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 [√] No ***8(a) Set-Aside*** [ ] Yes [√] No ***SIC Code:*** 8731 ***Size Standard:*** *500 employees*	***Level of Effort:*** [ ] Yes [√] No ***Total Effort:*** N/A
NIH-NIAID-DAIDS-01-15	[ ] Yes [√] No		

TITLE: "Clinical Site Operations and Monitoring Project"

Issue Date:	***Due Date/Time:***	***Technical Proposal Page Limits:***
May 8, 2000	October 15, 2000	[√] Yes [NTE 50 pages] [ ] No

ISSUED BY:

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

We reserve the right to make awards without discussion.

NO. OF AWARDS:

[√] Only 1 Award
[ ] Multiple Awards

PERIOD OF PERFORMANCE:

5 Years beginning on or about June 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 -- Donald E. Collie ***[COLLECT CALLS WILL NOT BE ACCEPTED.]***

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BACKGROUND/STATEMENT OF WORK

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I. BACKGROUND

The Division of Acquired Immunodeficiency Syndrome (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), is requesting proposals to establish and maintain a Clinical Research Operations and Monitoring Center. This new contract will support the operational, regulatory, and site-monitoring needs of clinical trials and research funded by DAIDS that are not currently supported by the contract services established for DAIDS funded networks. For the most part, services provided by this contract will be for investigator-initiated clinical research funded as grants or contracts to individual investigators.

DAIDS currently sponsors approximately 50 clinical studies through non-network grants and contracts and is responsible ultimately for adequate study conduct and monitoring. The types of studies are broad and varied and include therapeutic, vaccine and non-vaccine prevention clinical trials and epidemiologic, pathogenesis, and behavioral studies. The studies are performed at domestic and international sites. For the most part, projects that involve the testing of new investigational agents or medical interventions are, or will be performed under an Investigational New Drug (IND) held by the investigator or the grantee's institution.

The primary goal of this five-year effort is to ensure that the data produced by DAIDS-funded investigators are of the highest quality and are in compliance with Good Clinical Practice/International Conference on Harmonisation (GCP/ICH) guidelines and Department of Health and Human Services guidelines. In order to meet the goals of this contract, the Contractor's role will be multifaceted. For selected clinical research studies and trials, the Contractor will be asked to: a) provide expert assistance and advice to facilitate protocol development; b) monitor the ability of the site(s) to initiate and conduct studies in accordance with current U.S. and international guidelines on human subjects protection and good clinical practice and laboratory guidelines; c) provide guidance and training to sites for study implementation and conduct; and d) provide administrative and logistical support including establishing a data base that captures essential information about the clinical research planned and conducted by DAIDS non-network grantees.

In summary, this multifaceted effort will support and enable DAIDS staff to monitor and provide assistance as necessary to DAIDS–funded investigators. The services provided will enhance the capability of domestic and international sites to perform clinical research and will ensure that research of high quality is conducted in full compliance with DAIDS regulatory and ethical standards.

Specific responsibilities of the Contractor are described in the Statement of Work.

II. SPECIAL INSTRUCTIONS TO THE OFFEROR

While multi-organization arrangements are acceptable in order to meet the requirements of the contract, single organization performance of these tasks is preferred. Proposals that include multi-organization arrangements must address how inter-organization coordination and communication will be achieved, as well as what inter-organization problems might be expected and how they might be resolved.

Describe in detail the responsibilities and time commitment for all personnel who will be assigned to the contract, and an administrative framework showing clear lines of authority. Provide documentation on the decision-making authority of the Project Director and other key personnel, the extent to which outside consultants will be used as well as assurance of their availability, and the percentage of time each staff member (including proposed Subcontractors and consultants) will contribute to the project. The Offeror shall provide resumes of all proposed staff with endorsements and explanations of previous efforts, that reflect length and variety of experience in similar tasks and that clearly demonstrate relevant training, expertise and specific accomplishments. Provide an organizational chart of all personnel.

Since this is a new contract, the needs of non-network grantees with respect to operations support, monitoring and training are not known with precision and will vary over time. The Offeror shall provide examples of how the workload will be adjusted among staff if tasks associated with operational support, training and/or monitoring needs vary over time. The Contractor will be expected to provide technical support for protocol development, and begin site monitoring and or training visits within two months of contract award.

It is expected that the Principle Investigator have at least a PhD. It is expected that personnel responsible for technically reviewing study documents will have at least a bachelor's degree or equivalent in nursing, pharmacy, biology or other biomedical sciences. They must have a strong background in clinical trials methodology, writing protocol documents (including those for intervention and epidemiology studies), familiarity with informed consent requirements, and working on HIV/AIDS studies. As noted above, the educational and work experience of the personnel involved in reviewing study documents must be documented. Staff or consultants providing technical support for IND preparation must have demonstrated experience in preparing IND packages.

It is expected that site monitors and trainers will have a bachelor's degree or equivalent in nursing, pharmacy, biology or other biomedical sciences. They must have experience in clinical research and preferably have experience in site monitoring clinical trials, working on HIV/AIDS studies, working with community and hospital clinic staffs, teaching clinical staff, and performing quality assurance audits. The Offeror shall describe the education and work experience of the monitors and trainer. As noted above, the Offeror shall describe how monitors and trainers will be assigned to studies, and whether they will be centrally, regionally or locally based. Describe whether monitors will be responsible for all types of studies, only those of a particular research types (e.g. vaccine vs. epidemiologic vs. therapeutic trials), or just certain phases of studies. The Offeror shall include examples of completed site monitoring visit reports and training material.

