity to present summaries of their programs and research. The travel expenses for the Program Directors of the Mycology Research Units and NARSA Executive Committee members shall not be borne by this contract; however, travel expenses for the representatives from the other collaborating groups should be included in the cost estimate for these meetings.

o. Attending and participating in one meeting per year in Bethesda, Maryland convened by CRAB, DMID to discuss good clinical practice and regulatory issues related to clinical trials. The individual serving as the Coordinating Unit Coordinator shall attend this meeting.

5. Maintain the facilities and equipment to be utilized for communication and coordination between the BAMSG Steering Committee , Research Subcommittees and investigators, BAMBU, industrial sponsors, other collaborating groups, and NIAID. The Contractor shall use e-mail and word-processing software that is compatible with that used at NIAID.

[NOTE (H) TO OFFEROR: Microsoft Word is the word-processing and Outlook is the e-mail software currently utilized by NIAID.]

6. Provide coordination for the conduct of collaborative clinical trials with other organizations conducting and sponsoring clinical studies and trials. This shall include:

a. Developing a detailed plan for establishing and maintaining collaborations with other government-sponsored (including non-U.S.) clinical trial groups, including all policies and procedures, that shall be submitted for review and approval by the Project Officer. If collaborations are to be performed with other NIAID clinical trials groups, such as the AIDS Clinical Trials Group (ACTG), the BAMSG shall agree to follow procedures for study conduct to be determined by NIAID in consultation with the leadership of each clinical study group.

b. Ensuring that communication with the ACTG is ongoing concerning possible collaborations. A BAMSG investigator shall serve as a liaison to the ACTG Complications Research Agenda Committee. Similar collaborations will be encouraged and fostered with other established clinical trial groups, such as those supported by the National Cancer Institute (NCI), the Immune Tolerance Network supported by the Division of Allergy, Immunology and Transplantation, NIAID, and the Cooperative Studies Program supported by the Department of Veterans Affairs. Collaboration with the Centers for Disease Control and Prevention, National Center for Infectious Diseases will also be strongly encouraged, particularly in the design and development of interventions to address emergence and spread of antibacterial resistance. The plan for such collaborations shall be reviewed for approval by the Project Officer.

[NOTE (I) TO OFFEROR: It is anticipated that at least two of the studies conducted during the contract period will be performed in collaboration with NCI-supported clinical trial groups and/or the Collaborative Network for Clinical Research on Immune Tolerance and Autoimmunity Centers of Excellence (University of Chicago, contract no. N01 AI-95380).]

7. Participate in the preparation of all manuscripts and presentations involving data from BAMSG studies. All publications shall acknowledge NIAID support. The Project Officer shall have access to all data generated with the support of this contract and shall have 15 working days to review manuscripts and three working days to review abstracts before submission. The Contractor shall ensure that publications are expeditiously prepared for submission.

[NOTE (J) TO OFFEROR: The current guidelines for publications resulting from work sponsored by this contract are provided in Attachment A.2.]

8. The Contractor shall maintain a hard copy file of all BAMSG publications and presentations.

9. The Contractor shall develop and maintain a Directory of BAMSG Investigators that shall include, but not be limited to: the name, title, degree(s), phone number, FAX number, electronic mail address and mailing address of each principal investigator, study coordinator, and other clinicians, researchers and scientists at each BAMSG participating clinical site involved in BAMSG activities. The directory shall include similar information about other BAMSG participants including BAMSG Coordinating Unit personnel, BAMSG Research Subcommittees, BAMSG Steering Committee, BAMSG Advisory Panel, BAMSG DSMB, BAMBU personnel, NIAID personnel, industrial representatives, FDA personnel, scientific consultants, and patient representatives who are actively involved in BAMSG activities. The Contractor shall update the Directory on a semi-annual basis, and duplicate and distribute it to all BAMSG participants and other persons identified by the Project Officer.

10. If directed by the Project Officer, the Contractor shall assume responsibility for completion of studies currently being conducted by the NIAID Mycoses Study Group (MSG, University of Alabama at Birmingham, contract no. N01-AI-65296). The division of responsibilities assumed by this Contractor and BAMBU will be the same as for new work proposed for the respective contractors. Ongoing studies may include:

    MSG #37: "A multicenter, prospective, randomized, double-blind clinical trial comparing oral intraconazole (cyclodextrin solution) versus placebo in the treatment of aspergilloma."

    MSG #43: "A phase I evaluation of the safety and pharmacodynamic activity of a murine derived anticryptococcal antibody 18B7 in HIV-infected subjects who have responded to therapy for cryptococcal meningitis."

    MSG #44: "Invasive fungal infections 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 prophylaxis of fungal infections in patients undergoing a hematopoietic stem cell transplant."

    [NOTE (K) TO OFFEROR: For information about these studies please refer to Attachments A.3 through A.6.]

11. The Contractor shall prepare a Transition Plan for transfer of the functions specified in this statement of work to a successor contractor upon 30 days notice by the Project Officer. The Plan shall be subject to review and approval of the Project Officer. The Contractor shall cooperate in and implement the approved Plan to ensure an orderly transition to a successor contractor.

ATTACHMENT A.1.

