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<br>***8(a) Set-Aside*** [ ] Yes [√ ] No<br>***SIC Code:*** 7379<br>***Size Standard:*** *$18 Million* | ***Level of Effort:***<br>[ ] Yes [√] No<br>***Total Effort:*** |
|---|---|---|---|
| NIH-NIAID-DMID-01-14 | [ ] Yes<br>[√] No | | |

***TITLE:*** *Data Coordinating Center for Clinical and Epidemiologic Studies in Infectious Diseases*

| ***Issue Date:*** June 1, 2000 | ***Due Date/Time:*** October 5, 2000<br>4:00pm EST | ***Technical Proposal Page Limits:***<br>[√ ] Yes *(see "How to Prepare and Submit Electronic Proposals")*<br>[ ] No |
|---|---|---|

***ISSUED BY:***

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

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

***NO. OF AWARDS:***

[√ ] Only 1 Award
[ ] Multiple Awards

***PERIOD OF PERFORMANCE:***

7 Years beginning on or about July 1, 2001.

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

The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. If your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with PHS Clause 352.215-10 entitled "Late Proposals, Modifications of Proposals and Withdrawals of Proposals" located in this Solicitation.

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

| ***Telephone*** **(301) 496-3699** | ***Fax*** **(301) 402-0972** | ***E-Mail*** mailto:dk28a@nih.gov |
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# *TABLE OF CONTENTS*

# BACKGROUND / STATEMENT OF WORK / NOTES TO OFFERORS

## *INTRODUCTION*

Overview: To address the present needs of the Government, the Division of Microbiology and Infectious Diseases (DMID), National Institute of Allergy and Infectious Diseases (NIAID), is requesting proposals to serve as a Data Coordinating Center for Clinical and Epidemiologic Studies in Infectious Diseases (DCC for CESID). The primary goal of this seven-year effort is to facilitate the evaluation of new vaccines or other prophylactic or therapeutic agents of priority to the Division. These will predominantly be multicenter Phase I/II - Phase III clinical trials conducted primarily at domestic sites. Most sites will be DMID sponsored Vaccine and Treatment Evaluation Units (VTEUs) or other DMID sponsored centers. The Contractor's primary role will be to coordinate clinical trials or epidemiologic studies with respect to elements of study planning and logistics, training and communications, data collection, management and analysis and related support activities. This will typically involve a multicenter effort and a collaborative relationship with clinical investigators, other supporting Contractors and DMID staff. Secondary roles will include assisting DMID in reviewing a variety of protocols and case report forms for studies to be conducted under a variety of contract or grant mechanisms providing training relating to clinical trials management, assisting DMID in development of standardized operating procedures, and developing interfaces between existing data systems. Specific responsibilities of the Contractor are described in the Statement of Work.

## *BACKGROUND*

[Return to Table of Contents]

A particularly large clinical research effort is currently being conducted by the following DMID VTEU Contractors, which have a long history of support:

| VTEU Contractor | Contract No. |
|---|---|
| Cincinnati Children's Medical Center | N01-AI-45252 |
| Harbor-UCLA Medical Center | N01-AI-45249 |
| University of Maryland | N01-AI-45251 |
| University of Rochester | N01-AI-45248 |
| St. Louis University | N01-AI-45250 |
| University of Maryland - Adult/Elderly | N01-AI-85342 |

Originally, each had a different area of focus and supported predominantly small, Phase I or sometimes Phase II, single center studies. With additional focus on vaccines in the late 1980s, DMID realized a need to conduct larger and/or expedited studies that would meet rigorous FDA requirements. Therefore, it became important to coordinate the clinical research resources already in place at each of the VTEUs.

In 1991 a five-year contract was awarded to Technical Resources, Inc. (now Technical Resources International; Contract No. N01-AI-15131). This Contract established a Data Center to organize multicenter trials and to coordinate and manage the flow of data between VTEUs, DMID staff and manufacturers of test products. Significant efforts were also devoted to secondary support of trials, in particular, for trials performed by foreign contractors.

In 1996, the above contract was recompeted and awarded to The EMMES Corporation (Contract No. N01-AI-65313). This contract continued the support of multicenter clinical trials, but also included a strong statistical support component, which supported both VTEU studies and a variety of others.

As successful translational research in a variety of areas has yielded new products requiring clinical evaluation and data support, the need for high quality clinical trial support for the VTEUs and other independent projects has been steadily growing.

This contract will provide for an increased emphasis on review of DMID supported protocols and on evaluation and training of study and data management at clinical sites, as well as continued support of the work of the previous contracts.

Several clinical trials supported by the two previous contractors have been subject to substantial time pressures for study initiation, conduct and/or reporting. The continuing high profile nature of this research and other factors suggest that these pressures will continue.

