OMB No. 0990-0115

# Electronic Request for Proposal
## SOLICITATION COVER PAGE

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

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

| *RFP Number:* | *Just In Time:* | *Small Bus. Set-Aside* [ ] Yes [X] No<br>*8(a) Set-Aside* [ ] Yes [ X ] No<br>*SIC Code:* 8731<br>*Size Standard:* 500 or more | *Level of Effort:*<br>[ ] Yes [X] No<br>*Total Effort:* N/A |
|---|---|---|---|
| NIH-NIAID-DAIDS-01-13 | [ ] Yes<br>[X] No | | |

*TITLE:* **Microbiological Tuberculosis Drug Screening**

| *Issue Date:* | *Due Date/Time:* | *Technical Proposal Page Limits:* |
|---|---|---|
| **September 27, 2000** | **January 8, 2001 ; 4 :30 PM, EST** | [X] Yes *(see "How to Prepare and Submit Electronic Proposals")*<br>[ ] No |

*ISSUED BY:*
Paul McFarlane _____
Senior Contracting Officer
Contract Management Branch, DEA
NIH, NIAID
6700-B Rockledge Drive
Room 2230, MSC 7612
Bethesda, MD 20892-7612

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

| *NO. OF AWARDS:* | *PERIOD OF PERFORMANCE:* |
|---|---|
| [ ] Only 1 Award<br>[X] Multiple Awards | **5 Years beginning on or about August 31, 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* -- **Eric Young** *--COLLECT CALLS WILL NOT BE ACCEPTED--*

| *Telephone:* | *Fax* | *E-Mail* |
|---|---|---|
| *Direct* **(301) 496-8371**<br>*Main* **(301) 496-0612** | **(301) 402-0972** | cy39g@nih.gov |

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7. *PROPOSAL INTENT RESPONSE SHEET (must be submitted on/before **Monday, December 4, 2000**)*

8. *UNIFORM CONTRACT FORMAT - GENERAL -* (SECTIONS B – H) *[Disregard Sections I and J which have been incorporated as part of the sample contract at this website.]*

9. *GENERAL CLAUSES and ADDITIONAL CLAUSES / SUBSTITUTED CLAUSES*- (SECTION I)

   This is a listing 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.

   **ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (SEPTEMBER 2000)**

   **ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS – FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (SEPTEMBER 2000)**

   **ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH NONPROFIT ORGANIZATIONS OTHER THAN EDUCATIONAL INSTITUTIONS - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (SEPTEMBER 2000)**

   Any authorized additions, substitutions and/or modifications other than the General Clauses will be based on the type of contract/Contractor and will be determined during negotiations.

10. *LIST OF ATTACHMENTS - (SECTION J):*

11. *REPRESENTATIONS AND CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS OR QUOTERS (NEGOTIATED) - (SECTION K)*

    If you intend to submit a proposal, you MUST complete this document and submit it as part of your Business Proposal. If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

12. *INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS - (SECTION L)*

    1. General Information
    2. Instructions to Offerors
       a. General Instructions
       b. Technical Proposal Instructions
       c. Business Proposal Instructions

# BACKGROUND/STATEMENT OF WORK/NOTES TO OFFERORS

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## BACKGROUND

### TUBERCULOSIS DRUG SCREENING

### INTRODUCTION

The purpose of this contract is to support the National Institute of Allergy and Infectious Diseases (NIAID) in its mission to stimulate research towards discovery of improved therapies for tuberculosis, an infection associated with the acquired immunodeficiency syndrome (AIDS) and an increasing health risk to the general population. The rising incidence of tuberculosis, particularly in conjunction with the spread of human immunodeficiency virus (HIV), has contributed to a public health emergency. The emergence of multidrug resistant tuberculosis has produced sizable medical challenges to the treatment and containment of infectious tuberculosis in the face of limited chemotherapeutic options. Active discovery and development efforts for anti-tuberculosis drugs essentially ceased in the 1960's with declining case surveillance and treatment infrastructure.

In order to facilitate the development of improved drugs for the treatment of tuberculosis, and particularly multi-drug resistant tuberculosis, the NIAID requires the directed acquisition and evaluation of selected novel synthetic and pure natural product compounds as potential tuberculosis antimicrobials. It is envisioned that compounds will be submitted under confidentiality agreements by pharmaceutical houses or research institutions in exchange for microbiological information on the relative potency of their compounds against *Mycobacterium tuberculosis*. The goal of this effort will be to encourage the rapid and efficient exploration of new classes of compounds for development as potential anti-tuberculosis agents.

This solicitation contains two parts, with a separate work statement for each part. Offerors shall submit completely separate proposals in response to Part A and/or Part B. Offerors may respond to more than one Part, but must submit separate Technical and Business proposals for each (under separate cover) to be considered. If submitting for both Parts, offerors must clearly describe how work under each Part will be coordinated. Part A and Part B proposals will be evaluated independently.

Three existing contracts will provide the facility for coordinating acquisition and data management, for animal efficacy testing, and for technology transfer, respectively. The contract awarded under Part A will serve as the central facility for microbiological *in vitro* testing of novel compounds. The contract awarded under Part B of this solicitation will provide advanced testing of large compound libraries using high-throughput formats and specialized (biochemical target-directed) assays and is likely to serve as a pre-screen for Part A. These five contracts will be highly interactive, will exchange data at least monthly, and will formulate directions for testing in conjunction with the Project Officer.

Because of the critical public health need to rapidly identify and develop new candidate drugs to combat tuberculosis, the highly technical nature of the work required, and the numerous microbiological assays producing critical information, close coordination of the Contractors' efforts by the Project Officer will be necessary. At the present time, NIAID has a Microbiological Tuberculosis Screening contract that is scheduled to end on September 30, 2001. The current contractor is funded through an inter-agency agreement with:

Health Resources and Services Administration, DHHS
Gillis W. Long Hansen’s Disease Center
Y1-AI-5016C.

# STATEMENT OF WORK

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**(Offerors should refer to document titled Notes to Offerors, which provides specific notes and directions to Offerors concerning the preparation of their proposal. See RFP Attachments.)**

## STATEMENT OF WORK – Part A

### MICROBIOLOGICAL TUBERCULOSIS DRUG SCREENING

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the work described below. Specifically, the Contractor shall:

1. Evaluate approximately 4,000 to 5000 compounds per year for antimicrobial growth-inhibition activity against *Mycobacterium tuberculosis.*

    a. Screen synthetic and pure natural product compounds as potential anti-tuberculosis agents for use in the intensive and continuation phases of treatment. Compounds shall be provided to the Contractor by the Tuberculosis Antimicrobial Acquisition and Coordinating Facility Contractor and/or by the Project Officer.
    b. Determine the minimal inhibitory concentrations (MIC) of compounds, identified as active in Work Statement 1.a., against virulent, wild type strains of *M. tuberculosis*. MIC determinations must be conducted using methods acceptable in accredited clinical microbiology laboratories in the United States.
    c. Determine the cytotoxicity of compounds, identified as active in Work Statement 1.a., for actively dividing mammalian cells ($IC_{50}$).
    d. Determine the MIC and minimal bactericidal concentration (MBC) of compounds, identified as active in Work Statement 1.a., against drug resistant strains of *M. tuberculosis*.

2. Improve, standardize, and adopt new assays for determining the activity of compounds against dormant (slowly growing, persistent, or quiescent) *M. tuberculosis* organisms.

3. Evaluate approximately 1000 selected compounds per year for inhibition of replication of intracellular *M. tuberculosis.*

    Evaluate therapeutic agents for efficacy against *M. tuberculosis* in an infected mammalian cell culture test system. This system must also provide a quantitative assessment of cytotoxicity of compounds for control, uninfected mammalian cells. This measure of cytotoxicity will be in addition to Work Statement 1.c. Compounds will be supplied or approved by the Project Officer for testing.

4. Develop and utilize new assays.

    Standardize and adopt new assays, as approved by the Project Officer, to increase testing efficiency and to employ the latest technological developments.