OUTLINE FOR CONCEPTS

Title:

Patient risk group:

Disease:

Intervention:

- Test agents and comparators:
- Dosing:
- Duration of therapy:
- Duration of administration:

Background/rationale:

Study objectives:

Hypothesis to be tested:

Study design:

- Eligibility/exclusion criteria:
- Randomization/stratification plan:
- Sample size with justification:
- Anticipated duration of recruitment phase:
- Anticipated duration of study:
- Interim monitoring plan, if applicable:
- Primary endpoints/outcomes:
- Secondary endpoints/outcomes:
- Study visit schedule and primary evaluations (including any performed by a central laboratory):
- Any proposed substudies:

Data analyses planned:

Party responsible for data management and site monitoring:

Collaborating clinical trial group(s), if any:

Sponsor(s):

IND holder, if applicable:

ATTACHMENT A.2.

GUIDELINES FOR MANUSCRIPT WRITING

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

    a. The study protocol chair;
    b. The study biostatistician from BAMBU;
    c. Other appropriate individuals may include study investigators, other BAMBU, BAMSG 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 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 Principal Investigator and representatives of industrial sponsors (where appropriate) for comments and suggestions, and to the NIAID for approval by the Project Officer.

5. If additional manuscripts result from a BAMSG 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 Principal Investigator.

7. The NIAID contract number for the BAMSG and BAMBU 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, BAMSG Coordinating Unit, BAMBU, industry sponsors (if any), collaborating groups (if any), and the BAMSG and BAMBU 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, the BAMSG Coordinating Unit, BAMBU, industry sponsors (if any), collaborating groups (if any), and the Project Officers.

11. A copy of the final revised manuscript should be sent to each of the authors the BAMSG Coordinating Unit, BAMBU, industry sponsors (if any), collaborating groups (if any), and the 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 Principal investigator, study biostatistician from BAMBU, and the BAMSG and BAMBU Project Officers.

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

ATTACHMENT A.3.

Protocol Summary/Schema

MSG Study #: 37

Title: A Multicenter, Prospective, Randomized, Double-Blind Clinical Trial Comparing Itraconazole Oral Solution In Cyclodextrin To Placebo in the Treatment of Aspergilloma

Disease: Aspergilloma

Drug: Itraconazole Oral Solution in Cyclodextrin

Principal Investigators: David A. Stevens, M.D.
Marc A. Judson, M.D.

IND Holder: NIAID

Study Objectives: Main Objective- to compare the safety and efficacy of itraconazole oral solution in cyclodextrin with placebo (hydroxypropyl-β-cyclodextrin) in the treatment of pulmonary aspergilloma.

Specific Objectives:

1. To evaluate the efficacy and safety of itraconazole oral solution in cyclodextrin in the treatment of patients with pulmonary aspergilloma.
2. To determine association between serum itraconazole drug levels and outcome.
3. To identify subpopulations of patients with aspergilloma that would benefit in terms of morbidity and mortality by treatment with itraconazole oral solution in cyclodextrin.

Statement of Hypothesis:

Assuming symptomatic and asymptomatic patients will be analyzed together, sample size determination is based on a comparison of the two treatment groups with respect to success rate at 12 months. It is anticipated that the success rate of the placebo will be 5%. A sample size of 86 subjects evenly divided between two treatment arms will be sufficient to detect an increase in the success rate to 30% in patients treated with oral itraconazole solution in cyclodextrin at the two-tailed 5% significance level with a power of 80%. To allow for a dropout rate of 10%, 96 subjects will be recruited.

Study Design: Prospective, Randomized, Double-Blind Placebo Controlled

Randomization: Subjects who are symptomatic or asymptomatic with aspergilloma will be randomized in a double-blind 1:1 ratio to receive either itraconazole oral solution in cyclodextrin 200 mg twice daily (20cc) or placebo [hydroxypropyl-β-cyclodextrin] (20cc) twice daily for 12 months.

Enrollment:

Estimated:	96
Date of initiation:	May 1998
Date of completion:	Ongoing
Number of Sites:	20

Data Analyses: The primary analysis will be a comparison of itraconazole oral solution in cyclodextrin and placebo with respect to success rate. Success is defined as an improvement in radiographic findings for asymptomatic subjects, and as an improvement in radiographic findings and hemoptysis in symptomatic subjects.

Study Population: Subjects entered in this study must meet the following inclusion and exclusion criteria: [*For complete listing of entry criteria and contraindicated medications, see Section 4.0 of the Protocol*]

Inclusion

Males and females; ≥ 18 years of age; able to give informed consent; clinical evidence of aspergilloma as evidenced by a radiologically defined aspergilloma plus at least one of the following: positive histology for *Aspergillus* and/or a positive culture of tissue, or the presence of *Aspergillus*- specific precipitating antibody.

Exclusion

Pregnant or breast feeding females; inability to give informed consent; inability to take oral medications; clinical or pathological evidence of invasive aspergillosis; concurrent treatment with other systemic antifungals; concurrent treatment with rifampin, rifabutin, oral midazolam, triazolam, phenytoin, vincristine, vinblastine, carbamazepine, phenobarbital, terfenadine, astemizole, or loratadine or cisapride; lovistatin or simvastatin; allergies to azoles; use of any investigational drug within one month of study entry; liver enzymes >5 times the upper limit of normal or total bilirubin > 2.0 mg/dl.

ATTACHMENT A.4.