Note that monitors working with international sites will need to be proficient in the local languages when clinical records are not in English. In addition, monitors must be knowledgeable about the countries where they serve as monitors, the local health care systems, and specific clinical research regulation or ethical/monitoring considerations, as appropriate. The Offeror shall document all previous and current projects of similar nature, including the contract number or grant number, the sponsoring agency, the Project Officer (or other individual responsible for oversight, if not a government client), and a description of the project. Document multi-continent presence and experience.

For purposes of budget preparation, use the assumptions provided in Part III, the NOTES TO OFFERORS. The following project milestones are mentioned in Part IV, Statement of Work:

Deadline	*Deliverable*
Month 1	*SOP for coordinating DAIDs internal review of designated studies (IV.A.6)*
Month 2	*Staff will be provided micro-computers, MS Word software, and access to Internet email. (IV.D.2)*
Month 2	*SOP for initial and ongoing training of monitors (IV.B.6)*
Month 2	*SOP for accomplishing training tasks (IV.C.1)*
Month 3	*Develop database(s) and filing system (IV.D.3, D.4, D.5)*

III. NOTES TO OFFERORS

Note to Offeror #1: For budgeting purposes, assume technical review of 40 clinical studies per year including the informed consent and 40 sets of case report forms. See paragraph A.1 of S.O.W..

Note to Offeror #2: For budgeting purposes, assume direct technical and editorial assistance with 8 clinical studies per year including the informed consent and 8 sets of case report forms. See paragraph A.2 of S.O.W..

Note to Offeror #3: For budgeting purposes, assume that 3 INDs will be prepared per year. See paragraph A.4 of S.O.W..

Note to Offeror #4: Although DAIDS anticipates that study sites will typically perform any required translation of the protocol, case report forms and necessary documents, circumstances may require the Contractor to arrange for an appropriate consultation for assistance with translation. For budgeting purposes, assume that this will involve only translation between English and a local language to include two consent forms of six pages each per year. The local languages are likely to include French, Spanish, Portuguese, and African tribal languages, among others. See paragraph A.5 of S.O.W..

Note to Offeror #5: At present two (2) DAIDS Committees, the Prevention Science Review Committee and the Clinical Science Review Committee (PSRC and CSRC respectively) are responsible for reviews of DAIDS-supported clinical research, whether supported within a clinical trials/epi network or awarded to an individual investigator. The Contractors affiliated with the larger clinical trials networks support some of the Committees' activities. The Offeror can expect to coordinate the review with those Contractors or in the case of an NIAID/DAIDS internal review groups, the Contractor will coordinate with the Project Officer. For budget calculations, the Offeror shall assume that 25 clinical studies per year will be reviewed by the PSRC, CSRC or an internal DAIDS Committee. See paragraph A.6 of S.O.W..

Note to Offeror #6: Flexibility will be required of the Contractor with respect to the number and schedule of site visits. Monitoring visits will be requested as determined by the Program Officer responsible for study oversight in conjunction with the Project Officer. These sites may be experiencing significant problems planning, implementing or monitoring the research, carrying an unusually high subject load, or performing complex or high-priority protocols. The extent of monitoring i.e. the total number of person-months of follow-up review will vary. In general, the Contractor will be expected to accomplish as much data monitoring as possible as designated by the monitoring assignment. The Project Officer will develop the monitoring assignments in conjunction with the Contractor. The Contractor must ensure that assignments are clear and feasible from the monitor's perspective. For planning purposes, assume that a monitor will spend 1-3 days visiting each of 20 domestic sites/year and 2-4 days visiting each of 8 international sites/year. Assume for budgeting purposes that domestic sites are equally distributed in the NE, SE, SW and Western United States, and that international sites are in Africa. For budgeting travel, use the monitors' residence as the departing city.

Laptop computers with modems will be required by the study monitors to communicate with DAIDS while traveling on site visits. The Government will not furnish the Contractor with equipment or software. See paragraph B.1 of S.O.W..

Note to Offeror #7: For budget purposes, assume onsite training is to coincide with monitoring visits. See Note to Offeror #6 and paragraph C.2 of S.O.W.

Note to Offeror #8: The Contractor shall maintain compatibility with NIAID software throughout the duration of the contract; NIAID currently uses Microsoft Office 2000 as its basic office software suite. See paragraph D.1 of S.O.W..

Note to Offeror #9: For all IND studies held by a DAIDS grantee (or Institution), a copy of the seven- day telephone or facsimile safety report submitted to the FDA must be submitted to DAIDS within 24 hours. For non-IND studies, a copy of the fifteen-day written safety report submitted to the FDA must be submitted to DAIDS within 24 hours of notifying the FDA. For budgeting purposes, assume 50 AEs will be reported each year from grantees for studies supported by DAIDS and this contract. See paragraph D.2 of S.O.W..

Note to Offeror #10: DAIDS currently funds approximately 110 grantees performing clinical research studies. For budgeting purposes, assume an administrative database for 110 clinical research studies and 30 new studies each year. See paragraph D.3 of S.O.W..

Note to Offeror #11: The Contractor will need to attend 6 meetings per year held at the DAIDS offices in Bethesda, Maryland. The meetings will last one day. The Offeror can assume that attendance will be required by the PI and Co-PI. See paragraph D.10 of S.O.W..

IV. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, directly or through Subcontractors and/or consultants, to perform the tasks described in Parts A through E of this Work Statement.