5. Provide safe facilities and resources.

    a. Conduct work in accordance with the clause outlined under "SAFETY CONTROLS AND STANDARDS" (See Attachment A.1.).
    b. Conduct work under this contract under Biosafety Level 3 guidelines when appropriate and in accordance with all applicable Federal, state and local laws, codes, ordinances and regulations, and with basic references and related modifications. (See Attachment A.1.)
    c. Provide facilities and equipment to receive, store, and manipulate infectious *M. tuberculosis* and potentially hazardous compounds and maintain their stability.
    d. Provide protective garments, equipment and sufficient monitoring to assure safe handling of potentially hazardous microorganisms and materials. Specifically, the Contractor shall comply with all applicable health and safety regulations while conducting the work set forth herein.

e. Assure that no identifiable data on the compounds or products and the results of testing will be kept in files open to the public, and that facilities for computer operation, data entry, and file storage are secure from unauthorized access. Only those contract employees or Government employees directly engaged in this project shall have access to the files of information regarding source and nature of confidential or proprietary materials and results of testing.

6. Receive, Store, and Record Compounds.

Develop and maintain efficient, effective procedures for documentation of receipt of compound shipments from the acquisition contractor or the Project Officer. Provide for a computerized inventory of compound identifiers, amounts available, storage locations, and standardized microbiological activity.

7. Provide Monthly Reports and Meet with the Project Officer.

a. Report data generated under this contract to the Project Officer in the form of monthly progress reports and quarterly progress reports as described in the contract Reporting Requirements (written reports and computer files).
b. To facilitate timely transmission of data and information, the Contractor shall establish and maintain an efficient data management system and electronic communication (electronic mail) with the Project Officer's office and with the Tuberculosis Antimicrobial Acquisition and Coordinating Facility (TAACF).
c. The Contractor's Principal Investigator and key personnel shall meet with the Project Officer at periodic intervals, to be scheduled after contract award, to review progress, anticipated or existing problems, and discuss the work to be performed.
d. At least one of the Contractor's key personnel must attend and present information at one NIAID-sponsored meeting per year, at the direction of the Project Officer, on the compounds acquired and analyzed under the Contract.

8. Maintain confidentiality of data.

The Contractor shall be bound by the same terms as the Government with respect to the confidential nature of information provided by contributing suppliers. The Contractor shall provide advance copies of draft manuscripts for publication (including abstracts and public presentations) based on data generated under this contract to the Project Officer, and obtain clearance before submitting for publication or presentation. Support from the Government contract must be acknowledged in all abstracts, presentations, and publications.

9. Ensure an orderly transition to a successor Contractor.

By the end of the fourth year of this contract, the Contractor shall have developed and submitted procedures for an orderly transition of data and samples to a subsequent Contractor or to the Government, subject to Project Officer approval, and shall deliver, if requested by the Project Officer and by the expiration date of the Contract, the following items: original data and any necessary information related thereto, and any Government-owned property, if applicable.

## [END OF STATEMENT OF WORK – Part A]

**(Offerors should refer to document titled Notes to Offerors, which provides specific notes and directions to Offerors concerning the preparation of their proposal. See RFP Attachments.)**

# STATEMENT OF WORK – Part B

## MICROBIOLOGICAL TUBERCULOSIS DRUG SCREENING

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the work described below. Specifically, the Contractor shall:

1. Develop and implement biochemical, target-specific *Mycobacterium tuberculosis* drug screening assays in a high-throughput format

    a. Develop or adapt assays to high-throughput formats (defined as 96 or more reaction wells arranged for simultaneous testing and operation by computer-directed robots).
    b. Screen libraries of synthetic or pure natural product compounds as potential anti-tuberculosis agents for use in the intensive and continuation phases of treatment. Compounds shall be provided to the Contractor by the Tuberculosis Antimicrobial Acquisition and Coordinating Facility Contractor and/or by the Project Officer.
    c. Assemble data into computer formats compatible with existing NIAID Tuberculosis Drug Development contractors' data (see attached notes).

2. Develop and implement *M. tuberculosis* metabolic stage-specific drug screening assays in a high-throughput format.

    a. Develop or adapt assays to high-throughput formats for screening of compounds against actively growing *M. tuberculosis*.
    b. Develop or adapt assays to high-throughput formats for screening of compounds against dormant (slowly growing, persistent, or quiescent) *M. tuberculosis*.

3. Using published computational or neural network methods, design and implement an *in silico* system for predicting drug characteristics such as solubility, human intestinal absorption, bioavailability, and potential toxicities. It is anticipated that the majority of information for these predictions will be identified and obtained by the Contractor from publicly available databases and publications.

4. Provide recommendations to the Project Officer for tuberculosis drug screening using existing, available libraries.

5. Provide safe facilities and resources.

    a. Conduct work in accordance with the clause outlined under "SAFETY CONTROLS AND STANDARDS" (See Attachment A.1.).
    b. Conduct work under this contract under Biosafety Level 3 guidelines when appropriate and in accordance with all applicable Federal, state and local laws, codes, ordinances and regulations, and with basic references and related modifications.
    c. Provide facilities and equipment to receive, store, and manipulate infectious *M. tuberculosis* and potentially hazardous compounds and maintain their stability.
    d. Provide protective garments, equipment and sufficient monitoring to assure safe handling of potentially hazardous microorganisms and materials. Specifically, the Contractor shall comply with all applicable health and safety regulations while conducting the work set forth herein.
    e. Assure that no identifiable data on the compounds or products and the results of testing will be kept in files open to the public, and that facilities for computer operation, data entry, and file storage are secure from unauthorized access. Only those contract employees or Government employees directly engaged in this project shall have access to the files of information regarding source and nature of confidential or proprietary materials and results of testing.

6. Receive, Store, and Record Compounds.

    Develop and maintain efficient, effective procedures for documentation of receipt of compound shipments from the acquisition contractor or the Project Officer. Provide for a computerized inventory of compound identifiers, amounts available, storage locations, and standardized microbiological or biochemical activity.

7. Provide Monthly Reports and Meet with the Project Officer.

   a. Report data generated under this contract to the Project Officer in the form of monthly progress reports and quarterly progress reports as described in the contract Reporting Requirements (written reports and computer files). To facilitate timely transmission of data and information, the Contractor shall establish and maintain an efficient data management system and electronic communication (electronic mail) with the Project Officer's office and with the Tuberculosis Antimicrobial Acquisition and Coordinating Facility (TAACF).
   b. The Contractor's Principal Investigator and key personnel shall meet with the Project Officer at periodic intervals, to be scheduled after contract award, to review progress, anticipated or existing problems, and discuss the work to be performed.
   c. At least one of the Contractor's key personnel must attend and present information at one NIAID-sponsored meeting per year, at the direction of the Project Officer, on the compounds acquired and analyzed under the Contract.

8. Maintain confidentiality of data.

   The Contractor shall be bound by the same terms as the Government with respect to the confidential nature of information provided by contributing suppliers. The Contractor shall provide advance copies of draft manuscripts for publication (including abstracts and public presentations) based on data generated under this contract to the Project Officer, and obtain clearance before submitting for publication or presentation. Support from the Government contract must be acknowledged in all abstracts, presentations, and publications.

9. Ensure an orderly transition to a successor Contractor.

   By the end of the fourth year of this contract, the Contractor shall have developed and submitted procedures for an orderly transition of data and samples to a subsequent Contractor or to the Government, subject to Project Officer approval, and shall deliver, if requested by the Project Officer and by the expiration date of the Contract, the following items: original data and any necessary information related thereto, and any Government-owned property, if applicable.