Protocol Summary/Schema

MSG Protocol #:	43
Title:	Phase I evaluation of the safety and pharmacodynamic activity of a murine derived anticryptococcal antibody 18B7 (mAb 18B7) in HIV-infected subjects who have responded to therapy for cryptococcal meningitis **.**
Disease:	Cryptococcosis
Biologic:	18B7 anticryptococcal capsular polysaccharide monoclonal antibody
Protocol Chair:	Robert A. Larsen, M.D.
IND Sponsor:	NIAID/DMID
DMID Protocol Number:	97-037
Study Objectives:	Primary: To assess the safety and determine the maximum tolerated dose (MTD) of mAB 18B7 administered intravenously in HIV-infected subjects who have responded to therapy for cryptococcal meningitis. Secondary: 1. To determine the pharmacokinetic characteristics of mAb 18B7 in serum. 2. To conduct pharmacodynamic studies of the ability of mAb 18B7 to reduce or eliminate cryptococcal polysaccharide antigen from the serum of study subjects. 3. To assess the penetrance of mAb 18B7 into the cerebrospinal fluid (CSF) within four to six hours of the initiation of infusion. 4. To determine if human anti-mouse antibodies (HAMA) develop to mAb 18B7 in serum of study subjects.
Study Design:	This is a Phase I, multi-institution, open-label, non-randomized, dose escalation study of mAB 18B7 in HIV-infected subjects who have responded to therapy for cryptococcal meningitis that has been designed to determine its MTD.

The MTD will have been exceeded if the proportion of subjects in a dosing cohort developing a possibly, probably or definitely study-related serious adverse event (SAE) equals or exceeds one third except if one (and only one) of the first three subjects in a dosing cohort develops an SAE. An SAE is defined as a grade 3, 4 or lethal adverse event (see attached table for grading of adverse events). This study will also obtain safety and pharmacokinetic/pharmacodynamic information about the infusion of mAb 18B7.

Study Subjects:

Inclusion criteria: HIV-infected males or females who are ≥ 18 years of age; culture proven history of cryptococcal meningitis, successful completion of a minimum of six weeks of induction therapy for cryptococcal meningitis with resolution of signs and symptoms of cryptococcal meningitis and negative CSF culture for cryptococcus; a cryptococcal serum antigen level of ≥ 1:64 and on stable antiretroviral therapy for ≥ four weeks prior to dosing.

Exclusion criteria: A history of having received any murine-derived materials, participating in another study protocol that precludes the use of an experimental agent, an active opportunistic infection within the preceding 30 days before study entry, use of systemic glucocorticoid therapy or any other immunomodulators within 30 days of study entry.

Enrollment and Dosing:

Six escalating dosing cohorts will be examined to determine the MTD. The six dosing cohorts will receive 0.01, 0.05, 0.2, 0.5, 1.0, and 2.0 mg/kg of mAb 18B7 infused intravenously using an infusion pump over two hours.

Eligible subjects who have given informed consent will be enrolled, assigned to a dosing cohort, and receive infusion of mAb 18B7 one at a time. Prior to giving permission for the next subject to be enrolled and receive an infusion, the MSG Central Unit will determine that:

1. At least 24 hours have elapsed since the previous subject was enrolled and received an infusion, and
2. The previous subject(s) in the same dosing cohort has (have) not developed an SAE.

The Protocol Chair, MSG Central Unit, and NIAID will confer by conference call to review the status of the previous subjects and determine how to proceed by applying the following rules to determine whether the MTD has been exceeded or if additional subjects or dosing cohorts should be examined:

(1) The initial three subjects in each dosing cohort will be enrolled one at a time, receive their assigned dose of mAb 18B7, and observed for development of adverse events.

(2) If no subject out of the initial three on dose levels 0.01 through 1.0 mg/kg develops an SAE after at least 14 days since the last subject received their infusion then the dose will be escalated to the next higher dose level.
(3) If one subject out of the initial three on dose levels 0.01 through 1.0 mg/kg develops an SAE after at least 14 days since the last subject received their infusion then up to three more subjects will be added to that specific dosing cohort one at a time.
(4) If no additional subjects in the second set of three subjects on a dose level where one of the initial set of three developed an SAE (in other words, only one of six on a dose developed an SAE) after at least 14 days since the last subject received their infusion then the dose will be escalated to the next higher dose level.
(5) If a second subject on a specific dose develops an SAE, even if it is before there are six total subjects on that level, then the MTD will have been exceeded and no additional subjects will be added to this or any higher doses. [Note that if this occurs on the initial dosing cohort (0.01 mg/kg) the study will TERMINATE.]
(6) If the 2.0 mg/kg dose is reached without having determined the MTD, then the same logic as expressed in the steps above will apply, except that there will be no further escalation past 2.0 mg/kg (unless the protocol is modified.)
(7) Once the dose that appears to be the MTD is determined, additional subjects will be added to that dose cohort one at a time until the total number of subjects on that dose equals nine.
(8) If the proportion of subjects at a dose developing an SAE equals or exceeds one third then the MTD will have been exceeded and the next lower dose will be considered the MTD and we will return to step 7 above until nine subjects are examined at a dose and no more than two of them have developed an SAE after at least 14 days since the last subject received their infusion.

Acceptable proportions of subjects developing an SAE to subjects examined at a specific dose include zero, 1/1, 1/2, 1/3, 1/4, 1/5, 1/6, 2/7, 2/8, and 2/9. Proportions exceeding the MTD rule and requiring returning to the next lower dose (or terminating, if the dose is 0.01 mg/kg) include 2/2, 2/3, 2/4, 2/5, 2/6, 3/8, and 3/9.

Sample Size: The minimum number of evaluable subjects in this study will be two. The maximum number will be 54; however, replacements may be needed, e.g., if a patient fails to have any follow-up visits. If there are no SAEs at any dose that are possibly, probably, or definitely related, the sample size will be 24, if no replacements are needed.