# STATEMENT OF WORK

[Return to Table of Contents]

## All Notes to Offeror will immediately follow this Statement of Work.

Independently, and not as an agent of the Government, the Contractor shall furnish services, qualified professional and technical personnel, material, equipment, and facilities not otherwise provided by the Government under the terms of this contract as needed to perform the work set forth below.

Specifically the Contractor shall:

**I. Coordination and Consultation**

A. Provide statistical scientific advice concerning theoretical issues such as power, sample size, impact of interim analyses, inclusion of women and minorities in study populations, inclusion of children in research involving human subjects, and provide leadership regarding research options in both individual and group settings such as meetings and conference calls with clinical investigators and DMID staff, taking into account clinical and/or statistical input advanced by others.

B. Collaborate with clinical investigators and DMID staff to develop and refine the experimental design, including study design, appropriate control groups, sample size and power estimates, randomization and stratification/ blocking methods, data collection forms, interim and final analysis methods and quality assurance methods.

C. As requested by the Project Officer, coordinate successive development of drafts of the study protocol, study forms and manual of procedures.

D. As requested by the Project Officer, develop and document new applications of statistical or information science theory and present to DMID staff and investigators.

II. **Computer Systems Design**

A. Design, develop and validate state of the art data collection and computer-based data and study management systems and related procedures, including any customization necessary for a particular study. Ensure compatibility with any existing systems and furnish all related software. The system shall provide for receiving, entering, verifying, processing, editing (including within and between form validity, logic and consistency checks), updating, correcting, storing, tracking, retrieving and analyzing data. System types shall include, but not be limited to, those to manage all study data from the various clinical and laboratory sites, adverse event tracking across studies, study logistics, study status reporting and clinical project tracking. At least some studies (to be decided by the Project Officer) shall require entry of data by the Data Coordinating Center (DCC) (i.e., not at clinical sites).

B. Provide security against anticipated risks, including loss of confidentiality of subject records (both hard copy and electronic) and data summaries and viral or catastrophic loss of study data or important software.

C. Provide the potential for expedited processing of selected high-priority information (e.g., for monitoring a study's progress) and for ready transferal of data and data documentation to DMID or others at any point during a study, as requested by the Project Officer. The system shall provide sufficient flexibility and accessibility to answer any inquiry in a timely manner, typically no more than one day.

D. Provide predicted upper limits for time duration of the steps needed to accomplish the data management procedures described above.

E. Design and develop a quality control system for monitoring the accuracy, completeness and timeliness of data at each stage beginning with the initial case report forms and proceeding to creation of final datasets.

G. When requested by the Project Officer, provide consultation or limited assistance in establishing or modifying computer hardware or software systems at clinical research centers in order to aid them in conducting NIAID sponsored research, including assistance in establishing their own quality assurance procedures.

H. Establish reliable electronic communication with DMID, which permits sending e-mail and sharing items such as word processor and data files. Provide for rapid pick-up and delivery of hard copy documents as requested by the Project Officer.

I. Update systems to accommodate any changes in technology and in accepted practices since the time of contract award.

III. **Study and Data Management**

A. Prepare a study manual of procedures (a detailed description of the study and its procedures) with guidance from the study investigators and/or DMID staff, and update as required. Copy and distribute the manual to study sites and DMID staff.

B. Prepare and distribute instructional materials regarding study procedures to conduct standardized training for study investigators, staff and clinical site monitors.

C. Initiate or participate in telephone conference calls, correspondence, and meetings with study personnel as needed to address common scientific or practical issues which may arise regarding the study. For some meetings involving the DCC, make logistical arrangements for meeting location, and prepare and distribute minutes of those meetings.

D. Produce and distribute standardized forms for collection of all non-laboratory data needed on study subjects, including eligibility, demographic and other baseline data, sequential clinical outcome assessments and acute and long term adverse events (via mail-in cards and/or clinic visits); perform these functions also for laboratory data when not performed by a separate laboratory center.

E. If requested by the Project Officer, design, produce and distribute labels for study materials (test articles, specimen containers or data collection forms). Labels must be designed to accommodate practical constraints such as freezer tolerance, vial size limitations, etc.

F. Receive, check, track, enter, verify, process, monitor, correct, update, file and store the data collected from the study sites securely and in accordance with applicable FDA regulations, using the computerized data management system developed. Contact study personnel as needed to obtain clarifications or corrections for questionable data or to correct deficiencies. Conduct quality assurance studies to monitor performance of the data management operation. All subject records must be securely kept. In some situations, both subject records and data summaries shall be securely kept due to their proprietary nature.