**[END OF STATEMENT OF WORK – Part B]**

# NOTES TO OFFERORS

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## RFP NIH-NIAID-DAIDS-01-13
## MICROBIOLOGICAL TUBERCULOSIS DRUG SCREENING

GENERAL NOTE TO OFFEROR: In responding to this RFP, Offerors must describe in detail the responsibilities and level of effort of all proposed personnel who will be assigned to the contract. Documentation shall also be provided on the qualifications, experience, education, competence, availability, and decision-making authority of the Principal Investigator, key personnel, and technical and support staff. Offerors must provide necessary facilities, including all major equipment, and capabilities to perform all the functions of the Work Statement and to safeguard against accidental infection with highly infectious Mycobacterium tuberculosis.

It is understood that no single institution may have the expertise and facilities required to perform all items in the work statement, however, work statement item #1 may not be subcontracted. If a subcontractor is proposed for particular tasks, similar technical information shall be provided (as part of the proposal) as that required by the prime Contractor (i.e., technical approach, methods, experience, personnel qualifications, facilities, resources, etc.). The subcontractor's cost detail shall also be provided in the Business Proposal. The prime Contractor shall be responsible for all work performed under this contract including that performed by any subcontractor(s) proposed.

The handling and transportation of all reagents and Government-owned property under this Contract shall be in accordance with all applicable local, state and Federal regulations including health and safety standards (See Attachment A.1 to the Work Statement for details on health and safety standards).

**NOTE 1 TO OFFEROR**: This note is linked to work statement item #1 of work statement Part A. The Offeror shall, at the time of proposal, have a validated in vitro system suitable for large scale screening of compounds for potential activity against M. tuberculosis. For purposes of preparing a cost proposal for Part A, the Offeror should assume 5,000 compounds will be screened per year under Work Statement 1.a., and that 500 compounds per year will be identified as potentially active through screening and will require further evaluation under 1.b. and 1.c. An advance understanding will be included in any resultant contract stating that all materials supplied to the contractor are to be considered confidential and will be utilized by the contractor solely for research purposes. No unauthorized use of these materials will be permitted.

**NOTE 2 TO OFFEROR**: This note is linked to work statement item #2 of work statement Part A. The Offeror shall, at the time of proposal, have a proposed in vitro system suitable for evaluation of the effect of therapies against dormant M. tuberculosis. For purposes of preparing a cost proposal, the Offeror should assume a total of 100 therapies would be evaluated per year.

**NOTE 3 TO OFFEROR**: This note is linked to work statement item #3 of work statement Part A. The Offeror shall, at the time of proposal, have a validated in vitro system suitable for evaluation of therapies with potential for treatment of intracellular M. tuberculosis infections in humans. For purposes of preparing a cost proposal, the Offeror should assume a total of 1000 therapies would be evaluated per year. Combination studies should not be included in the cost estimations. Quantifiable measures of cytotoxicity due to the test compounds must be proposed.

**NOTE 4 TO OFFEROR**: This note is linked to work statement items # 1, #2, #3 and #4 of work statement Part A and to work statement items #1 and #2 of work statement Part B. For the purposes of preparing a proposal, the Offeror should propose one (1) assay system for each of these work statement items. For work statement Part A, these systems must be in place and immediately available upon award of a contract. For work statement Part B, specific assays must be proposed for development or immediate implementation. Alternative assays should be described and discussed for possible implementation in both parts, but no costs for the alternative assays should be included in the business proposal. It is conceivable that new test systems may emerge in the scientific literature during the project period or new systems may need to be developed in order to study specific aspects of candidate therapies. Because the Government does not know if or what alternative assays are likely to be needed, no costs or effort should be included in the cost proposal. It is expected that any necessary modifications of the evaluation system will not increase the negotiated contract cost. The Offeror shall include in the proposal some documentation of ability to modify or develop new assays with specific examples of emerging technologies potentially adaptable to microbiological screens.

**NOTE 5 TO OFFEROR**: This note is linked to work statement item #5 of work statement Part A and Part B. The Offeror shall include a Safety and Health Plan for compliance with Biosafety Level 3 guidelines in the Technical proposal and include a summary of the Offeror's safety and health operating procedures manual. See Attachment A.1 for the DHHS safety and health clause (proposed), which will become part of any resultant contract. Written documentation from a biosafety officer (or equivalent) should be provided (e.g., a safety management program) to assure compliance with all safety guidelines and regulations, training and monitoring of personnel for exposure to infectious or hazardous reagents, and safe disposal of such agents.

**NOTE 6 TO OFFEROR**: This note is linked to work statement item #6 of work statement Part A and Part B. For the purposes of preparing a cost proposal, assume receipt of approximately 12 shipments per year. The Offeror shall establish a mechanism for prompt notification of the Project Officer of the dates compounds were received. The Offeror shall include details of the proposed notification mechanism and plan in the Technical Proposal.

**NOTE 7 TO OFFEROR**: This note is linked to work statement item #7 of work statement Part A and Part B. The Offeror should propose a plan for efficient data management and retrieval, as well as for electronic digital communication (including the ability to transmit and receive electronic mail) with the Division of AIDS computer network system. The Government will not authorize purchase of stand-alone computers under this contract for this purpose. The NIAID is connected to the INTERNET and uses IBM-compatible computer hardware for data management and communication. The Offeror should supply an IBM-compatible computer and should submit electronic reports in Microsoft Word version 7.0 for Windows and Microsoft Excel version 7.0 for Windows. For the purpose of preparing a cost proposal, the Offeror should assume that monthly reports will be submitted each containing one table of identifiers and data. The Offeror should also include costs for quarterly reports and one final report. Guidelines for preparing reports are in Reporting Requirements and Deliverables.

For the purpose of preparing a cost proposal, assume a minimum of 3 visits of one key personnel per year to 6700-B Rockledge Drive, Bethesda, MD 20817 to meet with the Project Officer for one day and attendance of one key personnel for four days at the annual meeting of the National Cooperative Drug Discovery Groups for the Treatment of Opportunistic Infections to be held in the greater Washington, D.C. area.

**NOTE 8 TO OFFEROR**: This note is linked to work statement item #8 of work statement Part A and Part B. An Advance Understanding will be inserted in any resultant contract, stating the following: 1. The Contractor agrees that manuscripts/abstracts based on data/information generated under this contract shall not be submitted for publication until written Project Officer clearance has been received. A "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information; and 2. The Contractor agrees they will operate in accordance with the Government regarding the confidential nature of information provided by contributing suppliers or through the Project Officer under the standard "Screening Agreement for Submitting Products to the Division of AIDS' (See the Sample Screening Agreement RFP Attachment ?)

**NOTE 9 TO OFFEROR**: This note is linked to work statement item #8 of work statement Part A and Part B. Because the Contractor(s) will be handling compounds that are to be provided by third-party suppliers, there are some special considerations the Contractor(s), the Supplier(s) and the NIAID will need to make regarding the patent rights and data rights assignments under this effort. These special issues are being addressed by the NIAID with the planned inclusion of patent and data rights clauses prepared with language that deviates from their original text. See RFP Attachments. The Department of Health and Human Services has approved the text of these clauses. NIAID plans to seek a Determination of Exceptional Circumstances (DEC) which will be approved by the NIH Director (prior to award) to allow their inclusion in the contract(s), in addition to the standard clauses FAR 52.227-11, Patent Rights – Retention by the Contractor (Short Form) [June 1997] and FAR 52.227-14, Rights in Data – General (June 1987). Offerors should carefully read these clauses and understand their significance and impact on the proposed effort.

# REPORTING REQUIREMENTS AND DELIVERABLES

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**REPORTING REQUIREMENTS AND DELIVERABLES**

The Contractor shall submit technical progress reports covering the work accomplished during each reporting period. Distribution of written reports is listed below in paragraph E.