Date of Study Initiation: Summer, 2000

Date of Completion:

Number of Sites:	Six sites with GCRC in-patient units.
Data Analysis:	Toxicity data will be presented by severity level for each cohort dose level. The incidence of all adverse events and treatment discontinuations will be summarized for each dose group. If there are sufficient numbers of subjects in each dose group, chi-square analysis will be used to compare the dose groups with respect to the incidence of specific adverse events. 95% confidence intervals will be constructed for these events. The following analyses will be utilized to explore on a preliminary basis the possibility of efficacy of the antibody: for each dose group, and for all groups combined, 95% confidence intervals will be constructed to evaluate the mean changes from the log of the entry serum anticryptococcal antigen titers to titers at 15 minutes, 30 minutes, 60 minutes, 2 hours, 4 hours, 6 hours, 8 hours, 12 hours, 24 hours, one week and two weeks after the single dose. No hypothesis testing will take place. Serial measurements of the serum levels of murine derived monoclonal anticryptococcal antibody will be used for pharmacokinetic analysis. One compartment and multicompartment models will be fitted to the data. The best fit will be chosen according to R^2 and Akaike Information Criteria. Pharmacokinetic parameters, such as half-life ($T_{\frac{1}{2}}$), area under the time-concentration curve (AUC), volume of distribution at steady state (V_{dss}), clearance rate (Cl) and mean residence time (MRT), will be calculated.

Attachment A.5.

Protocol Summary/Schema

MSG Study Number:	44
Title:	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
Disease:	Candida
Drug:	AmBisome 2 mg/kg/day (IV) ***versus*** Fluconazole 400 mg/day (IV)
Protocol Chair:	A. W. Karchmer, M.D.
IND Holder:	NIAID
Study Objectives:	Liver transplant recipients can be determined as being high risk for IFI based upon defined clinical and microbiologic criteria that can be determined at the time of or within five days after orthotopic liver transplantation (OLT). High risk patients will be randomized to receive either AmBisome or fluconazole for 14 days and will be followed clinically and microbiologically for 100 days post-transplant to determine the occurrence of IFI and mortality. This is a 2-component study which will: (1) evaluate the efficacy and safety of AmBisome 2 mg/kg/day versus fluconazole 400 mg (IV) given daily for 14 days as prophylaxis against invasive fungal infections (IFI) in liver transplant recipients determined to be at high risk for IFI, (2) determine through an observational study the incidence of IFI in liver transplant patients who are at low risk for IFI.
Statement of Hypothesis to be Tested:	Risk factor data suggest that invasive fungal infections are concentrated in a specific subpopulation (high risk) of those undergoing liver transplantation and that considerable cost savings could be achieved by focusing prophylactic antifungal therapy in this group rather than giving prophylaxis to all patients (high and low risk).
Study Design:	Prospective, randomized, multicenter double-blinded prophylaxis trial with prospective, observational cohort.
Randomization:	1:1 ratio of the prophylaxis regimen stratified by study site and patient (recipient) CMV status (positive or negative). Blinded study drug will be administered for 14 days post-randomization.

Enrollment:

Date of initiation:	August 19, 1999
Date of completion:	Ongoing
Patients per month:	Approximately 14
Number of sites:	18

Data Analyses:

The primary efficacy analysis will be an intent-to-treat analysis comparing the cumulative incidence of IFI between AmBisome and fluconazole groups using the Kaplan-Meier estimates at 100 days. A 95% confidence interval will be constructed about the difference and a statistical test (F-test) performed to test the null hypothesis that there is no difference in efficacy rates between the two treatments. Estimation of the distribution of survival time will be done using the Kaplan-Meier analysis with the log-rank test. All cause survival will be estimated initially, and survival estimates based on IFI will be analyzed separately. These events will also be included in the Kaplan-Meier estimates of disease specific estimates. The logistic regression model will be utilized to evaluate factors related to IFI incidence and the Cox proportional hazards model will be used to evaluate the time to proven IFI and survival time as a function of treatment and covariates such as site, baseline colonization status and other baseline demographic and clinical characteristics. Other planned analyses include comparison of treatment groups with respect to superficial fungal infections, fungal colonization, post-prophylaxis fungal infection, use of empiric amphotericin B, and compliance with study drug usage.

It is anticipated that one interim analysis will take place after half of the patients have been enrolled and evaluated. Using the Lan-Demets stopping function with the O'Brien-Fleming type boundaries, the interim analysis will be performed at the nominal significance level of .0035, with the final significance level equal to .049. In addition, a futility analysis will be performed to assess whether the alternate hypothesis is achievable. If the ratio of the hazard rate of AmBisome to fluconazole is > 1, then consideration of trial closure should be considered.

Study Population:

COMPONENT 1- PROPHYLAXIS TRIAL – 300 male and female liver transplant patients, who are $\geq$ 18 years of age, are HIV-negative and at high risk for invasive fungal infection, will be randomized on a 1:1 ratio to the prophylaxis regimen

COMPONENT 2 - OBSERVATIONAL COHORT - 200 male and female liver transplant patients, who are $\geq$ 18 years of age, are HIV-negative who were screened for entry into the prophylaxis trial but will not be randomized to the prophylaxis regimen because they are at low risk for invasive fungal infection.

Endpoints:

COMPONENT 1 - PROPHYLAXIS TRIAL

Primary:

1. Incidence of proven invasive fungal infections within 100 days after orthotopic liver transplant (OLT).

Secondary:

1. Mortality at 100 days after OLT
2. Combined incidence of proven and probable invasive fungal infections within 100 days after OLT.
3. Toxicity attributed to prophylactic agents.
4. Description of the patterns of fungal colonization (strain variation including species and antifungal susceptibility of colonizing strains) and correlation of these findings with strains subsequently recovered from invasive pathogens.