G. For studies performed in non-English-speaking populations, translate into English, forms and/or documents not translated by the study site staff, and if requested, manage raw data (including entry) from such trials. As requested by the Project Officer, translate consent forms, participant diaries, and other documents if needed into the language spoken by the participant.

H. Prepare and provide study data (subject specific and/or summary data) and accompanying documentation to NIAID staff, study investigators and commercial product sponsors, as requested by the Project Officer. The Contractor shall also be able to provide an electronic copy of an investigator's data to them on an on-going basis throughout the trial. These data may be used for special investigations, selected data analyses, local data management or other purposes. In general, the data shall be provided in a format compatible with the system and software of the recipient. Upon completion of each study, prepare a final, cleaned, edited and documented data set containing all study data. Deliver an electronic copy of the data set to the Project Officer. If so requested by the Project Officer, an electronic version of the data and supporting documentation suitable for use by the public shall be provided.

I. Assist DMID and/or its site monitoring Contractor in performing and/or participating in site visits, usually with DMID and/or site monitoring Contractor (e.g., protocol implementation and data recording and management).

J. Coordinate with DMID or site monitoring Contractor in planning aspects of clinical monitoring and, where appropriate, work with such staff in conducting and reporting on site visits and in addressing any deficiencies found during these site visits (e.g., selecting which computerized data elements should be verified).

K. Design and implement methods to enhance scientific interaction among participating investigators and staff and encourage a sustained, high level of commitment. These methods shall include, but not be limited to, means of informing participating staff about study progress.

IV. **Data Analyses**

A. Conduct comprehensive final statistical analyses, including descriptive as well as univariate and multivariate inferential analyses, as requested by the Project Officer.

B. If requested by the Project Officer, perform appropriate interim analyses for safety and possible efficacy, and summarize and present the findings to an external Data and Safety Monitoring Board (DSMB).

C. Conduct analyses of quality assurance data generated in connection with the trials.

V. **Reporting**

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

B. Prepare materials such as tables, text, graphs and diagrams as needed in collaboration with investigators and DMID staff for presentation at study meetings or professional meetings and assist in writing portions of manuscripts or other reports concerning study findings.

C. Prepare reports with custom formats and selection groups summarizing data for monitoring study progress or product safety or for use by the separate site monitoring Contractor. For high profile studies (assume a third of all studies), DMID or the DSMB could request that monitoring reports be produced frequently (for example, monthly). This shall include, but not be limited to, data reports or listings for the monitoring Contractor for identification of discrepancies between computerized data and data recorded in on-site source documents such as patient charts, progress notes, and diagnostic reports, or identification of common problems with use of the data collection instruments, or of protocol violations.

D. Prepare a written report for each site visit conducted by the DCC that includes the purpose of the visit, activities participated in, strengths and potential weakness of the systems and procedures assessed, and steps taken or recommended to improve identified weaknesses. Reports need not duplicate the formal monitoring report prepared by the regulatory site monitor.

VI. **Assessment and Training**

A. Devise and provide training materials and, as authorized by the Project Officer, conduct training in both individual and group settings. Training topics shall include, but not be limited to, design of data collection forms, protocol development, data management and quality control. Training shall be provided in a variety of settings, including, but not limited to, individual clinical sites and central locations such as the DCC or NIAID. A visit to the clinical site or another coordinating center may be required to assess its data management and quality control procedures and to appropriately tailor the training level.

VII. **Contract Transition**

Prepare for an orderly transition to a subsequent Contractor. Develop and submit to the Project Officer at least 60 days prior to Contract expiration a written transition plan outlining the secure and orderly transfer of this project to a designated Contractor, if other than the incumbent. This plan shall include provisions for transferring files, computer programs, including all source codes, and all written documentation for any studies and for general DCC operating procedures. Carry out the plan as approved, providing detailed instructions for employees of the new Contractor on the operation of the data management system as well as on particular study records and datasets.

# NOTES TO OFFERORS

[Return to Table of Contents]

**GENERAL NOTE:** For budgetary planning purposes, assume that the Contract will support studies over seven years as follows:

1) The Contractor will coordinate (includes all elements in the Work Statement) 20 multicenter trials as follows:

   a) 16 are Phase II with a sample size of 120 subjects and 3 study arms each; assume that each requires a total of 6 months for enrollment plus up to 1 additional year for follow-up;
   b) 4 are Phase III with 2000 subjects and 2 study arms each; assume that each requires a total of 1.5 years for enrollment plus up to 1.5 additional years for follow-up.