A. PROVIDE TECHNICAL SUPPORT TO FACILITATE PROTOCOL DEVELOPMENT

To assist certain NIAID grantees and Contractors (hereinafter called "grantees") in facilitating protocol development for clinical trials the Contractor shall:

1. Review and assess the completeness, consistency, comprehensibility, and scientific soundness of study protocols, case report forms (CRFs) and informed consent forms proposed by the grantees, and recommend improvements.

2. Provide logistical and technical support for development of designated protocols and/or associated case report forms that may include writing and editing the protocol or CRFs based on technical recommendations from expert reviewers.

3. Advise, assist and/or facilitate as required by the Project Officer in the collection and review of regulatory documentation. Requirements that shall be included are Office for Protection of Human Subjects from Research Risks (OPRR) single project assurances (or multiple project assurances), IRB approvals, U.S. State Department clearances for conducting proposed research with foreign investigators agreements with host countries' Ministries of Health, as well as other regulatory documentation that is required for either a DAIDS-sponsored or grantee-sponsored Investigational New Drug (IND) application.

4. Assist NIAID grantees in preparing IND Applications. This shall include, but not be limited to, the following:

   a) Provide technical assistance, as necessary, in the assembly of initial and subsequent IND submissions.

   b) Contact various offices and committees in the NIAID, National Cancer Institute (NCI) or pharmaceutical company responsible for preclinical screening, animal toxicology, chemistry, pharmacology, literature research and clinical research in order to gather information for use in potential new IND submissions.

   c) Access various scientific and information databases to retrieve scientific data for possible inclusion in a new IND.

   d) Edit, index, assemble and duplicate acquired data for subsequent submission to the FDA after approval by the Project Officer.

   e) Obtain letters from drug company sponsors authorizing the cross-filing of information from other sources.

5. Provide any needed translation (from or into English) of forms, documents and/or data not translated by study site staff.

6. Within one month of award, Contractor shall outline an SOP used for coordination of DAIDS internal reviews of proposed domestic and international studies. This shall include but not be limited to:

   a) Receiving copies of the proposed clinical research study and protocols from the Project Officer.

   b) Assisting in planning and scheduling necessary DAIDS required reviews and notifying/confirming speakers and guests.

   c) Copying and distributing materials to participants for DAIDS reviews.

   d) Drafting, revising, and distributing consensus reviews or minutes to appropriate groups and individuals as required by DAIDS.

   e) Soliciting from the grantee a written response to all consensus reviews.

f) Obtaining and organizing information that documents the current status of the natural history, epidemiology, pathology and pathogenesis, clinical aspects, therapeutics and prognosis of disease conditions related to HIV infection and the biology of the involved pathogens from available databases such as MEDLINE or meeting abstracts for preparation of NIAID required reviews.

B. MONITOR CLINICAL STUDY SITES, PHARMACIES AND LABORATORIES

The Contractor shall conduct monitoring activities by assigning monitors for designated studies. The Project Officer will review and approve each assignment prior to its implementation.

1. Study monitors' responsibilities shall include, but shall not be limited to the following:

a) Site Initiation: The study monitor shall assess the individual clinical sites' preparedness and adequacy to undertake the types of clinical research proposed at the site. This shall include but not be limited to assessing: the appropriate staffing, facilities (e.g. pharmacy, laboratory, clinical unit, record storage area) and resources for the scope of work; the sites' understanding of, and formalization of, procedures to implement Good Clinical Practice (GCP) and Good Laboratory Practice (GLP); the sites' understanding of and ability to meet relevant U.S. (including DHHS, NIAID), international, and host-country regulatory requirements, including documentation of approvals, and Serious Adverse Experience (SAE) reporting as required per DAIDS policies.

b) Operations management review: The study monitor shall assess site operations and implementation of the study. This shall include review of the study personnel and their roles, staff responsibilities for day-to-day management of the study, site personnel's overall knowledge of the study being conducted, availability of and adequacy of standard operating procedures outlined by the site, oversight of subsites (if any), outreach/recruitment, internal quality management plan and implementation, maintenance of regulatory files, the adequacy of the facilities and study equipment, and the availability of a secured area for storing confidential information (e.g., signed informed consents, research records).

c) Regulatory audit: The study monitor shall ensure that all regulatory requirements for the study are met. This shall include performing a regulatory audit to ensure that the site's regulatory-related procedures are adequate and approvals are in order. The site shall have on file: a current FDA Form 1572, the latest protocols along with IRB-approved consents, current laboratory certifications, current investigator's brochures, documentation of annual IRB renewals, documentation that all adverse events have been reported promptly and in accordance with protocol and regulatory requirements and in accordance with DAIDS policy, and documentation of informed consent for all trial volunteers.

d) Data collection review: The study monitor shall ensure that the patient research records are accurate and well maintained. This may include a full chart review or the review of a selected sample of subjects on the study. The monitor shall assess the site's compliance with the requirements of the protocols being conducted and maintenance of clinical records including: adherence to inclusion and exclusion criteria; reporting of serious adverse experiences; reporting of protocol violations; documentation of objective findings such as clinical endpoints and adverse reactions; recording of data onto case report forms (CRF) and the adequacy of source documents. Related special study assignments may include the need to verify endpoints by comparison of research records with source documents, adverse events or other specific data items, for specific subjects as requested.

e) Laboratory audits: The study monitor shall confirm adequate staff training and procedures regarding the collection, labeling, routing, and storage of laboratory specimens as required by the protocol. The monitor shall determine the location of a sample of stored specimens to ensure that the database records are consistent with site specimen storage, and clinical and laboratory site records. The monitor shall ensure that the storage facilities are consistent with current guidelines with respect to temperature, specimen labeling, and the specimen storage system.

f) Pharmacy operations assessment and audit: The study monitor shall review the organization and utilization of the pharmacy and staff, including: adequacy of the facilities and equipment; adequacy of the pharmacy's procedures to ensure that the treatment regimens or interventions are stored and dispensed in accordance with the protocol; adequacy of procedures to ensure that confidentiality of subject records, treatment assignment lists and accountability documents are maintained. Pharmacy review shall include performing inventories of investigational agents physically present and reconciliation with accountability records.