COMPONENT 2 - OBSERVATIONAL COHORT STUDY

Primary:

1. Incidence of proven invasive fungal infections within 100 days after OLT.

Secondary:

1. Mortality at 100 days after OLT.
2. Combined incidence of proven and probable invasive fungal infection within 100 days after OLT.
3. Description of the patterns of fungal colonization (strain variation including species and antifungal susceptibility of colonizing strains) and correlation of these findings with strains subsequently recovered from invasive pathogens.

Attachment A.6.

Protocol Summary/Schema

MSG Study Number: 46

Title:	A Phase 3, Randomized, Double-Blind, Comparative Trial of FK463 Versus Fluconazole for Prophylaxis of Fungal Infections in Patients Undergoing a Hematopoietic Stem Cell Transplant
Disease:	Fungal Infections
Drug:	FK463 and Fluconazole
Principal Protocol Chair:	Tom Walsh, M.D.
IND Holder:	Fujisawa Healthcare, Inc., IND #55,322
Study Objectives:	To determine the efficacy and safety of FK463 versus fluconazole in preventing fungal infections in patients undergoing a hematopoietic stem cell transplant.
Statement of Hypothesis:	FK463 is equivalent to fluconazole in preventing fungal infections in patients undergoing an autologous (for hematologis malignancies) or allogeneic hematopoietic stem cell transplants.
Study Design:	Phase 3, multicenter, randomized, double-blind trial comparing intravenous FK463 to intravenous fluconazole
Randomization:	Stratified by study center, age (6 months to 12 years of age or 13 years of age and older), type of transplant (autologous, matched-sibling allogeneic or any other allogeneic transplant). Patients receiving and allogeneic transplant will be further stratified by risk of transplant related mortality (low risk or high risk). The definitions for transplant related mortality risk are defined in Appendix A. The Research Data Operations Department of Fujisawa Healthcare, Inc. (FHI) will generate the randomization schedule.
Enrollment:	Estimated: 800, 400 in each treatment arm Date of initiation: November, 1999 Number of Sites: 30
Data Analyses:	The efficacy of FK463 will be compared to that of fluconazole. A combination of tests of non-inferiority and superiority will be performed. The non-inferiority of FK463 to fluconazole over a difference of 10% will be tested. In the event that FK463 is found to be non-inferior, the superiority of FK463 to fluconazole will be assessed.
Study Population:	Patients aged 6 months and older, undergoing an autologous (for hematologic malignancies) or allogeneic hematopoietic stem cell.

REPORTING REQUIREMENTS AND DELIVERABLES

[Return to Table of Contents]

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

A. Technical Reports

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

(1) Semi-Annual Technical Progress Reports - by the fifteenth working day of the month following the end of each six month period, the Contractor shall submit five (5) copies of a semi-annual Technical Progress Report, comprising four (4) copies to the Project Officer and one (1) copy to the Contracting Officer. Such reports shall include the following specific information:

a. A cover page that lists the contract number and title, the period of performance being reported, the contractor's names and address, the author(s), and the date of submission.

b. SECTION I - An introduction covering the purpose and scope of the contract effort.

c. SECTION II - A description of overall progress plus a separate description for each task or other logical segment of work on which effort was expended during the report period.

d. SECTION III - A description of current technical or substantive performance and any problems encountered and/or which may exist along with proposed corrective action. Each clinical study should be reported separately according to the number assigned by the Project Officer. An explanation of any difference between planned progress and actual progress, why the differences have occurred, and if behind planned progress what corrective steps are planned. The status of all ongoing trials shall be summarized in terms of study results and publications. A summary assessment of the performances of all sites shall be included and is to address patient accrual and retention on protocols, adherence to protocols and research standards, and timeliness and accuracy of completion of case report forms. The summary shall document how accrual meets the current guidelines for inclusion of minorities and both genders.

e. An anticipated work plan for the following six months.

f. Preprints, reprints, and abstracts of all contract-supported work resulting in publication or presentation in the reporting period shall be submitted along with the report.

NOTE: Semi-annual Technical Progress Reports are not due for periods in which an annual or final report is due.

(2) Annual Reports - Within 30 days after the anniversary date of the contract, the Contractor shall submit five (5) copies of an Annual Technical Progress Report, as above, comprising four (4) copies to the Project Officer and one (1) copy to the Contracting Officer. Such reports shall detail, document, and summarize the results of the entire contract work for the period covered. These reports shall be in sufficient detail to explain comprehensively the results achieved. Also to be included in the report is a summary of work proposed for the next reporting period. A one-page summary of each ongoing and completed protocol shall be submitted at this time. An annual report will not be required for the period when the final report is due. Preprints and reprints of papers and abstracts not submitted in the semi-annual report shall be submitted.

(3) Annual Research Agenda - Within 60 days after the anniversary date of the contract, the Contractor shall submit five (5) copies of the most recently reviewed and approved Annual Research Agenda, as above, comprising four (4) copies to the Project Officer and one (1) copy to the Contracting Officer. Such report shall detail, document, and summarize the prioritized research agenda developing strategies and a plan with scientific rationale that identifies the gaps in the existing knowledge of therapeutic status and how the proposed studies will address the gaps. The agenda must address public health needs for the appropriate resistant bacterial pathogens and risk groups. The agenda must establish priorities among the project areas. The agenda must be updated annually and submitted for review and approval by the NIAID.