A. Monthly Reports. A high degree of interaction, cooperation, and communication will be required by the Contractor and the Contractor for the Tuberculosis Antimicrobial Acquisition and Coordinating Facility (TAACF). Therefore, reporting requirements will include reports to be exchanged between the contracts as well as to the Project Officer. The following represent the minimum requirements:

1. The Contractor shall submit a shipment receipt summary to the Contractor for the Tuberculosis Antimicrobial Acquisition and Coordinating Facility and the Project Officer every month by the fifteenth calendar day of the month. This summary will include details of all shipments received during the previous calendar month such as the shipment number, compound code identifiers, condition of compound received (including color), the date of receipt, and microbiological data generated on each compound, and assay identifier(s). This report shall be submitted both as one paper copy and as digital computer files on a 3.5 inch high density diskette or through modem transfer to Contractor for the Tuberculosis Antimicrobial Acquisition and Coordinating Facility and the Project Officer. The computer files must be compatible with the Division of AIDS, Therapeutics Research Program (TRP) Tuberculosis Database software (ISIS /Base) and appropriate licensing or software purchases shall be provided by the Contractor.

B. Quarterly Reports. By the fifteenth calendar day after completion of each quarter, the Contractor shall submit 2 paper copies of the progress report of work performed in the previous quarter AND 2 copies on magnetic media as computer files in Microsoft Word™ version 7.0 for Windows for text and Excel™ version 7.0 for Windows for tables and ISIS/Base format readable using an IBM-type personal computer. It remains the responsibility of the Contractor to assure receipt by the indicated government official listed below of all reports by the established due dates. A quarterly report is not required in the quarter that the final report is due. Quarterly reports shall be submitted in addition to monthly reports.

Each quarterly report shall consist of:

1. A cover page containing:

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

2. A table of contents indicating page number for each major section.

3. Summary of all compounds acquired and test results obtained during the quarter.

4. Cumulative summary of all compounds acquired and test results obtained under the contract.

5. Summary of current technical or administrative problems encountered, their resolution or the proposed corrective action.

6. Reports from meetings attended and contacts with potential compound suppliers.

7. Recommendations to the project officer of the most promising compounds evaluated in comparison to known TB drugs.

C. Final Report

The Contractor shall submit 4 paper copies of the final report which documents and summarizes the results of the entire contract for the period of performance AND as 1 copy on digital, magnetic media as computer files in Microsoft Word™ version 7.0 for Windows for text and Excel™ version 7.0 for Windows for tables readable using an IBM-type personal computer, or as specified by the Project Officer. This report will provide a final inventory and contain a cover page described in B.1. above and the information required in B.2. through B.5. above. The final report shall be submitted by the completion date of the contract.

D. Other Deliverables. The Contractor, subject to Project Officer approval shall deliver to the Government or its designee by the completion date of the contract, the following items (with the exception of item (4) which shall be delivered by the end of the fourth year or earlier as directed by the Project Officer).

(1) A computer-generated listing of accurate and updated information on compound inventory, including activities of the Contractor, data files, original data and any necessary information related thereto;

(2) Labeled and inventoried paper files;

(3) Any other government-owned property;

(4) The transition plan required in item #9 of the Work Statement;

(5) One complete copy of the final, updated and verified Tuberculosis Database as a computer file;

(6) A written assurance from the authorized institutional official that all files containing data relating to this contract have either been transferred or destroyed.

E. Technical Reports Distribution

| Deliverable | No. of Copies | Addressee/Distribution | Due Dates |
|---|---|---|---|
| Quarterly | *1 | Project Officer,<br>Division of AIDS, NIAID<br>6700-B Rockledge Drive, MSC 7624<br>Bethesda, MD 20892-7624 | Quarterly |
| Quarterly | *Original | Contracting Officer,<br>CMB, DEA, NIAID<br>6700-B Rockledge Drive; MSC 7612<br>Bethesda, MD 20892-7612 | Quarterly |
| Monthly | *1 | Same as Project Officer above | Monthly |
| | *1 | Contractor site to be identified** | Monthly |
| Final | *3 | Same as Project Officer above | completion date |
| Final | *Original | Same as Contracting Officer above | completion date |

* Plus one copy on 3.5 inch, high density computer diskette or other digital medium approved by the Project Officer.
** Tuberculosis Drug Development: Tuberculosis Antimicrobial Acquisition and Coordinating Facility.

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

# TECHNICAL EVALUATION FACTORS FOR AWARD

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## 1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against THREE factors. The factors in order of importance are: Technical, Cost/Price, and Small Disadvantaged Business (SDB) Participation. Although technical factors are of paramount consideration in the award of the contract, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

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.

Proposals submitted in response to this solicitation will be subjected to review by an ad hoc technical review committee. 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 merit of each proposal will be evaluated carefully, based on responsiveness to the RFP and thoroughness and feasibility of the technical approach taken. Offerors must submit information sufficient to evaluate their proposal based on the detailed criteria listed below. Failure to provide the information required to evaluate the proposal may result in rejection of that proposal without further consideration. While high competency is sought, capabilities that exceed those needed for successful performance of the contract work statement are not requested.

## 2. MANDATORY QUALIFICATION CRITERIA

***The following qualification criterion establishes conditions that must be met at the time of Final Proposal Revision submission in order for proposals to be considered for award:***

Offerors must provide documentation that appropriate facilities are available for that portion of the project utilizing virulent *M. tuberculosis* to be conducted at Biosafety Level 3 as described in Biosafety in Microbiological and Biomedical Laborat ories, Centers for Disease Control and Prevention and the National Institutes of Health, fourth edition, HHS Pub. No. (CDC) 93-8395 published by the U.S. Government Printing Office, May 1999, stock number 17-040-00547-4. The documentation shall include a signed statement by the institutional official authorized to commit to a contractual agreement that the proposed work plan, staff biosafety training plan, and risk assessment evaluation have been reviewed and approved by the Institutional Biosafety Committee. A listing of the committee's membership with names, titles, and affiliations and a copy of the approval memorandum or letter from the committee chair must be included.

## 3. COMPARATIVE IMPORTANCE OF PROPOSALS

The technical proposal will receive paramount consideration in the selection of the Contractor(s) for this acquisition, but not to the exclusion of cost or price. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. During the source selection process, the closer that offerors are determined to be in technical ability, the greater the importance of cost or price. When offerors are considered to be essentially equal in technical ability, a greatest value analysis will be conducted to determine the award.

The Government reserves the right to make an award based on the greatest value to the Government in terms of cost or price, and other factors.

## 4. PROPOSAL EVALUATION CRITERIA

Proposals submitted in response to this RFP will be evaluated based on the following factors that are listed and weighted in order of their relative importance. Proposals will be judged solely on the written material provided by the offeror. It is anticipated that one award per part will be made as a result of this acquisition, dependent on the availability of funds.

| CRITERIA | WEIGHT |
|---|---|
| **1. <u>Technical Approach</u> (55 points)**<br><br>The technical adequacy and feasibility of the approach presented in the technical proposal, as reflected in the documentation provided including the alternative strategies and relevant experience, for:<br><br>**(a) Understanding of the problem**<br><br>o Evidence of understanding of the proposed project and of the disease;<br>o Evidence of understanding of the anti-infective drug development process;<br>o Adequacy of understanding of the metabolism and pathobiology of *M. tuberculosis*, particularly related to interpretation of preclinical drug evaluations;<br>o Adequacy of plans for protection of confidential and proprietary information;<br>o Demonstrated skill in developing and validating screening assays.<br><br>**(b) Suitability of procedures**<br><br>o Appropriateness, technical design, and reproducibility of assay(s) proposed for work statement item #1;<br>o Appropriateness, technical design, and reproducibility of assay(s) proposed for work statement item #2;<br>o Appropriateness, technical design, and reproducibility of assay(s) proposed for work statement item #3; | **<u>55 Points</u>**<br><br>**25 Points**<br><br>**30 Points** |
| **2. <u>Personnel Qualifications</u> (35 points)**<br><br>**(a) Principal Investigator:**<br><br>o Relevance and quality of recent work;<br>o Demonstrated experience with technical approaches required;<br>o Documented availability for the proposed project;<br>o Documented experience with managing projects of similar complexity.<br><br>**(b) Other personnel/staffing plan**<br><br>o Relevance and extent of experience of other professional and research technical and support staff and their documented capability to conduct proposed studies;<br>o Documented experience in similar projects and appropriate computer skills;<br>o Adequacy of the staffing plan, including clear lines of authority and the time commitment of the professional and technical staff, for the conduct of the project. | **<u>35 Points</u>**<br><br>**20 Points**<br><br>**15 Points** |

| **3. Facilities and Resources (10 points)** | **10 Points** |
|---|---|
| (a) Documented availability of adequate facilities (suitable office, computer, and laboratory space), equipment, and resources necessary to meet the requirements of the RFP.<br><br>Note: A detailed floor plan of the proposed facility which shows location of the equipment and resources to be dedicated to this project MUST be provided.<br><br>(b) Adequacy of plans for compliance with all safety guidelines and regulations, including training and monitoring of personnel for exposure to hazardous chemical and biological agents, and safe disposal of such agents.<br><br>(c) Documentation of facilities to receive and store compounds, and maintain their stability. | |
| **TOTAL** | **100 Points** |