2) The Contractor will provide partial support of 10 other trials as follows:

   a) data management and quality assurance for 4 Phase II trials of 100 subjects each;
   b) descriptive analyses and reports for 3 Phase II trials of 100 subjects each;
   c) quality control checks, secondary editing and confirmatory analyses for three Phase III vaccine efficacy trial of 20,000 subjects each.

3) The contractor will also provide consultation in study design, protocol preparation, study manual and forms design for a total of 70 epidemiologic and clinical studies. For 10 of these, the contractor will coordinate the development of the protocol, and design and prepare the study forms and manual of procedures.

**NOTE 1:** Budget for the following travel:

- Two staff personnel to attend 2 three-day scientific meetings per year, of VTEU or other investigators and NIAID staff and for a working meeting of investigators involved in a DCC-supported trial or for training. Assume that half of these meetings will be held in Rockville, Maryland, and the other half will be held in San Francisco, California.

- 3 one-day meetings per year in the Washington, DC area with DMID staff for planning or evaluation of specific DCC activities.

**NOTE 2:** If the Offeror proposes to utilize a distributed data entry system, its establishment as well as its use for any particular study must be justified.

**NOTE 3:** Describe the various components of the proposed system and how they will function with respect to the clinical centers.

**NOTE 4:** Technical information to guide decisions for communication management:

- The NIAID wide area network (WAN) consists of servers, workstations, routers, cabling, telecommunications lines, operating systems and applications. This WAN connects several networks in the Washington, D.C., metropolitan area with the Rocky Mountain Labs in Montana.

- The NIAID servers are a mixture of Pentium, Pentium II and Pentium III high performance personal computers. They all operate under the Microsoft Windows NT Server network operating system (currently version 4.0). TCP/IP (Transmission Control Protocol/Internet Protocol) and AFP (Apple File Protocol) are the basic network communications protocols employed for all connectivity to these servers.

- The pc workstations are primarily Intel Pentium III (and a few Macintosh) personal computers. The Intel based workstations run Windows 98 Second Edition along with some older Windows 95 machines. These workstations typically use TCP/IP to communicate with server devices.

- Connectivity between the networks is facilitated by routers and telecommunications lines. The NIAID uses CISCO routers to connect the networks at different physical locations via a T1 (1.54mb/sec), and T3 (44.736 Mbps) circuits or FNS (Fiber Network System, a Bell Atlantic service) 10 mb/sec telecommunications lines.

The overall network is collapsed into a "backbone" CISCO 7000 router.

- The NIAID internal building cable plants are based on 100 mb/sec ethernet. NIAID employs Ethernet hubs made by a variety of manufacturers including Cabletron to connect networked devices across 100baseT (twisted pair telephone-type (category 5), coaxial and fiber optic cabling.

- The NIAID has settled on several Windows applications as Institute standards. These include Microsoft Word for word processing, Microsoft Access for data bases, Microsoft PowerPoint for presentations, and Microsoft Excel for spreadsheets. Microsoft Exchange is the Institute standard for electronic mail. To access electronic mail, the workstation clients Use Microsoft Outlook. Other non-Windows environment software, such as dBase III Plus, are currently still available.

- NIAID supports email connectivity from its clients, contractors and from other government agencies via the Internet SMTP (Simple Mail Transport Protocol) email facility. Additionally, NIAID has a World Wide Web entry accessible via url (universal resource locator) http://www.niaid.nih.gov/.

- Although not necessarily required, the Contractor can establish a TCP/IP connection with the NIH IBM mainframe computer system with the capability to transfer study data to and from that system and also the ability to manipulate data via the SAS system there, thereby adding flexibility to the joint capacity of DMID and the DCC.]

**NOTE 5:** Standardized study-specific training will most often be conducted by telephone. Assume that this training will be conducted in-person once a year in the Washington, DC area.

**NOTE 6:** The Contractor is prohibited from collecting or maintaining information about any participant enrolled in a research study which would allow that individual to be personally and directly identified.

**NOTE 7:** Generally for foreign trials, data entry and translation of the protocol and primary study forms will be the responsibility of the study site contractor. Based on past experience, however, foreign trials may generate secondary data forms and documents for which the DCC must provide translation. In addition, as part of data quality assurance, a sample of the foreign study records may require verification or reentry by the DCC. For planning purposes, assume one foreign trial will require translation of a procedure manual and 10 pages of study forms, and primary study records (approximately 15 pages each) for 500 participants will require data entry.

**NOTE 8:** Include sample standard operating procedures for data entry and quality assurance and quality control checks.

**NOTE 9:** Include costs for 2 to 3 site visits to each VTEU over the seven years of the Contract.

**NOTE 10** For budgetary planning purposes, assume that three sites will require on-site assessment and training per year for the first 5 years, and training in a central location will be required once per year for 7 years.