(4) Collaborative Plan – Within 60 days after contract award the Contractor shall submit to the Project Officer for review and approval one copy of a detailed plan describing how collaborations with industry, small business, other NIH grantees and contractors, and other governmental agencies will be pursued to support conduct of future clinical studies for serious fungal and, in particular, healthcare-associated resistant bacterial infections. This plan shall outline how collaborations with industrial sponsors willing to negotiate Cooperative Research and Development Agreements (CRADA), small business innovative research and technology transfer grantees, and other NIH grantees and contractors will be developed. The plan shall also address the prioritized research agenda indicating how implementation of the submitted concepts will be funded.

(5) Lists of Responsibilities - Submit to the Project Officer one copy of a list of responsibilities (LOR) delineating the role of the BAMSG Coordinating Unit and investigators, industry sponsor(s) (if any), collaborative groups (if any), BAMBU, and NIAID at least 60 days prior the expected implementation date for each study for review and approval by the Project Officer. A sample list of responsibilities is provided in Attachment B.1.

(6) Directory of BAMSG Investigators - Submit five (5) copies to the Project Officer of the semi-annual updates of the Directory of BAMSG Investigators.

(7) Final Report - By the completion date of the contract, the Contractor shall submit five (5) copies of a comprehensive Final Report, as above, comprising four (4) copies to the Project Officer and one (1) copy to the Contracting Officer. This final report shall detail,

document and summarize the results of the entire contract work for the period covered. This report shall be in sufficient detail to explain comprehensively the results achieved. Additional specific requirements are set forth in ARTICLE C.1. Preprints and reprints not included previously submitted shall be included.

(8) Transition Plan - Submit a Transition Plan for transfer of the functions specified in the statement of work within 60 days of the request of the Project Officer. The Plan shall be subject to review and approval of the Project Officer.

B. If the Contractor becomes unable to deliver the reports specified hereunder within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of anticipated delays with reasons, therefore.

C. Technical Report Distribution

Copies of the technical reports and other deliverables shall be submitted as follows:

Deliverable	No. of Copies	Addressee/Distribution	Due Dates
Semi-Annual Progress	4	Project Officer (P.O.) DMID, NIAID, NIH Bethesda, MD 20892-7640	Semi-Annually (Specific dates will be listed in the contract document.)
Semi-Annual Progress	1	Contracting Officer (C.O.) CMB, NIAID, NIH 6700-B Rockledge Drive Bethesda, MD 20892-7612	Same as above
Annual Report	4	Same as P.O. above	Within 30 days after the contract anniversary date
Annual Report	1	Same as C.O. above	Same as above
Annual Research Agenda	4	Same as P.O. above	Within 60 days after the contract anniversary date
Annual Research Agenda	1	Same as C.O. above	Same as above

Deliverable	No. of Copies	Addressee/Distribution	Due Dates
Collaborative Plan	1	Same as P.O. above	Within 60 days after contract award
List of Responsibilities	1	Same as P.O. above	Within 60 days prior to the expected implementation date of each study
Directory of BAMSG Investigators	5	Same as P.O. above	Semi-annually (as specified in the contract document)
Transition Plan	1	Same as P.O. above	If notified by the P.O., within 30 days after notification
Final	4	Same as P.O. above	Completion date
Final	1	Same as C.O. above	Same as above

ATTACHMENT B.1.

SAMPLE LIST OF RESPONSIBILITIES

The Contractor shall prepare for approval by the Project Officer a list of responsibilities for each study to indicate who will:

Compose and submit protocol
generate informed consent forms
approve informed consent forms
distribute protocol and informed consent forms to participating sites
design case report forms (CRF)
print CRF
distribute CRFs to sites
conduct site assessment/orientation/start-up visits
initiate contracts & payments to investigators
collect pre-study regulatory documents
sponsor Investigational New Drug (IND) application
submit protocol and regulatory documents to FDA
ship study medication to repository or sites
generate randomization codes
hold randomization codes
perform CRF/drug supply/regulatory site monitoring
perform quality assurance monitoring
report serious adverse events to FDA and Institution Review Boards (IRB)
    -3 & 10 day reports
    -annual safety reports
monthly update of enrollment and waivers
harvest completed CRFs
conduct secondary review of CRFs
log in CRFs, generate queries to investigators
perform data entry and logic checks
resolve all queries and ensure audit trail
submit annual IND report to FDA
submit any protocol revisions, updated 1572s to FDA
obtain copies of annual IRB renewals from the sites
maintain lab samples (serum/isolate) in a repository
serve as central lab facility for drug levels/susceptibilities
analyze data
present data to Data and Safety Monitoring Board (DSMB)
distribute DSMB reports to IRBs
participate in manuscript preparation

TECHNICAL EVALUATION FACTORS FOR AWARD

[Return to Table of Contents]

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, past performance, cost/price, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price, and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price.

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

2. 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
	55 points

A. TECHNICAL APPROACH

The proposal should demonstrate the soundness and practicality of the technical approach for executing the entire set of requirements specified in the Work Statement. Adequate justification and substantiation for the recommended methods will be assessed as demonstration of the Offeror's understanding of the scope and purpose of this work, including discussion of potential difficulties that may arise in its performance. Adequacy, suitability and availability of necessary patient populations at the participating clinical sites to ensure achievement of the scientific research agenda and enrollment in protocols, including women, minorities and children, as appropriate, must be documented in the proposal. The evaluation will assess*:*

1. Scientific Research Agenda: 25 points

The adequacy of the prioritized scientific research agenda addressing all four of the risk groups specified in item 1 of the statement of work; scientific rational for studies to address gaps in the existing knowledge; innovative approaches, particularly for Orphan Studies utilizing the reserve funds. The process for decision making and establishment of priorities within and among the project areas must also be documented in the proposal.