**5. EVALUATION OF TARGETS FOR EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

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

The extent of the offeror's Small Disadvantaged Business (SDB) Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

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

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

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

# SECTION I. GENERAL CLAUSES

[Return to Table of Contents]

**ARTICLE I.1. GENERAL CLAUSES FOR A 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:

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| 52.203-5 | Apr 1984 | Covenant Against Contingent Fees (Over $100,000) |
| 52.203-6 | Jul 1995 | Restrictions on Subcontractor Sales to the Government (Over $100,000) |
| 52.203-7 | Jul 1995 | Anti-Kickback Procedures(Over $100,000) |
| 52.203-8 | Jan 1997 | Cancellation, Rescission, 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 | Aug 2000 | Printed or Copied 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 | Jul 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 NO. | DATE | TITLE |
|---|---|---|
| 352.202-1 | Apr 1984 | Definitions - Alternate I (Apr 1984) |
| 352.228-7 | Dec 1991 | Insurance - Liability to Third Persons |
| 352.232-9 | Apr 1984 | Withholding of Contract Payments |
| 352.233-70 | Apr 1984 | Litigation and Claims |
| 352.242-71 | Apr 1984 | Final Decisions on Audit Findings |
| 352.270-5 | Apr 1984 | Key Personnel |
| 352.270-6 | Jul 1991 | Publication and Publicity |
| 352.270-7 | Apr 1984 | Paperwork Reduction Act |

[ End of GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT - Rev. 9/2000].

**ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)**

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

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| 52.203-6 | 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, Rescission, 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 | Aug 2000 | Printed or Copied Double-Sided on Recycled Paper (Over $100,000) |
| 52.209-6 | Jul 1995 | Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000) |
| 52.215-2 | Jun 1999 | Audit and Records - Negotiation (Over $100,000), Alternate II (Apr 1998) |
| 52.215-8 | Oct 1997 | Order of Precedence - Uniform Contract Format |
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| 52.215-15 | Dec 1998 | Pension Adjustments and Asset Reversions |
| 52.215-18 | Oct 1997 | Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions |
| 52.215-19 | Oct 1997 | Notification of Ownership Changes |
| 52.215-21 | Oct 1997 | Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data – Modifications |
| 52.216-7 | Mar 2000 | Allowable Cost and Payment (Paragraph (a) is modified to delete the words "Subpart 31.2" and to add the words "Subpart 31.3") |
| 52.216-11 | Apr 1984 | Cost Contract - No Fee |
| 52.219-8 | Oct 1999 | Utilization of Small Business Concerns (Over $100,000) |
| 52.219-9 | Oct 1999 | Small Business Subcontracting Plan (Over $500,000) |

| | | |
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| 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 |
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| 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 | Jul 2000 | Restrictions on Certain Foreign Purchases |
| 52.227-1 | Jul 1995 | Authorization and Consent, Alternate I (Apr 1984) |
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| 52.249-5 | Sep 1996 | Termination for the Convenience of the Government (Educational and Other Nonprofit Institutions) |
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[ End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS – Rev. 9/2000].

**ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH NONPROFIT ORGANIZATIONS OTHER THAN EDUCATIONAL INSTITUTIONS - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)**

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| 52.245-5 | Jan 1986 | Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract), Alternate I (Jul 1985) |
| 52.246-23 | Feb 1997 | Limitation of Liability (Over $100,000) |
| 52.249-5 | Sep 1996 | Termination for the Convenience of the Government (Educational and Other Nonprofit Institutions) |
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| 352.242-71 | Apr 1984 | Final Decisions on Audit Findings |
| 352.249-14 | Apr 1984 | Excusable Delays |
| 352.270-5 | Apr 1984 | Key Personnel |
| 352.270-6 | Jul 1991 | Publication and Publicity |
| 352.270-7 | Apr 1984 | Paperwork Reduction Act |

[ End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH NONPROFIT ORGANIZATIONS OTHER THAN EDUCATION INSTITUTIONS - Rev. 9/2000].

# SECTION J
# LIST OF ATTACHMENTS

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

- How to Prepare and Submit an Electronic Proposal
- Packaging and Delivery of Proposals
- Proposal Intent Response Sheet ***Submit on/before:*** **Monday, December 4, 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.

- FAR 52.227-11 Patent Rights – Retention by the Contractor (Short Form) (June 1997) (NIAID Deviation) **AND** FAR 52.227-14 Rights in Data – General (NIAID Deviation)
- Sample Screening Agreement

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

### *Applicable to Business Proposal*

- **NIH-2043, Proposal Summary and Data Record**
- **Small Business Subcontracting Plan** *[if applicable]*
- **Summary of Proposed Estimated Cost (plus fee) and Labor Hours**
- **Detailed Breakdown of Proposed Costs (Excel cost spreadsheet template)**
- **Offeror's Points of Contact**

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

- **Annual Technical Progress Report Format for Each Study** *[Applicable when contract involves Human Subjects unless it has been determined by the Government that the inclusion of Women and Minority Groups in the Study Population is not appropriate.]*
- **NIH(RC)-1: Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH(RC)-2: Invoice Instructions for NIH Fixed-Price Contracts**
- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **Procurement of Certain Equipment, NIH(RC)-7 (OMB Bulletin 81-16)**
- **NIH(RC)-11: Research Patient Care Costs**
- **NIH-2706: Financial Report of Individual Project Contract**
- **Instructions for Completing Form NIH-2706**
- **Privacy Act System of Records, #09-25-0200**
- **Safety and Health (Deviation), PHS Clause 352.223-70**
- **Sample Screening Agreement**
- **FAR 52.227-11 Patent Rights – Retention by the Contractor (Short Form) (June 1997) (NIAID Deviation) and FAR 52.227-14 Rights in Data – General (NIAID Deviation)**

## 52.227.11 Patent Rights (Deviation) [Return to List of Attachments]

This clause deviation applies to discoveries resulting from routine screening activities involving the use of proprietary compounds. Discoveries resulting from research activities pertaining to the development of new screening assays or other unanticipated discoveries developed by the Contractor without the use of proprietary compounds will be covered by the standard patent rights clause [FAR 52.227-11, Patent Rights – Retention by the Contractor (Short Form) (June 1997)]

Definitions. (1) "Invention" means any invention or discovery which is or may be patentable or otherwise protectable under title 35 of United States Code, or any novel variety of plant which is or may be protected under the Plant Variety Protection Act (7 U.S.C. 2321, et. seq.)

"Made" when used in relation to any invention means the conception or first actual reduction to practice of such invention.

"Nonprofit organization" means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

"Practical application" means to manufacture, in the case of a composition or product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

"Small business firm" means a small business concern as defined at section 2 of Pub. L. 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this clause, the size standards for small business concerns involved in Government procurement and subcontracting at 13 CFR 121.3-8 and 13 CFR 121.3-12, respectively, will be used.

"Subject invention" for the purpose of this clause means any invention of the contractor conceived or first actually reduced to practice in the performance of work under this contract, provided that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act, 7 U.S.C. 2401(d)) must also occur during the period of contract performance. It does not refer to research activities that lead to the development of new screening assays or other discoveries not directly related to the scope of this contract. These new screening assays or other unanticipated discoveries developed by the contractor without the use of proprietary compounds will not be subject to the provisions of this deviation but will be covered by the standard Patent Rights Clause which is also incorporated in this contract.