# REPORTING REQUIREMENTS AND DELIVERABLES

[Return to Table of Contents]

In addition to the ad hoc reports requested by the Project Officer, the Contractor shall submit to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during each reporting period. These reports shall be brief and factual and prepared in accordance with the format specified below.

1. Quarterly Progress Reports

   The Contractor shall deliver Quarterly Progress Reports within thirty (30) days following the end of each quarter (three months), which describe the progress made on each study during the previous quarter. Quarterly reports shall not be required on due dates for the Annual or Final Reports. The contents of the report shall be as referred to in item 6.A below. When the Project Officer deems it a scientific necessity, the Contractor shall be required to submit on a more frequent basis all or some part of the required information on a particular study.

2. Annual Reports

   The Contractor shall submit Annual Reports which document and summarize the results of the entire contract work on each study for the prior twelve month period. The Contractor shall deliver these reports within thirty (30) days following the end of each twelve month period. An Annual Report is not required on the due date for the Final Report. The contents of these reports shall be as referred to in item 6.B below.

3. Study Reports

   At the end of each study a report shall be due to the Project Officer which shall include a summation of the work performed and results obtained. This report shall be in sufficient detail to explain comprehensively the tasks accomplished and the results achieved, and shall summarize data analyses performed in text, tabular and graphical form. This report shall be due within thirty days after the Project Officer certifies that the work is complete, and in all cases on or before contract expiration date.

   The contents of the report shall be as referred to in item 6.B below.

4. Final Report

   The Final Report shall cover the entire contract period. It shall include a summation of the work performed and the results obtained for every study supported during the entire period of performance. This report shall be in sufficient detail to explain comprehensively the tasks accomplished and the results achieved, and shall summarize data analyses performed in text, tabular and graphical form. The Final Report shall be submitted on or before contract expiration date. The contents of the report shall be as referred to in item 6.B below.

   The contractor shall submit, with the Final Report, a Summary of Salient Results (not to exceed 200 words) achieved during the performance of the contract.

5. Final Data Tape and Other Materials

   At the completion of the contract or of a particular study, as determined by the Project Officer, the Contractor shall turn over to the Contracting Officer a cleaned and edited data tape and other materials, as specified in Attachment 1, Statement of Work, Item VII.

6. Specific Format

Except for the common cover page (see A.1 below), a separate report shall describe progress made in each study under active support by the Contractor.

A. QUARTERLY Technical Reports:

1. A cover page containing:

    a. Contract number and title;
    b. Period of performance being reported and title of report;
    c. Contractor's name and address;
    d. Author(s); and
    e. Date of submission.

2. SECTION II - For each study, a summary of all relevant descriptive information for the current quarter and cumulatively for the study to date, for all clinical sites combined as well as for each one separately. Examples of such information include number of patients enrolled, patient attrition, and study phase (for example, planning, enrollment, analysis, close-out).

3. SECTION III - A brief description of all impediments in achieving the goals of the contract during the current quarter, whether impacting performance or costs, and recommendations for their resolution or a description of the intervention if already resolved.

4. SECTION IV - A section that outlines the status of all identified work tasks from the Statement of Work.

5. SECTION V - A brief description of tasks to be completed during the next quarter and of any difficulties anticipated.

B. ANNUAL, STUDY AND FINAL Technical Reports:

Shall be submitted in accordance with the following format:

1. A cover page containing:

    a. Contract number and title;
    b. Period of performance being reported and title of report;
    c. Contractor's name and address;
    d. Author(s); and
    e. Date of submission.

2. SECTION II - For each study, a summary of all relevant descriptive information for the current quarter and year, and cumulatively to date, for all clinical sites combined as well as for each one separately. Examples of such information include number of patients enrolled, patient attrition, and study phase (for example, planning, enrollment, analysis, close-out).

3. SECTION III - A brief description of all impediments in achieving the goals of the Contract during the current reporting period, whether impacting performance or costs, and recommendations for their resolution. (This section shall not be required in Study or Final Reports.)

4. SECTION IV - A section that outlines the status of all identified work tasks from the Statement of Work.

5. SECTION V - A summary report of any analyses performed during the reporting period, the data to be presented in tabular and graphical form with explanatory text.

6. SECTION VI - A summary report of data made available to any of the collaborating investigators during the reporting period.

7. SECTION VII - Additional information for the reporting period, as requested by the Project Officer.

8. SECTION VIII - A brief description of tasks to be completed during the next reporting period and of any difficulties anticipated. (This section shall not be required in Study or Final Reports.)