2. Populations: 20 points

The adequacy and suitability of the proposed participating clinical sites and collaborations with a demonstrated ability to recruit, retain, and follow appropriate patient populations for completion of the studies must be documented. The recruitment plans should describe specific approaches for maximizing inclusion of minorities, both genders, and children, when appropriate.

3. Sample Concepts: 10 points

The adequacy and suitability of the sample concepts for studies to address the most important needs for each of the risk groups identified in the scientific research agenda. This will include

assessment of the adequacy of the clinical trial design, statement of hypothesis, selection and definition of endpoints, monitoring plan, and the likelihood of the results of the studies to guide clinical practice.

B. PERSONNEL **25 points**

The Offeror shall demonstrate the adequacy and relevance of training, expertise, experience, and availability of personnel and appropriate levels of utilization of contractor/subcontractor staff (if any) required to plan and implement this project as described in the Work Statement. The Principal Investigator and Co-PI should have M.D. degrees. They and the Steering Committee members must have documented evidence of experience in clinical trials involving appropriate patient populations as well as demonstrated management abilities involved in conducting multicenter clinical research. All staff should possess the requisite training and experience to perform their scientific and administrative duties.

C. PLAN FOR INDUSTRY COLLABORATIONS **20 points**

The Offeror shall present a plan for developing collaborative relationships with potential sponsors including large pharmaceutical companies, small business, other NIH grantees and contractors, and other governmental agencies. The plan must demonstrate how these relationships will be utilized to develop industry participation and obtain industry support of studies to implement the research agenda addressing all four of the risk groups specified in item 1 of the statement of work. The Plan shall also demonstrate the Offeror's knowledge of government/industry interactions and issues such as development of Clinical Trial Agreements, Cooperative Research and Development Agreements, Intellectual Property Rights/Transfers.

TOTAL 100 points

3. PAST PERFORMANCE EVALUATION FACTOR

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

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

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

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

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

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

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

The following rating method shall be used in the evaluation of past performance information:

+2 **Excellent** - Based on the offeror's performance record, no doubt exists that the offeror will successfully perform the required effort. Sources of information are consistently firm in stating that the offeror's performance was superior and that they would unhesitatingly do business with the offeror again.

+1 **Good** - Based on the offeror's performance record, little doubt exists that the offeror will successfully perform the required effort. Sources of information state that the offeror's performance was good, better than average, etc., and that they would do business with the offeror again.

0 **None** - No past performance history identifiable.

-1 **Marginal** - Based on the offeror's performance record, some doubt exists that the offeror will successfully perform the required effort. Sources of information make unfavorable reports about the offeror's performance and express concern about doing business with the offeror again.

-2 **Poor** - Based on the offeror's performance record, serious doubt exists that the offeror will successfully perform the required effort. Sources of information consistently stated that the offeror's performance was entirely unsatisfactory and that they would not do business with the offeror again.

4. EVALUATION OF TARGETS FOR EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusion about overall commitment and realism of the Offeror's SDB participation targets will be highly influential in determining the relative merits of the Offeror's proposal and in selecting the Offeror whose proposal is considered to offer the best value to the Government.

The extent of the Offeror's SDB participation targets will be evaluated before determination of the competitive range. The evaluation will be based on information provided by the Offeror in their technical proposal. Evaluation of SDB participation will be a subjective assessment based on consideration of all relevant facts and circumstances. The Government is seeking to determine whether the Offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform as the prime contractor.

Offers will be evaluated on the following sub-factors:

1) The extent of participation of SDB concerns in terms of the value of the total acquisition.

2) The complexity and variety of the work SDB concerns are to perform. Greater emphasis will be given for arrangements where the SDB shall be performing work appropriate to the scientific objectives expressed in the statement of work.

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

[Return to Table of Contents]

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS - 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), Alternate II (Apr 1998)
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	March 2000	Allowable Cost and Payment (Paragraph (a) is modified to delete the words "Subpart 31.2" and to add the words "Subpart 31.3")
52.216-11	Apr 1984	Cost Contract - No 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, Alternate IV (Jun 1987)
52.232-9	Apr 1984	Limitation on Withholding of Payments
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
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)

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), Alternate I (Jul 1985)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-5	Sep 1996	Termination for the Convenience of the Government (Educational and Other Nonprofit Institutions)
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 - Alternate I (Apr 1984)
352.228-7	Dec 1991	Insurance – Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.249-14	Apr 1984	Excusable Delays
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity
352.270-7	Apr 1984	Paperwork Reduction Act

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS - Rev. 3/2000].

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH NONPROFIT ORGANIZATIONS OTHER THAN EDUCATIONAL INSTITUTIONS - 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), Alternate II (Apr 1998)
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	March 2000	Allowable Cost and Payment (Paragraph (a) is modified to delete the words "Subpart 31.2" and to add the words "Subpart 31.7")
52.216-11	Apr 1984	Cost Contract - No 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
52.232-20	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), Alternate I (Jul 1985)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-5	Sep 1996	Termination for the Convenience of the Government (Educational and Other Nonprofit Institutions)
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 - Alternate I (Apr 1984)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.249-14	Apr 1984	Excusable Delays
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity
352.270-7	Apr 1984	Paperwork Reduction Act

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH NONPROFIT ORGANIZATIONS OTHER THAN EDUCATION INSTITUTIONS - Rev. 3/2000].