"Compound Suppliers" means any entities or organizations designated by the NIAID that supply to NIAID a product, patented or unpatented, which may be submitted for screening and testing for possible treatment of viral diseases including HIV and associated opportunistic infections.

"NIAID" means the National Institute of Allergy and Infectious Diseases of the National Institutes of Health (NIH).

"NIH" means the National Institutes of Health.

Allocation of principal rights.

Retention of pre-existing rights. Compound Suppliers shall retain all preexisting rights to those compounds in which the compound supplier has a proprietary interest.

Assignment to the NIH or Compound Supplier. The Contractor agrees to assign to the NIH or to a Compound Supplier designated by the NIAID, the entire right, title, and interest throughout the world to each subject invention except to the extent that rights are retained by the Contractor under subparagraph (b)(3) of this clause and subject to a nonexclusive, nontransferable, irrevocable, paid-up license to the United States government to practice or have practiced the subject invention for or on behalf of the United States throughout the world.

Greater Rights Determinations. The Contractor, or an employee-inventor after consultation by the NIAID with the Contractor, may request greater rights to an identified subject invention of the contract in accordance with the procedures of FAR paragraph 27.304-1(b) (and FAR paragraph 27.304-1(c) in the case of an employee-inventor). The NIAID is more likely to grant greater rights if the compound is proprietary to the Government or the supplier is not interested in developing the invention. In addition to the considerations set forth in paragraph 27.304-1(b), NIAID will consider whether granting the requested greater rights will interfere with rights of the Government or any Compound Supplier or otherwise impede the ability of the Government or the Compound Supplier to develop and commercialize new compounds, dosage forms, therapies, technologies or other approaches with potential for the treatment of viral diseases including HIV and associated infections in a rapid, efficient, and cost effective manner. A request for a determination of whether the Contractor or the employee-inventor is entitled to retain such greater rights must be submitted to the NIAID Contracting Officer at the time of the first disclosure of the invention pursuant to subparagraph (c)(1) below, or not later than eight (8) months thereafter, unless a longer period is authorized in writing by the Contracting Officer for good cause shown in writing by the Contractor. Each determination of greater rights under this contract shall be subject to paragraph (c) of the FAR clause at 52.227-13, and to any reservations and conditions deemed to be appropriate by NIAID such as the requirement to assign or exclusively license the rights to subject inventions to the Compound Supplier. A determination by NIAID denying a request by the Contractor for greater rights in a subject invention may be appealed within 30 days of the date the Contractor is notified of the determination to an agency official at a level above the individual who made the determination. If greater rights are granted, the Contractor must file a patent application of the invention. Upon request, the Contractor shall provide the filing date, serial number and title, a copy of the patent application (including an English-language version if filed in a language other than English), and patent number and issue date for any subject invention in any country for which the Contractor has retained title. Upon request, the Contractor shall furnish the Government an irrevocable power to inspect and make copies of the patent application file.

Invention disclosure by Contractor.

The Contractor will disclose each subject invention to the NIAID Contracting Officer as provided in paragraph (j) within two months after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure to the NIAID Contracting Officer shall be in the form of a written report and shall identify the contract under which the invention was made and the inventor(s). It shall be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale (offer for sale), or public use of the invention and whether a manuscript describing the invention has been submitted for publication and, if so, whether it has been accepted for publication at the time of disclosure. In addition, after disclosure to the agency, the Contractor will promptly notify the agency of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the Contractor.

Contractor action to protect the Government’s interest in the event greater rights are granted to the Contractor.

The Contractor agrees to execute or to have executed and promptly deliver to the NIH all instruments necessary to—(i) Establish or confirm the rights the Government has throughout the world in subject inventions pursuant to paragraph b.2. above, and (ii) Convey title to the NIH or to a Compound Supplier when requested under paragraph b.2. of this clause and to enable the NIH or a Compound Supplier to obtain patent protection throughout the world in that subject invention.

The Contractor agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the Contractor, each subject invention made under contract in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on subject inventions and to establish the Government’s rights or a Compound Supplier’s rights in the subject inventions. This disclosure format should require, as a minimum, the information required by subparagraph (c)(1) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars. The Contractor will notify the NIH of any decisions not to continue the prosecution of a patent application, pay maintenance fees, or defend in a reexamination or opposition proceeding on a patent, in any country, not less than 30 days before the expiration of the response period required by the relevant patent office.

The Contractor agrees to include, within the specification of any United States patent application it files and any patent issuing thereon covering a subject invention the following statement, “This invention was made with Government support under (identify the Contract) awarded by the National Institute of Allergy and Infectious Diseases. The Government has certain rights in the invention.”

The Contractor agrees to provide a final invention statement and certification prior to the close-out of the contract listing all subject inventions or stating that there were none.

(e) Subcontracts. (1) The Contractor will include this clause, suitably modified to identify the parties, in all subcontracts, regardless of tier, for experimental, developmental, or research work. The subcontractor will retain all rights provided for the Contractor in this clause, and the Contractor will not, as part of the consideration for awarding the contract, obtain rights in the subcontractor's subject inventions.

In the case of subcontracts, at any tier, NIH, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and NIH with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (c)(1)(ii) of FAR clause 52.227-13 which is incorporated by reference in paragraph b.3. of this clause.

Reporting on utilization of subject inventions in the event greater rights are granted to the Contractor. The Contractor agrees to submit, on request, periodic reports no more frequently than annually on the utilization of a subject invention or on efforts at obtaining such utilization that are being made by the Contractor or its licensees or assignees when a request under subparagraph b.3. has been granted by the NIH. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and such other data and information as the agency may reasonably specify. The Contractor also agrees to provide additional reports as may be requested by the NIH in connection with any march-in proceeding undertaken by the NIH in accordance with paragraph (h) of this clause. As required by 35. U.S.C. 202(c)(5), the NIH agrees it will not disclose such information to persons outside the Government without permission of the Contractor.

Preference for United States industry in the event greater rights are granted to the Contractor. Notwithstanding any other provision of this clause, the Contractor agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any product embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the NIH upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

March-in rights in the event greater rights are granted to the Contractor. The Contractor agrees that, with respect to any subject invention in which it has acquired title through the exercise of the rights specified in subparagraph (b)(3), the NIH has the right in accordance with the procedures in FAR paragraph 27.304-1 and any supplemental regulations of the agency to require the Contractor, an assignee or exclusive licensee of a subject invention to grant a nonexclusive, partially exclusive, or exclusive license in any field of use to a responsible applicant or applicants, upon terms that are reasonable under the circumstances, and if the Contractor, assignee, or exclusive licensee refuses such a request, the NIH has the right to grant such a license itself if the NIH determines that—

Such action is necessary because the Contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention in such field of use;

Such action is necessary to alleviate health or safety needs which are not reasonably satisfied by the Contractor, assignee, or their licensees;

Such action is necessary to meet requirements for public use specified by Federal regulations and such requirements are not reasonably satisfied by the Contractor, assignee, or licensees; or

Such action is necessary because the agreement required by paragraph (g) of this clause has not been obtained or waived or because a licensee of the exclusive right to use or sell any subject invention in the United States is in breach of such agreement.