2. The Contractor shall be responsible for recruiting and training site monitors. Within two months following contract award, the Contractor shall develop Contractor's Standard Operating Procedures (SOP) for initial and ongoing training of monitors. The SOP shall address the frequency of training and the mechanisms to be used (e.g., lectures, regional training, written guidelines and on-the-job training). Monitors shall be trained in the proposed methods and procedures to be utilized in site monitoring.

3. Within one week of completing a site visit, the Contractor shall e-mail a copy of the Study/Site Monitoring Report to the Project Officer.

4. The site visit report shall include, as appropriate: a) The name and address of the site visited and the dates of the visit; b) A summary of the results of each monitoring and verification task performed; c) A separate detailed listing by study and subject identification number of all deficiencies as revealed by the visit; d) Recommendations for corrective actions to be taken to resolve any problems and deficiencies noted; e) A description and assessment of any problems identified from previous visits that have not been corrected, the reasons why problems have not been corrected, and recommendations for corrective action when appropriate; f) A summary of the monitor's debriefing of the site staff, including the names and titles of the staff with whom all problems and deficiencies have been discussed, a description of the site's plans for corrective action, and the site personnel responsible for implementing corrective action; g) A brief description of improvements noted in site performance; and h) A site initiation report, operations management report, a regulatory audit report, a laboratory audit report, and pharmacy audit report.

5. The monitor shall follow up to verify correct handling of past site visit issues or findings as requested by the Project Officer.

6. The Contractor shall generate reports, as requested by Project Officer, that summarize information from monitoring visits.

C. TRAIN AND PROVIDE GUIDANCE ON POLICY, PROCEDURES, AND GOOD CLINICAL PRACTICE

The Contractor shall:

1. Within two months following contract award, the Contractor shall develop and submit to the Project Officer for approval a written SOP for accomplishing the training tasks described in part C of this S.O.W. The Contractor shall periodically revise the SOP, at the request of the Project Officer, to ensure that it accurately reflects the training work the Contractor is to perform.

2. Prepare training materials and provide training to both new and experienced site personnel on the Federal regulations and Good Clinical Practice (GCP) Guidelines for clinical research including the NIAID policy and reporting requirements (see http://grants.nih.gov/grans/guide/nitice-files/N01-AI-00-003.html), policies and procedures of DAIDS, including required serious adverse experience reporting. Training and instruction shall use mechanisms such as presentations at meetings, written training guides, and conference calls, as well as training during site visits. The Contractor shall prepare training materials and manuals and shall include sample SOPs for accomplishing the training tasks as described in this part of the Statement of Work. The Contractor shall periodically revise this SOP at the request of the Project Officer to ensure that it accurately reflects the training work the Contractor is to perform. The plans for training will need to be reviewed in advance by the Project Officer.

3. Within one week of completing a training visit, email a copy of the training visit report to the Project Officer.

4. Provide sites with guidance or assistance in the development, writing and compiling of general SOPs, including site management, protocol implementation, source documentation, and the development of local monitoring and an internal quality assurance management plan, and provide any guidance needed for implementing these procedures. Assist in refining and improving SOPs on an ongoing basis.

5. Provide sites with guidance or assistance as needed to develop standard operating procedures for the collection, labeling, shipping and storage of laboratory specimens. Assess the adequacy of laboratory quality control procedures. Assist in developing laboratory blinding schemes by providing necessary materials, such as coded labels, where needed.

D. PROVIDE INFORMATION MANAGEMENT

The Contractor shall:

1. Establish a reliable electronic communication link with DAIDS. The system shall permit sending email and sharing word processor and data files. The Contractor shall maintain compatibility with NIAID software throughout the duration of the contract.

2. Within two months following award, the Contractor shall provide it monitoring staff with micro-computers, printers, software and internet mail as necessary to facilitate communication.

3. Within three months following contract award, the Contractor shall develop, establish and maintain a computerized tracking system for the receipt and disposition of adverse experience (AE) and safety reports submitted to DAIDS from grantees. The Contractor shall:

   a) Collect and present, by hard copy and/or electronic methods, all information regarding adverse experiences sent by grantees to DAIDS medical and regulatory staff, including Safety Reports or Information Reports about adverse experiences.

   b) Request additional information from grantees, as needed, and perform follow-up on the resolution of adverse events (AEs).

4. Within three months following contract award, the Contractor shall develop and maintain a database that tracks general administrative information and information which includes, but is not limited to, data required by the NIAID policy and reporting requirements for grantees conducting research that involves human subjects. See NIAID policy on the Monitoring of Clinical Trials and Studies (See http://grants.nih.gov/grants/guide/notice-files/NOT-AI-00-003.html). The Contractor shall be responsible for following up with individual grantees to assure that required reporting deadlines are met.

   The database shall contain general administrative information about the grantee, which includes but is not limited to, details of the clinical study proposed, documentation required by DAIDS related to the clinical study (IRB approval date, open/close dates, accrual and demographics, amendments to the protocol, termination of the protocol, temporary suspension of the protocol, any change in informed consent or IRB approval status, temporary suspension or permanent termination of patient accrual); and published reports, abstracts and publications.