C. Technical Progress Report and Deliverables Distribution.

Copies of the Technical Progress Reports and other deliverables shall be submitted as follows:

| Deliverable | No. of Copies | Addressee/Distribution | Due Dates |
|---|---|---|---|
| Quarterly Report | 2 | Project Officer<br>BB, DMID, NIAID, NIH<br>6700-B Rockledge Drive<br>Room 3150, MSC 7630<br>Bethesda, Maryland 20892-7630 | within 30 days after end of previous quarter |
| Quarterly Report | 1 | Contracting Officer<br>CMB, NIAID, NIH<br>6700-B Rockledge Drive<br>Room 2230, MSC 7610<br>Bethesda, Maryland 20892-7610 | same as above |
| Annual Report | 2 | Same as PO above | within 30 days after anniversary date of the contract |
| Annual Report | 1 | Same as CO above | same as above |
| Study Report | 1 | Same as PO above | within 30 days after completion of contract |
| Final Report | 1 | Same as PO above | on or before contract completion date |
| Final Report | 1 | Same as CO above | same as above |
| Data Tape | 1 | Same as PO above | same as above |

If the Contractor becomes unable to deliver the reports specified above 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.

# TECHNICAL EVALUATION FACTORS FOR AWARD

[Return to Table of Contents]

## I. 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 Past Performance Participation. Although technical factors are of paramount consideration in the award of the contract, past performance, and cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price.

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

Past performance will be evaluated apart from the technical evaluation and the cost/price analysis (See Item III. below for additional past performance information). At Source Selection, the technical evaluation will count for 90% of the overall evaluation and past performance will count for 10% of the overall evaluation. In any event, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

## II. 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

The proposal should demonstrate:

1. Soundness and practicality of the technical approach for executing the entire set of requirements specified in the Statement of Work, with adequate justification and substantiation for the recommended methods; also, demonstration of Offeror's understanding of the scope and purpose of this work, including discussion of potential difficulties which may arise in the performance of this work. The evaluation will assess:

    a. Technical approach for establishing and operating a reliable, well-monitored, efficient, secure and responsive study and data management system, for procedures to handle data typically from multicenter clinical studies, and for interfacing with DMID and study sites.

    b. Technical approach for coordinating studies, including organizational and logistical aspects, training and interactions, including cultivation of commitment of participating clinical units and productive interaction among them.

    c. Technical approach for providing statistical scientific leadership and advice in planning assigned collaborative research efforts involving DMID-sponsored investigators such as the network of VTEUs and for conducting and interpreting statistical analyses.

2. Adequacy of the administrative framework, with lines of authority and responsibility clearly shown, and adequacy of the work plan. Time schedules and cost projections should be realistic and satisfactory for achieving contract objectives

while maintaining quality control.

**B. PERSONNEL** **35**

The proposal should demonstrate:

1. Appropriate training, expertise, experience, availability and levels of utilization of contractor/subcontractor staff required to plan and implement this project as described in the Statement of Work. The evaluation will assess:

    a. Roles, responsibilities and lines of authority of DCC staff in these activities.

    b. Documentation to endorse and explain previous efforts that reflect length and variety or experience in similar tasks and clearly demonstrate specific accomplishments.

2. Experience of Principal Investigator in providing statistical advice and in managing and directing statistical and data management support for multicenter clinical trials.

3. Composite expertise of professional personnel in trials of vaccines or treatments for infectious diseases, and particularly multicenter study management and statistical analyses, including evidence of interactive collaboration with clinicians.

4. Documented expertise of computing staff in computer methods for data management and statistical analysis of clinical data, documented expertise in electronic connections to remote systems and proficiency with software and operating system(s) proposed to accomplish the Statement of Work, including some proficiency with standard commercial software as necessary for consulting.

**C. FACILITIES AND RESOURCES** **15**

Adequacy and availability of the facilities and resources necessary for conducting study coordination and data management and analysis, including computers and other equipment, in order to successfully implement the requirements of this contract.

**TOTAL** **100**

## III. PAST PERFORMANCE FACTOR

The offeror's past performance will be evaluated after completion of the technical evaluation. Only those offerors comprising the competitive range will be evaluated. The Government will evaluate the quality of the offeror's past performance based on information obtained from references provided by the offeror, as well as other relevant past performance information obtained from other sources known to the Government.

Evaluation of past performance will be a subjective assessment based on a consideration of all relevant facts and circumstances. The Government is seeking to determine whether the offeror has consistently demonstrated a commitment to customer satisfaction and timely delivery of quality services at fair and reasonable prices.

The assessment of the offeror's past performance will be used as a means of evaluating the relative capability of the offeror and the other competitors. Thus, an offeror with an exceptional record of past performance may receive a more favorable evaluation than another whose record is acceptable, even though both may have acceptable technical and management proposals.