SECTION J
LIST OF ATTACHMENTS

[Return to Table of Contents]

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

- Packaging and Delivery of Proposals
- Proposal Intent Response Sheet ***Submit on/before July 1, 2000, 4:00 PM EST:***

  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

- **Optional Form 310, Protection of Human Subjects Assurance Identification/Certification/Declaration** *[When applicable, all institutions must have the form reviewed and approved by their Institutional Review Committee.]*
- **Technical Proposal Cost Information**
- **Summary of Current and Proposed Activities**
- **Government Notice for Handling Proposals**

Applicable to Business Proposal

- **Small Business Subcontract Plan** *[if applicable]*
- **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

- **Annual Technical Progress Report Format for Each Study** *[Applicable when contract involves Human Subjects unless it has been determined by the Government that the inclusion of Women and Minority Groups in the Study Population is not appropriate.]*
- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **Privacy Act System of Records, #09-25-0200**
- **Safety and Health (Deviation), PHS Clause 352.223-70**
- **Procurement of Certain Equipment, NIH(RC)-7 (OMB Bulletin 81-16)**

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

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

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 this 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.

PROPOSAL INTENT RESPONSE SHEET

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

RFP No.: NIH-NIAID-DMID-01-11
RFP Title: "Bacteriology and Mycology Study Group (BAMSG)"

Please review the attached Request for Proposals. Furnish the information requested below and return this page by July 1, 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 Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Brenda Brooks
RFP-NIH-NIAID-DMID-01-11
FAX# (301) 480-5253
Email : bb76n@nih.gov

PACKAGING AND DELIVERY OF THE PROPOSAL

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

[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-01-11
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***
Brenda Brooks Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Brenda Brooks 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

[Return to Table of Contents]

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

[Return to Table of Contents]

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) 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.

b. **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 8731.
(2) The small business size standard is 500 employees.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in EVERY solicitation, (except for foreign acquisitions) the inclusion of the Standard Industrial Classification (SIC) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

c. **NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS**

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Section I.3., offerors will be evaluated by adding a factor of 10 percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment.

AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.

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

It is anticipated that one Award will be made from this solicitation and that the award will be made on/about March 15, 2001.

It is anticipated that the award from this solicitation will be a multiple-year cost reimbursement type contract completion with a term of five 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 47,840 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. 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.

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.

(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 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) **Human Subjects**

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (SEPTEMBER 1985)

a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Protection from Research Risks (OPRR), National Institutes of Health, Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR, Part 46.

c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The Public Health Service will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consideration with OPRR, (telephone: 301-496-7041), is recommended.

e) In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OPRR an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.

f) It is recommended that OPRR be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(11) **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.

(12) **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 NIAID's policy to conduct discussions with all offerors in the competitive range, NIAID reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct 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 NIAID reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIAID requirements. Synopses of awards exceeding $25,000 will be published in the Commerce Business Daily.

(13) **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the apparent successful offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation. SECTION J, LIST OF ATTACHMENTS, to this RFP provides an example of such a plan.

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

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

c) The offeror understands that:

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

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for small business concerns and small business concerns owned and controlled by socially and economically disadvantaged persons to participate in the performance of the contract.

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

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

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to small business concerns and small business concerns owned and controlled by socially and economically disadvantaged individuals, and women-owned small business concerns, and that each such aspect of the offeror's plan will be judged independent of the other.

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

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, small disadvantaged, women-owned, and HUBZone small business concerns as subcontractors.

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

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to small, small disadvantaged, women-owned and/or HUBZone small business concerns.

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

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

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with small, small disadvantaged, women-owned, and HUBZone small business concerns.

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

(8) A description of the efforts the offeror will make to assure that small, small disadvantaged, women-owned, and HUBZone small business concerns have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

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

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate small, small disadvantaged, women-owned, and HUBZone small business concerns and award subcontracts to them.

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

(14) **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.

(15) **Extent of Small Disadvantaged Business Participation**

In accordance with FAR part 15.304(c)4, the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized SIC Major Groups shall be evaluated in unrestricted acquisitions expected to exceed a total estimated cost of $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1201 and 19.1202). The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth under the Technical Evaluation Criteria shall be used for this purpose. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

Offerors shall include with their business proposal, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized SIC Major Group(s). The applicable authorized SIC Major Group for this project is **8731**. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the business proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

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

EXAMPLE

Targets for SDB Participation - SIC Major Group 87

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

(16) **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations) which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research" which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), [(this was reprinted to correct typesetting errors from Federal Register dated March 9, 1994 (FR 59 11146-11151)], and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Offerors may obtain copies from these sources or from the contact person listed in the RFP.

Unless otherwise specified in this solicitation, the Government has determined that the work set forth herein does not involve a gender specific study or a single or limited number of minority population groups. Therefore, the NIAID believes that the inclusion of women and minority populations is appropriate for this project.

The format for the Annual Technical Progress Report for Clinical Research Study Populations (See LIST OF ATTACHMENTS of this RFP) shall be used in proposal preparation.

(17) **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are scientific or ethical reasons not to include them. For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. In the technical proposal, the offeror should create a section titled "Participation of Children." This section should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. The RFP will contain a review criterion addressing the adequacy of plans for including children as appropriate for the scientific goals of the research, or justification of exclusion.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

http://www.nih.gov/grants/guide/notice-files/not98-024.html

Offerors may also obtain copies from the contact person listed in the RFP.

(18) **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.

(19) **ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

(20) **Past Performance Information**

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

A list of the last five contracts completed during the past three years and the last three contract awarded currently in process that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

Include the following information for each contract or subcontract:

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

The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort. For the purpose of this solicitation, a "major subcontract" is defined as any subcontract exceeding $100,000.

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

a. Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

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

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.

a. 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.

(2) 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