5. Within three months following contract award, the Contractor shall develop and maintain a system for the receipt, file maintenance, storage and retrieval of correspondence, protocol documents, annual IRB approvals (for international sites, approval and annual documentation from the local IRB, is required, along with approval from a National IRB if applicable), research findings, reports, publications, abstracts, reprints and other material as specified by the Project Officer.

6. Produce and disseminate routine and ad hoc reports involving information on the clinical studies followed by this contract as requested by the Project Officer.

7. Respond to queries from DAIDS and other authorized individuals/groups on the status of studies.

8. Schedule and provide logistical support for meetings and conference calls between DAIDS staff and grantees, as required. Prepare and distribute agendas in advance of the meetings and calls, and write and distribute minutes as necessary. Maintain a file (hard copy and electronic file) of such reports.

9. Draft, copy, distribute by electronic mail, FAX, U.S. mail or courier service: letters, documents or reports, to grantees, clinical site personnel, pharmaceutical companies, FDA, and other related agencies and personnel.

10. Require Contractor management staff to attend meetings at the DAIDS to review grantee needs for specific protocols and sites, to plan for training activities, and to discuss other technical and administrative matters. Designated staff will depend on meeting purpose but shall include, unless otherwise discussed with the Project Officer, the PI and Co-PI.

E. FACILITATE AN ORDERLY TRANSITION TO A SUBSEQUENT CONTRACTOR

1. During a period prior to completion of this contract, to be specified by the Project Officer, the Contractor shall develop a written transition plan, subject to Project Officer approval, to ensure the orderly transfer of all or part of this project to a designated Contractor or Subcontractor, if other than the incumbent.

2. The Contractor shall actively collaborate with subsequent Contractors and Subcontractors to implement a transition plan to ensure the transfer of all or part of the data collected by the current Contractor and Subcontractors necessary to the fulfillment of the current contract, as well as relevant software and equipment to effect the transition within a three month.

3. The Contractor shall provide detailed instructions and/or training and orientation sessions on all aspects of this contract for employees of the new Contractor.

4. The Contractor shall ensure that all written standard operating procedures pertaining to all aspects of the project are accurate, complete and up-to-date, and shall provide these to the new Contractor.

5. The Contractor shall carry on contractual operations at full staffing levels agreed to by the Project Officer until the completion of the contract.

[END OF STATEMENT OF WORK]

REPORTING REQUIREMENTS AND DELIVERABLES

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The Contractor shall carry out the following reporting tasks:

A. Contractor Technical Progress Reports

The Contractor shall submit the following progress reports as specified below.

1. Quarterly Technical Progress Reports

Within 30 working days following the end of the first quarter, and for each successive quarter of the Contract, the Contractor shall submit a quarterly progress report as described below. The quarterly report should be factual and concise and consist of the following:

a) A title page containing:

(1) Contract number and title
(2) Sequence of report; e.g., "Year 1, 2nd Quarterly Report"
(3) Period of performance being reported
(4) Contractor's name and address
(5) Author(s) name
(6) Date of submission

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

(1) A brief introductory summary of the objective and scope of contract efforts for the quarter.
(2) A description of overall progress during the quarter on each study or project.
(3) In addition to or as replacement for textual descriptions, suitable summary information should be submitted in tabular or graphical format. Such information may include the following:
    a. A summary listing of site visits made, the purpose and outcome of the visit, and proposed follow-up plans;
    b. training sessions held and other such significant events during the quarter and cumulatively.
(4) A description of any technical or performance problems, their relationship to the negotiated Work Statement, their resolution, and recommended solutions or corrective actions taken or planned for problems that have yet to be resolved.
(5) Selected other information as may be required by the Project Officer.

A quarterly report shall not be required for the period when the annual or final report is due.

2. Annual Technical Progress Reports

Within 30 days following the end of each anniversary date of the contract, the Contractor shall submit an annual progress report as described below. The annual report should be factual and concise and consist of the following:

a) A title page containing:

(1) Contract number and title
(2) Sequence of report; e.g., "Year 1, 2nd Annual Report"
(3) Period of performance being reported
(4) Contractor's name and address
(5) Author(s) name
(6) Date of submission

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

(1) A brief introductory summary of the objective and scope of contract efforts for the quarter
(2) A description of overall progress during the quarter on each study or project
(3) In addition to or as replacement for textual descriptions, suitable summary information should be submitted in tabular or graphical format. Such information may include the following:
    a. A summary listing of site visits made, the purpose and outcome of the visit, and proposed follow-up plans;
    b. training sessions held and other such significant events during the quarter and cumulatively.
(4) A description of any technical or performance problems, their relationship to the negotiated Work Statement, their resolution, and recommended solutions or corrective actions taken or planned for problems that have yet to be resolved
(5) Selected other information as may be required by the Project Officer

An annual report shall not be required for the period when the final report is due.

3. Final Report

This report shall briefly summarize all the results achieved during the entire period of performance of this contract and shall be submitted no later than on/before the completion date of the Contract.

The final report shall contain:

a) A title page containing:

(1) Contract number and title
(2) Title of report
(3) Period of performance being reported
(4) Contractor's name and address
(5) Author(s) name
(6) Date of submission

b) The following information:

(1) A brief introductory summary of the objective and scope of contract efforts for the duration of the contract.
(2) Summation of the overall progress and worked performed during the performance period. This report shall be in sufficient detail to describe comprehensively the results achieved. An annual report shall not be required for the period when the final report is due.

c) Summary of Salient Results: A separate report or summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

4. If the Contractor becomes unable to deliver the reports or other deliverables here specified 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 at the address given below in paragraph 5., below.