Past performance will be ranked and the Government's conclusions about overall quality of the offeror's past performance may be influential in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered most advantageous to the Government.

By past performance, the Government means the offeror's record of conforming to specifications and to standards of good workmanship; the offeror's record of forecasting and controlling costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

At Source Selection (following the initial technical review and negotiations), past performance information of Offerors who compromise the competitive range will be evaluated using the following criteria:

**PAST PERFORMANCE RATING GUIDELINES**

Summarize contractor performance in each of the rating areas. Assign each area a rating of 0 (Unsatisfactory), 1 (Poor), 2 (Fair), 3 (Good), 4 (Excellent), or 5 (Outstanding). Use the following instructions as guidance in making these evaluations. Ensure that this assessment is consistent with any other assessments made (i.e., for purposes of adding increments).

Definitions

**QUALITY OF PRODUCT/SERVICE:**

- Compliance with contract requirements
- Accuracy of reports
- Appropriateness of personnel
- Technical excellence

| | |
|---|---|
| 0 = Unsatisfactory: | Nonconformances are compromising the achievement of contract requirements, despite use of Agency resources (i.e., program and contract staff guidance, other resources). |
| 1 = Poor: | Noncomformances require major Agency resources to ensure achievement of contract requirements. |
| 2 = Fair: | Noncomformances require minor Agency resources to ensure achievement of contract requirements. |
| 3 = Good: | Nonconformances do not impact achievement of contract requirements. |
| 4 = Excellent: | There are no quality problems. |
| 5 = Outstanding: | The contractor has demonstrated an exceptional performance level in any of the above four categories that justifies this rating. It is expected that this rating will be used in those rare circumstances when contractor performance clearly exceeds the performance levels described as "Excellent". |

**COST CONTROL:**

- Within budget (over/under target costs)
- Current, accurate, and complete billings
- Relationship of negotiated costs to actuals
- Cost efficiencies

| | |
|---|---|
| 0 = Unsatisfactory: | Cost issues are compromising performance of contract requirements. |
| 1 = Poor: | Cost issues require major Agency resources to ensure achievement of contract requirements. |
| 2 = Fair: | Cost issues require minor Agency resources to ensure achievement of contract requirements. |
| 3 = Good: | Cost issues do not impact achievement of contract requirements. |
| 4 = Excellent: | There are no cost issues. |

5 = Outstanding: The contractor has demonstrated an exceptional performance level in any of the above four categories that justifies this rating. It is expected that this rating will be used in those rare circumstances when contractor performance clearly exceeds the performance levels described as "Excellent".

**TIMELINESS OF PERFORMANCE:**

- Met interim milestones
- Reliable
- Responsive to technical direction
- Completed on time, including wrap-up and contract administration

0 = Unsatisfactory: Delays are compromising the achievement of contract requirements, despite use of Agency resources.

1 = Poor: Delays require major Agency resources to ensure achievement of contract requirements.

2 = Fair: Delays require minor Agency resources to ensure achievement of contract requirements.

3 = Good: Delays do not impact achievement of contract requirements.

4 = Excellent: There are no delays.

5 = Outstanding: The contractor has demonstrated an exceptional performance level in any of the above four categories that justifies this rating. It is expected that this rating will be used in those rare circumstances when contractor performance clearly exceeds the performance levels described as "Excellent".

**BUSINESS RELATIONS/CUSTOMER SATISFACTION:**

- Effective management
- Responsive to contract requirements
- Prompt notification of problems
- Reasonable/cooperative
- Concerned with interests of customer
- Flexible
- Pro-active
- Effective contractor-recommended solutions
- Effective small/small disadvantaged business subcontracting programs

0 = Unsatisfactory: Response to inquiries, technical/service/administrative issues is not effective and responsive.

1 = Poor: Response to inquiries, technical/service/administrative issues is marginally effective and responsive.

2 = Fair: Response to inquiries, technical/service/administrative issues is somewhat effective and responsive.

3 = Good: Response to inquiries, technical/service/administrative issues is usually effective and responsive.

4 = Excellent: Response to inquiries, technical/service/administrative issues is effective and responsive.

5 = Outstanding: The contractor has demonstrated an exceptional performance level in any of the above four categories that justifies this rating. It is expected that this rating will be used in those rare circumstances when contractor performance clearly exceeds the performance levels described as "Excellent".