Special provisions for contracts with nonprofit organizations in the event greater rights are granted to the Contractor. If the Contractor is a nonprofit organization, it agrees that—

Rights to a subject invention in the United States may not be assigned without the approval of the NIH, except where such assignment is made to an organization which has as one of its primary functions the management of inventions; provided, that such assignee will be subject to the same provisions as the Contractor;

The Contractor will share royalties collected on a subject invention with the inventor, including the Federal employee co-inventors (when the NIH deems it appropriate) when the subject invention is assigned in accordance with 35 U.S.C. 202(3);

The balance of any royalties or income earned by the Contractor with respect to subject inventions, after payment of expenses (including payments to inventors) incidental to the administration of subject inventions will be utilized for the support of scientific research or education; and

It will make efforts that are reasonable under the circumstances to attract licensees of subject inventions that are small business firms, and that it will give a preference to a small business firm when licensing a subject invention if the Contractor determines that the small business firm has plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business firms; provided, that the Contractor is also satisfied that the small business firm has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor. However, the Contractor agrees that the Secretary of Commerce may review the Contractor's licensing program and decisions regarding small business applicants, and the Contractor will negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the Contractor would take reasonable steps to more effectively implement the requirements of this subparagraph.

Communications. All invention disclosures and requests for greater rights shall be sent to the NIAID Contracting Officer. Additionally, a copy of all disclosures, confirmatory licenses to the Government, face page of the patent applications, waivers and other routine communications should be sent to Dr. George Stone, Office of Policy for Extramural Research Administration, Division of Extramural Invention and Technology Resources, National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Room 3190, MSC 7750, Bethesda, MD 20892-7750.

(End of clause)

## Rights in Data – General (Deviation)

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This clause deviation applies to discoveries resulting from routine screening activities involving the use of proprietary compounds. Data resulting from research activities pertaining to the development of new screening assays or other activities involving the use of non-proprietary compounds will be covered by the standard Rights in Data clause [FAR 52.227-14, Rights in Data – General (June 1987)]

*ADD THE FOLLOWING DEFINITION TO PARAGRAPH (a) OF THIS CLAUSE:*

*"Research compound" as used in this clause means patented or unpatented products or compounds to be used for screening and testing as anti-viral, anti-bacterial, anti-fungal, anti-parasitic, immunomodulating, and biological modifying agents with potential for the treatment of viral diseases including HIV and associated infections.*

*MODIFY PARAGRAPH (d) OF THIS CLAUSE TO READ:*

Release, publication and use of data. *(1) The Contractor shall have the right to use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of this contract, except to the extent such data may be subject to the Federal export control or national security laws or regulations. However, in order that information concerning possible inventions made under this contract is not prematurely published thereby adversely affecting the ability to obtain patent protection on such inventions, the Contractor will advise the NIAID Contracting Officer of any proposed publications or public disclosures relating to the work performed under this contract. Upon the NIAID Contracting Officer's request, the Contractor agrees to delay the public disclosure of such data or publication of a specified paper for a reasonable time specified by the Contracting Officer, not to exceed 6 months, to allow for the filing of domestic and international patent applications in accordance with Clause 52.227-11, Patent Rights (Deviation).*

*ADD THE FOLLOWING PARAGRAPH (j) TO THIS CLAUSE:*

*(j)* Research products or compounds. *The Contractor agrees that in accordance with paragraph (d)(2) proprietary information on research products or compounds, patented or unpatented, provided through this contract shall be used only for screening and testing as anti-viral, anti-bacterial, anti-fungal, anti-parasitic, immunomodulating, and biological modifying agents with potential for the treatment of viral diseases including HIV and associated infections and for no other purpose.*

# (SAMPLE) SCREENING AGREEMENT

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1. The organization providing compounds for evaluation _____ (SUPPLIER), may supply products, patented or unpatented, to the Division of AIDS (DIVISION), which may then screen and test them for possible treatment of mycobacterial infections including tuberculosis. If agreed to in writing by the SUPPLIER and the DIVISION, but not unless such written agreement is obtained, these products may also be entered into screening and testing as antiviral, antibacterial, antifungal, antiparasitic, immunomodulating, and biological modifying agents with potential for treatment of AIDS and associated opportunistic infections.

   Using protocols evaluated and approved mutually by the DIVISION and the SUPPLIER, the products will be screened by one or more of the DIVISION's contract testing laboratories (SCREENING CONTRACTORS), but will not be placed in the laboratories of any company in or affiliated with the pharmaceutical or chemical industries without the SUPPLIER's written permission.

2. In order to facilitate record keeping and handling of confidential materials, the following procedures will be used by the DIVISION:

   a. The SUPPLIER shall forward to the acquisition contractor (Southern Research Institute, hereafter referred to as SOUTHERN) the products to be tested together with data sheets in duplicate for each product, giving pertinent available data as to chemical constitution, stability, solubility, toxicity, previous biological efficacy and any precautions that need to be followed in handling, storing, shipping and/or testing.

   b. It is clearly understood that no data about the products, whether provided by the SUPPLIER or generated by the DIVISION or SOUTHERN, and the results of the testing will be kept in any files open to the public either by the DIVISION, SCREENING CONTRACTORS, or SOUTHERN. Only those employees directly engaged in the operation of the DIVISION will have access to the files of information regarding source and nature of confidential materials and results of testing, except as required pursuant to the Freedom of Information Act, 5 U.S.C. 552. In no case will information properly designated as proprietary or confidential by the SUPPLIER need to be released under this Act.

   c. Whenever possible, the SUPPLIER will be given the choice of the DIVISION's SCREENING CONTRACTORS, although at present there is no preference; and, it is understood that the DIVISION reserves the right to send the SUPPLIER's products to other SCREENING CONTRACTORS if the need arises. It is furthermore understood that the contracts between the DIVISION and the SCREENING CONTRACTORS will contain provisions to safeguard the SUPPLIER's rights under this Agreement.

   d. Because the DIVISION's screening effort will be accomplished in collaboration with the DIVISION's scientific staff and SOUTHERN's project team, as well as the SUPPLIER's own staff, the DIVISION will use its best efforts to facilitate rapid ongoing communications of screening data to the SUPPLIER.

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

   a. It is understood and agreed to, subject to applicable law, that the SUPPLIER shall retain all rights to those products in which the SUPPLIER has a proprietary interest. To clarify, the finding of activity in the designated screens does not result in any intellectual property rights for SOUTHERN or the SCREENING CONTRACTORS. The DIVISION agrees to notify the SUPPLIER of the names of the SCREENING CONTRACTORS prior to submitting SUPPLIER’s products to them. Subject notwithstanding, to the provision that, with respect only to those products determined by means of the various screening and testing processes to possess such significant activity (strong potential to be scheduled for clinical trial by the DIVISION, using mutually approved protocols), the U. S. Government shall have a royalty-free irrevocable, nonexclusive license for clinical trials under any patent that the SUPPLIER may have or obtain on such product or on a process for use of such product, to manufacture and/or use by or for the U. S. Government the invention(s) claimed by the patent(s) only for medical research purposes related to the treatment of mycobacterial infections including tuberculosis.

b. The DIVISION and SUPPLIER agree that publication of screening results is worthwhile and should be governed by the following. Specifically:

1) With regard to screening results on compounds in which the SUPPLIER has a proprietary interest, and that the DIVISION deems significant for research on mycobacterial infections including tuberculosis, the SUPPLIER agrees that the DIVISION may publish or otherwise disclose such results only with the written permission of the SUPPLIER, and that the SUPPLIER will not unreasonably withhold such permission. SUPPLIER in that regard agrees to pursue appropriate patent coverage in a timely manner, or to allow the U. S. Government to do so.

2) The SUPPLIER will inform the DIVISION prior to publishing screening data along with the available biological and physical data; appropriate credit shall be given to the U. S. Public Health Service.

3) In no case will the DIVISION publish information identifying the SUPPLIER as the source of a product without written approval from the SUPPLIER; appropriate credit shall be given to the SUPPLIER.

c. Following the receipt of complete test results by the DIVISION, the SUPPLIER will receive in a timely manner a full report including all screening data. The products scheduled for clinical trial, referred to herein under paragraph 3a, shall be designated by the DIVISION, and the aforementioned report will specify the products so selected. The SUPPLIER has the right to proceed with clinical trials in a timely manner at its own expense. The DIVISION agrees to assist the SUPPLIER with assessing the clinical potential of candidate compounds.