5. Copies of the technical reports shall be submitted as follows:

Deliverable	No. of Copies	Addressee/Distribution	Due Dates
Quarterly	5	Project Officer, DAIDS, NIAID 6700B Rockledge Drive, MSC 7620 Bethesda, MD 20892	30 calendar days following the end of each quarterly period.
Quarterly	1	Contracting Officer, CMB, NIAID 6700B Rockledge Drive, MSC 7612 Room 2230 Bethesda, MD 20892	30 calendar days following the end of each quarterly period.
Annual	5	To Project Officer	30 calendar days following the end of each quarterly period.
Annual	1	To Contracting Officer	30 calendar days following the end of each quarterly period.
Final (with Summary of Salient Results)	5	To Project Officer	On or before the completion date of the contract.
Final (with Summary of Salient Results)	1	To Contracting Officer	On or before the completion date of the contract.

TECHNICAL EVALUATION FACTORS FOR AWARD

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1. GENERAL

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

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

2. 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.

3. TECHNICAL EVALUATION CRITERIA

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

CRITERIA	WEIGHT
A. Technical Approach	**50 points**

1. Technical Support to Facilitate Protocol Development **(15 points)**

Adequacy and feasibility of plans to:

a. Provide technical reviews of study documents including protocols, case report forms and informed consents.
b. Provide technical support for preparations of Investigational New Drug (IND) Applications.
c. Support and assist in collection and review of regulatory documents prior to study initiation.
d. Coordinate DAIDS internal reviews prior to study initiation.

2. Monitor Clinical Research Sites and Provide Training **(25 points)**

Adequacy and feasibility of plans to:

a. Monitor domestic and international clinical sites and pharmacies not part of DAIDS clinical trials networks.
b. Provide experienced, trained monitors for domestic and international studies (must be knowledgeable about the countries local healthcare systems, and specific clinical research regulations or ethical/monitoring considerations).
c. Provide site visit reports within 1 week of site visit.
d. Provide appropriate notification of problems and recommended solutions.
e. Provide training on policy, federal regulations, and good clinical practice including specific policies and regulations relevant to international sites.
f. Provide and discuss sample training materials.
g. Assist with development, writing, refining, and improving the site's SOPs for study management, conduct, and internal quality management.

3. Provide Information Management **(10 points)**

Adequacy and feasibility of plans to:

a. Establish electronic communication with DAIDS.
b. Develop and maintain a database to track general administrative information. regarding grant and proposed clinical research and AE reports requirements and to generate reports.
c. Establish capacity for filing, storage and retrieval of protocol documents and related material.

B. Personnel Qualifications **35 points**

1. Principal Investigator, Co-Investigator(s) and Other Senior Staff **(20 points)**

    a. Qualifications and experience of the Principal Investigator and Co-Investigator(s) as supported by academic degree(s) and expertise, specialized training, relevant collaborative work involving clinical research, proven ability to provide the necessary scientific leadership for the project, and relevant work in planning and/or supporting clinical research as appropriate to the proposed role in the project.
    b. Documented availability of the Principal Investigator and Co-Investigator(s) for the proposed project.
    c. Availability and ability of at least one Co-Investigator to manage the project when the Principal Investigator is unavailable.
    d. Adequate documented training and experience appropriate for individuals providing technical expertise for those reviewing study-related documents, preparing INDs, and serving as site monitors.
    e. Documented ability to manage and coordinate multi-organization arrangements (if this arrangement is used in the proposal).

2. Other personnel/overall-staffing plan **(15 points)**

    a. Strength and adequacy of the experience of technical and administrative support staff and their documented training and capability to support proposed efforts as required for this project.
    b. Documentation to endorse and explain previous efforts that reflect length and variety or experience in similar tasks and clearly demonstrate relevant training, expertise and specific accomplishments.
    c. Suitability of the staffing and management plans for the conduct of the project, including the appropriateness of the time commitments of all the proposed positions, the clarity and appropriateness of assigned roles, responsibilities, lines of authority (provide an organizational chart for all personnel), and back-up staffing, and the evidence that they will be able to function as a team.

C. Organizational Experience, Facilities and Logistics **15 points**

    a. Appropriateness and suitability of the administrative and logistical approach to successfully provide the flexibility needed to meet the needs of the contract
    b. Ability to offer flexibility in tailoring approaches to incorporate diverse needs, circumstances, and cultural contexts across sites
    c. Appropriateness of the institutional experience in managing projects of similar complexity
    d. Suitability of proposed plans for start-up and for orderly transition to a successor Contractor

TOTAL 100 points

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

SECTION I. GENERAL CLAUSES

[Return to Table of Contents]

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

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

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

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

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

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

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

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

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

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/.

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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	Mar 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
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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)

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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)
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52.225-1	Feb 2000	Buy American Act - Balance of Payments Program - Supplies
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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

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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].

SECTON J
LIST OF ATTACHMENTS

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

- Packaging and Delivery of Proposals
- Proposal Intent Response Sheet ***Submit on/before September 1, 2000:***

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

- How to Prepare and Submit an Electronic Proposal

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

Applicable to Technical Proposal

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

Applicable to Business Proposal

- **Small Business Subcontract Plan**
- **NIH-2043, Proposal Summary and Data Record**
- **Contact Points**
- **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours (includes an Excel cost spreadsheet template)**

To become Contract Attachments

- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **Safety and Health (Deviation), PHS Clause 352.223-70**
- **Procurement of Certain Equipment, NIH(RC)-7 (OMB Bulletin 81-16)**
- **Confidentiality of Information**
- **Screening Agreement for Submitting Products to the DAIDS, NIAID**

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 50 PAGES.