**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 RESEARCH AND DEVELOPMENT CONTRACT - Rev. 3/2000].

# SECTON J
# LIST OF ATTACHMENTS

[Return to Table of Contents]

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

- Packaging and Delivery of Proposals
- Proposal Intent Response Sheet ***Submit on/before: September 5, 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 - 1**

*Applicable to Technical Proposal*

- **Technical Proposal Cover Sheet**
- **Technical Proposal Cost Summary**
- **Summary of Related Activities**
- **Government Notice for Handling Proposals**

*Applicable to Business Proposal*

- **NIH-2043, Proposal Summary and Data Record**
- **Summary of Proposed Estimated Cost (plus fee) and Labor Hours**
- **Detailed Breakdown of Proposed Costs (Excel cost spreadsheet template)**
- **Contact Points**

*To Become Contract Attachments and Reports Required During Contract Performance (as applicable)*

- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **Privacy Act System of Records, #09-25-0200**
- **Procurement of Certain Equipment, NIH(RC)-7 (OMB Bulletin 81-16)**

# HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

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

**ELECTRONIC SUBMISSION INSTRUCTIONS**

**PAGE LIMITS -- THE NARRATIVE PORTION OF THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 100 PAGES. APPENDICES, ATTACHMENTS, OPERATING MANUALS, NON-SCANNABLE FIGURES OR DATA, LETTERS OF INTENT, ETC.,SHALL NOT EXCEED 200 PAGES. CURRICULUM VITAEs (CVs) SHALL NOT EXCEED 2 PAGES.**

Pages in excess of the above limitations will be removed from the proposal and will not be read or evaluated. Note that although no page limit has been placed on the Business Proposal, Offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

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

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

- **Technical Proposal: c:\rfpDMID0114techprop.pdf**
- **Business Proposal: c:\rfpDMID0114busiprop.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 that Attachment.**.

**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

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

**RFP No.:** NIH-NIAID-DMID-01-14
**RFP Title:** Data Coordinating Center for Clinical and Epidemiologic Studies in Infectious Diseases

Please review the attached Request for Proposals. Furnish the information requested below and return this page by **September 5, 2000**. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

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

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

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

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

RETURN VIA FAX OR E-MAIL TO:
CMB, NIAID, NIH
Room 2230
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Dawn Caracci
RFP-NIH-NIAID- DMID-01-14
FAX# (301) 402-0972
Email : mailto:dk28a@nih.gov

# PACKAGING AND DELIVERY OF THE PROPOSAL

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

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

Shipment and marking shall be as indicated below:

**A. EXTERNAL PACKAGE MARKING:**

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

"RFP NO. NIH-NIAID-DMID-01-14
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

**B. NUMBER OF COPIES:**

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

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

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

**C. PAPER COPIES TO:**

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

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

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

# SECTION K

## REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

[Return to Table of Contents]

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

1. REPRESENTATIONS AND CERTIFICATIONS

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

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

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

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

# SECTION L
# INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

[Return to Table of Contents]

## 1. GENERAL INFORMATION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(f) Contract award.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

c. **SIC CODE AND SIZE STANDARD**

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

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

(2) The small business size standard is **$18.0 Million**.

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(s) will be made on/about July 1, 2001. It is anticipated that the award from this solicitation will be a multiple-year COST REIMBURSEMENT type COMPLETION contract with a PERIOD OF PERFORMANCE OF SEVEN (7) YEARS, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the TOTAL 7-year effort to be approximately 77,896 labor hours. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

f. **COMMITMENT OF PUBLIC FUNDS**

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

g. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

h. **RELEASE OF INFORMATION**

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

i. **COMPARATIVE IMPORTANCE OF PROPOSALS**

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

j. **PREPARATION COSTS**

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

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

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

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

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

(End of Provision)

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

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

(End of provision)

[Return to Table of Contents]

## 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) **Privacy Act**

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

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

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

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

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

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

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

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

-to the Department of Justice as required for litigation.

-to respond to congressional inquiries.

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

(11) **Selection of Offerors**

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

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

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

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

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

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

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

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

(12) **HUBZone Small Business Concerns**

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

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

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

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

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

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

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

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

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

**EACH INSTITUTION MUST:**

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

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

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

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

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

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

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

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

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

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

4) the Institution will otherwise comply with the regulations.

**Institutional Management of Conflicting Interests**

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

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

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

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

(16) **Past Performance Information**

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

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

Include the following information for each contract or subcontract:

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

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

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

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

(17) **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 [Return to Table of Contents]

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.

(5) **Information Technology Systems Security**

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

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

## c. BUSINESS PROPOSAL INSTRUCTIONS

[Return to Table of Contents]

### (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 are considered in the source selection process.

(4) **Other Administrative Data**

a) **Property**

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

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

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

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

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

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

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

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

c) **Financial Capacity**

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

d) **Incremental Funding**

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

> 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.

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

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

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

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

(End of Provision)

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

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

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

(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

[RETURN TO RFP COVER PAGE]