The DIVISION is confident that this agreement will lay the basis for mutually satisfactory cooperation in the field and in the treatment of mycobacterial infections including tuberculosis.

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

| | |
|---|---|
| ***John Y. Killen, M.D.*** | ***Name*** |
| Director, Division of AIDS | |
| NIAID, NIH | |
| | Title |
| Date | Company |
| | Address |
| | Address |
| | Date |

## HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

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**Detailed information regarding the electronic process for submission of proposals may be accessed through the CMB Hompage at the following website by clicking on "E-Proposals". http://www.niaid.nih.gov/contract/default.htm**

**PAGE LIMITS -- THE NARRATIVE PORTION OF THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 50 PAGES. The entire APPENDICES, (i.e., ATTACHMENTS, pertinent portions of any OPERATING MANUALS, NON-SCANNABLE FIGURES OR DATA, LETTERS OF INTENT, ETC.), SHALL NOT EXCEED 50 PAGES. CURRICULUM VITAEs (CVs) SHALL NOT EXCEED Two (2) PAGES. Any documentation or portions thereof which the offeror wishes to include as part of the Appendices, which are not able to be scanned (for submission electronically) may be provided in hardcopy, no more than ten (10) copies with the original technical proposal.**

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

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

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

- **Technical Proposal: c:\rfpdaids0113techprop.pdf**
- **Business Proposal: c:\rfpdaids0113busiprop.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 above. For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 3.0.**

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

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

## PROPOSAL INTENT RESPONSE SHEET

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**RFP No.: NIH-NIAID-DAIDS-01-13**
**RFP Title: Microbiological Tuberculosis Drug Screening**

Please review the attached Request for Proposal. Furnish the information requested below and return this page on or before **December 4, 2000** . Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

**Since your proposal will be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.**

[ ] 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):**
_____
_____

***Name of individual to whom electronic proposal instructions should be sent:**

**Name:** _____
**Title:** _____
**E-Mail Address:** _____
**Telephone Number:** _____

**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: Eric Young
RFP-NIH-NIAID-DAIDS-01-13
FAX# (301) 402-0972
Email : cy39g@nih.gov

# PACKAGING AND DELIVERY OF THE PROPOSAL

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

Shipment and marking shall be as indicated below:

**A. EXTERNAL PACKAGE MARKING:**

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

**"RFP NO. NIH-NIAID-DAIDS-01-13**
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*** |
|---|---|
| Eric Young<br>Contract Specialist<br>Contract Management Branch, DEA<br>NIAID, NIH<br>6700-B Rockledge Drive, Room 2230<br>Bethesda, Maryland 20817 | Eric Young<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

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

1. REPRESENTATIONS AND CERTIFICATIONS

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

http://rcb.nci.nih.gov/forms/rcneg.pdf

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

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

# SECTION L
# INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

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## 1. GENERAL INFORMATION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed--in whole or in part--for any purpose other than to

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

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

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

(f) Contract award.

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

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

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

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

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

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

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

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

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

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

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

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

*(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the*

*number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.*

b. **REQUEST FOR INFORMATION OR SOLICITATION FOR PLANNING PURPOSES** [FAR 52.215-3 (October 1997)]

(a) The Government does not intend to award a contract on the basis of this solicitation or to otherwise pay for the information solicited except as an allowable cost under other contracts as provided in subsection 31.205-18, Bid and proposal costs, of the Federal Acquisition Regulation.

(b) Although "proposal" and "offeror" are used in this Request for Information, your response will be treated as information only. It shall not be used as a proposal.

(c) This solicitation is issued for the purpose of: [state purpose].

(End of provision)

c. **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.

d. **NOTICE OF 8(a) COMPETITIVE SET-ASIDE**

Offers are solicited only from small business concerns expressly certified by the Small Business Administration (SBA) for participation in the SBA's 8(a) Program. Bids or proposals received from others will be considered non-responsive.

e. **SIC CODE AND SIZE STANDARD**

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

(1) The standard industrial classification (SIC) code for this acquisition is 8731 .
(2) The small business size standard is 500 or more.

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

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

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

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

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

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

It is anticipated that MULTIPLE AWARD(S) will be made from this solicitation and that the award(s) will be made on/about **August 31, 2001** .

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

h. **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 5-year effort to be approximately 64,480 labor hours for Part A and approximately 24,960 labor hours for Part B. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

**Labor Hours – Part A**

| Labor Category | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Total |
|---|---|---|---|---|---|---|
| PI | 416 | 416 | 416 | 416 | 416 | 2,080 |
| Professional | 2080 | 2080 | 2080 | 2080 | 2080 | 10,400 |
| Support | 10,400 | 10,400 | 10,400 | 10,400 | 10,400 | 52,000 |
| **TOTALS** | **12,896** | **12,896** | **12,896** | **12,896** | **12,896** | **64,480** |

**Labor Hours – Part B**

| Labor Category | Year 1 | Year 2 | Year 3 | Year 4 | Year 5 | Total |
|---|---|---|---|---|---|---|
| PI | 416 | 416 | 416 | 416 | 416 | 2,080 |
| Professional | 416 | 416 | 416 | 416 | 416 | 2,080 |
| Support | 4,160 | 4,160 | 4,160 | 4,160 | 4,160 | 20,800 |
| **TOTALS** | **4,992** | **4,992** | **4,992** | **4,992** | **4,992** | **24,960** |

i. **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.

j. **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.

k. **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.

l. **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.

m. **PREPARATION COSTS**

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

n. **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 Institute 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)

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

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

(End of provision)

## 2. INSTRUCTIONS TO OFFERORS

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### a. GENERAL INSTRUCTIONS

**INTRODUCTION**

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

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

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

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

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

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions.

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

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

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

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

(5) **Alternate Proposals**

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

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

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

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

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

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

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

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

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

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

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

(7) **Evaluation of Proposals**

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

(8) **Potential Award Without Discussions**

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

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

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

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

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

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

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

(10) **Human Subjects**

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

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

a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protection (OHRP), Department of Health and Human Services [http://ohrp.osophs.dhhs.gov/index.htm]. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

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

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

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

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

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

(11) **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at http://ohsr.od.nih.gov/cbt/. This site may be downloaded at no cost and modified for use by the offeror, if desired. In addition, the University of Rochester has made available its training program for individual investigators, and completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at http://www.centerwatch.com/order/pubs_profs_protect.html. If an institution has already developed educational programs on the protection of research participants, completion of these programs will also satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the following written information to the contracting officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(15) **Care of Live Vertebrate Animals**

The following notice is applicable when contract performance is expected to involve care of live vertebrate animals:

**Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects - (SEPTEMBER 1985)**

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office for Protection from Research Risks (OPRR), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS

award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OPRR. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OPRR, OLAW, negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OPRR, OLAW, may be contacted at Rockledge Center I – Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at http://www.grants.nih.gov/grants/olaw/olaw.htm.

(16) **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.

(17) **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.

(18) **Small Business Subcontracting Plan**

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

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

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

c) The offeror understands that:

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

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

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

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

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

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

d) Each plan must contain the following:

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

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

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

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

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

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

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

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

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

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

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

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

(19) **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.

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

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized SIC Major Groups shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled “Extent of Small Disadvantaged Business Participation” as set forth under the **Technical Evaluation Criteria**, shall be used for evaluation purposes. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

The Department of Commerce determines, on an annual basis, by Major Groups, as contained in the Standard Industrial Classification (SIC) Manual, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The SIC codes can be found at: http://www.sba.gov/regulations/siccodes/siccodes.pdf or http://www.sba.gov/regulations/siccodes/siccodes.doc

The Department of Commerce website for the annual determination is: http://www.arnet.gov/References/sdbadjustments.htm .

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

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

EXAMPLE

Targets for SDB Participation - SIC Major Group 87

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

*Note: FAR Subpart 9.6 defines “Contractor team arrangements” to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(21) **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**

(22) **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.

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

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

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

(24) **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

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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

## a. BUSINESS PROPOSAL INSTRUCTIONS

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(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

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