Pages in excess of this will be removed from the proposal and will not be read or evaluated. Offerors are encouraged to limit the overall size of the Technical Proposal (excluding appendices, attachments, operating manuals, non-scannable figures or data, letters of collaboration/intent, etc.). Note that although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

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

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

- Technical Proposal: c:\rfp____techprop.pdf
- Business Proposal: c:\rfp____busiprop.pdf

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

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

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

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

- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.
- Be aware of how large these graphics files become. Large files are discouraged.
- Limit scanned images as much as possible.
- Limit Appendices and Attachments to relevant technical proposal information (e.g., SOPs, pertinent manuals, non-scannable figures or data, resumes, letters of commitment/intent).

PROPOSAL INTENT RESPONSE SHEET

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RFP No.: NIH-NIAID-DAIDS-01-15
RFP Title: "Clinical Site Operations and Monitoring Project"

Please review the attached Request for Proposals. Furnish the information requested below and return this page by September 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: Donald E. Collie
RFP-NIH-NIAID-DAIDS-01-15
FAX# (301) 480-5253
Email : dc128b@nih.gov

PACKAGING AND DELIVERY OF THE PROPOSAL

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

Shipment and marking shall be as indicated below:

A. EXTERNAL PACKAGE MARKING:

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

"RFP NO. NIH-NIAID-DAIDS-01-15
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 15 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*
Donald E. Collie Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Donald E. Collie 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).

CONFIDENTIALITY OF INFORMATION

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Information, raw study data and site performance information provided to or generated by the Contractor under this contract shall be treated confidentially and protected by an Advance Understanding to be included in the resulting contract and worded as follows:

"Because there is a likelihood that the Contractor will be utilizing and evaluating materials [e.g.: information, raw study data and site performance information generated by the Contractor] provided to the Government by a third party Supplier, it is essential to include provisions that will protect the proprietary rights of the Supplier. These materials generally are supplied to the Government under conditions outlined in NIAID's standard Screening Agreement (a copy is incorporated into this RFP/contract) or other appropriate documents. The Contractor shall be bound by the same terms and conditions as the Government in these agreements, with respect to the proprietary and confidential nature of the information provided by the Supplier.

All information provided by the Supplier or Project Officer should be assumed to be confidential unless specifically identified as non-confidential in writing by the Project Officer. Confidential information may not be revealed without written permission. All materials supplied to the Contractor and all test results similarly are to be considered confidential. All materials supplied to the Contractor shall be utilized solely for contract-related research purposes and no unauthorized use or distribution of these materials will be permitted.

Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted for review and written approval by the NIAID Project Officer before submission for public presentation or publication. Contract support shall be acknowledged in all such publications. A "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information. The Project Officer will review all manuscripts/abstracts in a period of time not to exceed 20 calendar days from receipt, and will either grant clearance for publication/disclosure, recommend changes or, as applicable, refer the document to the Supplier of the compound for their review. When the Supplier does not consent to publication of the manuscript or abstract, the Project Officer shall withhold approval to publish in accordance with the terms and conditions of any existing Screening Agreement or Material Transfer Agreement between NIAID and the Supplier. NIAID will use its best efforts to assist and expedite the review process by the Supplier.

Should patents arise from this contract, they will be subject to federal law governing inventions. Every patent applicant (individual or institutional) is required to provide the Government with a non-exclusive, irrevocable, paid-up license to the invention."

SCREENING AGREEMENT

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Screening Agreement for Submitting Products to the Division of Acquired Immunodeficiency Syndrome (AIDS), National Institute of Allergy and Infectious Diseases, hereafter referred to as the DIVISION, by _____ , hereafter referred to as the SUPPLIER.

1. The SUPPLIER may supply products, patented or unpatented, to the DIVISION which may proceed to screen and test for possible treatment for AIDS and associated opportunistic infections including tuberculosis. These products are to be used for screening and testing as anti-viral, anti-bacterial, anti-fungal, anti-parasitic, immunomodulating, and biological modifying agents with potential for the treatment of AIDS and associated infections, and for no other purpose.

   Using protocols evaluated and approved mutually by the DIVISION and the SUPPLIER, the products will be screened by one or more of the DIVISION's contract testing laboratories, or in any other testing laboratories which may from time to time be added to the DIVISION's portfolio but in any event will not be placed in the laboratories of any company in the pharmaceutical or chemical industries without the SUPPLIER's written permission.

2. In order to facilitate records keeping and handling of confidential materials, the DIVISION utilizes the following procedures:

   a. The SUPPLIER shall forward to the DIVISION the products to be tested together with data sheets in duplicate for each product, giving pertinent available data as to chemical constitution, solubility, toxicity, previous biological efficacy and any precautions which need to be followed in handling, storing, and shipping.

   b. It is clearly understood that no data about the products and the results of the testing will be kept in files open to the public either by the DIVISION, the testing laboratories, or the data processing activities. Only those employees directly engaged in the operation of the DIVISION will have access to the files of information regarding source and nature of confidential materials and results of testing, except as required pursuant to the Freedom of Information Act, 5 U.S.C.552.

   c. Whenever possible the SUPPLIER will be given the choice of the DIVISION's contract testing laboratories, although at present there is no preference; and it is understood that the DIVISION reserves the right to send the SUPPLIER's products to another screening Contractor if the need arises. It is furthermore understood that the contracts between the DIVISION and the testing laboratories will contain provisions to safe guard the SUPPLIER's rights under this Agreement.

   d. Because the DIVISION's screening effort will be accomplished in collaboration with the DIVISION's scientific staff and academic collaborators, as well as the SUPPLIER's own staff, the DIVISION will work in concert to assure rapid ongoing communications of screening data to the SUPPLIER, and the SUPPLIER will in turn use its best efforts to keep the DIVISION informed on the SUPPLIER's own ongoing concomitant studies.

3. Although the SUPPLIER recognizes that the interchange of information is generally desirable in the field of treatment for AIDS, it is mutually understood that the SUPPLIER, in voluntarily supplying appropriately marked information deemed proprietary, including product and information regarding this product hereunder, is entitled to protection for any such technical information it may furnish.

   a. It is understood and agreed to, subject to applicable law, that the SUPPLIER shall retain all rights to those compounds or products in which the SUPPLIER has a proprietary interest. The SUPPLIER understands that Contractors have the right to elect to retain title to inventions made under NIAID-supported contracts [37 CFR 401.14(b)]. The SUPPLIER deserves the right to reach an agreement with these Contractors concerning the disposition of these intellectual property rights. The DIVISION agrees to notify the SUPPLIER of the names of the Contractors prior to submitting compounds or products to them. Subject notwithstanding, to the provision that, with respect only to those drugs which have been determined by means of the various screening and testing processes to possess such significant activity (strong potential to be scheduled for clinical trial by the DIVISION, using mutually approved protocols), the Government shall have a royalty-free, irrevocable, nonexclusive license for clinical trials under any patent which the SUPPLIER may have or obtain on such compound or product or on a process for use of such compound or product, to manufacture and/or use by or for the Government the invention(s) claimed by the patent(s) only for medical research purposes related to or connected with the treatment of AIDS and associated infections including tuberculosis.

b. The DIVISION agrees that the publication of biological data on products provided by the SUPPLIER is worthwhile and shall be encouraged. Specifically:

(1) With regard to screening results on compounds in which the SUPPLIER has a proprietary interest, and that the DIVISION deems significant for the research on therapies for AIDS and associated infections including tuberculosis, the SUPPLIER agrees that the DIVISION may publish or otherwise publicly disclose such results after a period of 6 months from the date of final reporting of screening and testing results to the SUPPLIER in order for patent applications to be filed. The DIVISION will consult with the SUPPLIER prior to publication within this period on screening and testing results.

(2) For all other compounds, the SUPPLIER will consult with the DIVISION prior to publishing screening data along with the available biological and physical data; such consent shall not be unreasonably withheld.

(3) In no case will the DIVISION publish information identifying the SUPPLIER as the source of the compound without written approval.

c. As soon as tests are completed and reported to the DIVISION, the SUPPLIER will receive from the DIVISION a full report including all screening data. The products scheduled for clinical trial, referred to herein, shall be designated by the DIVISION, and the aforementioned report will specify the compounds so selected. The DIVISION shall be consulted whenever the SUPPLIER desires to include screening data in a publication, and appropriate credit shall be given to the U.S. Public Health Service.

The DIVISION is confident that this agreement will lay the basis for mutually satisfactory cooperation in the field and in the treatment of AIDS and associated diseases.

In agreeing to the above, the SUPPLIER signs below, as well as the attached duplicate of this agreement, and returns both to the DIVISION for countersignature. One original will be returned for the SUPPLIER's files.

_____	_____
Director, Division of AIDS NIAID, NIH	Name (Signature)
_____	_____
Date	Title
	_____
	Organization
	_____
	_____
	Address
	_____
	Date

SECTION K

REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

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

1. REPRESENTATIONS AND CERTIFICATIONS

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

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

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

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

SECTION L
INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

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1. GENERAL INFORMATION

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

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

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

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

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

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

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

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

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

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

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

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

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

after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed--in whole or in part--for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of--or in connection with--the submission of this data, the Government shall have the right to

duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [*insert numbers or other identification of sheets*]; and

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

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

(f) Contract award.

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

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

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

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

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

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

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

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

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

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

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

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

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the

most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

b. **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 June 15, 2001.

It is anticipated that the award from this solicitation will be a multiple-year cost reimbursement, completion type contract with a term of five 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 27.5 total FTEs (approximately 5.5 FTEs per year. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

f. **COMMITMENT OF PUBLIC FUNDS**

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

g. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

h. **RELEASE OF INFORMATION**

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

i. **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) **Selection of Offerors**

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

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

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

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

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

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

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

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

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

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

(11) **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.

(12) **HUBZone Small Business Concerns**

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

(13) **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

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

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

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

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

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

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

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

(16) **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.

(17) **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.

(18) **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.

c. BUSINESS PROPOSAL INSTRUCTIONS

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

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

(2) **Proposal Cover Sheet**

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

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

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

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

1. **Direct Labor**

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

2. **Materials**

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

3. **Subcontracted Items**

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

4. **Raw Materials**

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

5. **Purchased Parts**

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

6. **Fringe Benefits**

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

7. **Indirect Costs**

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

8. **Special Equipment**

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

9. **Travel**

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

10. **Other Costs**

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

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

(3) **Qualifications of the Offeror**

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

(1) **General Experience**

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

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

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

(3) **Performance History**

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

(4) **Pertinent Contracts**

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

(5) **Pertinent Grants**

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

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

(4) **Other Administrative Data**

a) **Property**

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

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

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

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

(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