

REQUEST FOR PROPOSALS NO. NIH-NINDS-05-02

DOMAIN SPECIFIC TASKS OF EXECUTIVE FUNCTION

DATE ISSUED: April 1, 2005

DATE DUE: May 31, 2005

LADIES AND GENTLEMEN:

The National Institute of Neurological Disorders and Stroke (NINDS), NIH, invites you to submit a proposal in accordance with the requirements of the attached Request for Proposals (RFP) No. NIH-NINDS-05-02.

THIS PROCUREMENT IS FOR FULL AND OPEN COMPETITION. WE ANTICIPATE THAT ANY RESULTANT AWARD WILL BE A COST REIMBURSEMENT CONTRACT.

The North American Industry Classification System (NAICS) code that best describes this requirement is 541710. The small business size standard is 500 employees.

If you intend to submit a proposal in response to this solicitation, we ask that you inform the Contracting Officer of your intent, by completing the Proposal Intent Response Sheet, Attachment #2 by mailing it to the address below, or by e-mailing it to: hb106s@nih.gov.

It is your responsibility to monitor the web page: <http://www.FedBizOpps.gov/>, **OR** the NINDS public web site at http://www.ninds.nih.gov/funding/funding_announcements/RFP_all.htm, for any amendments that might be issued under this solicitation.

An original and ten (10) copies of the technical proposal and an original and four (4) copies of the business proposal must be received by the Contracting Officer, no later than 4:30 P.M. (Eastern Standard Time) on May 31, 2005, at the following address:

If hand-delivered or sending your proposal via an overnight delivery service, e.g., Federal Express, DHL, etc, your proposal must be delivered to the following address:

Contracts Management Branch, DER
National Institute of Neurological Disorders and Stroke, NIH
NeuroScience Center
6001 Executive Boulevard, Suite 3287
Rockville, Maryland 20852

If mailing your proposal through the U.S. Postal Service your proposal must be sent to the following address:

Contracts Management Branch, DER
National Institute of Neurological Disorders and Stroke, NIH
NeuroScience Center, MSC 9531
6001 Executive Boulevard, Suite 3287
Bethesda, Maryland 20892-9531

Your attention is directed to the solicitation provision entitled "LATE PROPOSALS AND REVISIONS" set forth in Section L, paragraph m, of this RFP, implemented by HHSAR 352.215-70. Please review these provisions so that you will be fully aware of the time requirements for submitting your proposal. It is your responsibility to ensure that your proposal is delivered by the due date and time, and at the specific location (Room 3287) as required in the solicitation.

If you deliver your proposal in person, you will be required to provide photo identification and provide a name and telephone number of the individual being visited, (in this case, Helene Braun at (301) 496-1813), at our building's guard station. You will then need to personally bring the boxes to Room 3287. Proposals must NOT be left with the guard.

Your proposal must be prepared in accordance with **Section L** entitled "Instructions, Conditions, and Notices to Offerors", **Section C** entitled "Description/Specification/Work Statement", and will be evaluated pursuant to **Section M**

entitled "Evaluation Factors for Award". Please be aware that in addition to hard copies, **Section L 1.a.** also requires you to submit a yearly and cumulative summary of proposed costs on a CD in Microsoft Excel[®] format.

This RFP does not commit the Government to pay any costs for the preparation and submission of a proposal. It is also brought to your attention that the Contracting Officer is the only individual who can legally commit the Government to expenditure of public funds in connection with this proposed acquisition.

Your proposal must provide a contact name and telephone number, your company name and complete mailing address. In addition, the Tax Identification Number (TIN) and Dun & Bradstreet Number must be provided. Please note that FAR Provision 52.204-6 Data Universal Numbering System (DUNS) Number, requires you to submit a DUNS number for your company along with your offer. If you do not have a DUNS number, you are requested to contact Dun and Bradstreet Information Services at 1-800-333-0505 to obtain one. **Please include this information on the first page of your business proposal.** If the address is different from the address to which payment should be mailed you must also include the complete payment address.

Requests for any information concerning this RFP, and all questions should be referred only to Helene Braun, Contract Specialist, who may be reached at hb106s@nih.gov or (301) 496-1813. Communications or discussions with any other individual outside of the Contracts Management Branch may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

Sincerely,

Kirkland L. Davis

Kirkland L. Davis
Chief, Contracting Officer, NINDS

SOLICITATION**SECTION A – SOLICITATION/CONTRACT FORM**

Page 1 of 116 pages

1. Request For Proposal (RFP) Number: NIH-NINDS-05-02	2. Issue Date: April 1, 2005	3. Just in Time: <input type="checkbox"/> NO <input checked="" type="checkbox"/> YES See Part IV, Section L.	4. Set Aside: <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES See Part IV, Section L.
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5. TITLE: DOMAIN SPECIFIC TASKS OF EXECUTIVE FUNCTION**6. ISSUED BY:**

National Institutes of Health
 National Institute of Neurological Disorders and Stroke
 Contracts Management Branch, DER
 NeuroScience Center, MSC 9531
 6001 Executive Boulevard, Suite 3287
 Bethesda, Maryland 20892-9531

7. SUBMIT OFFERORS TO:

The address noted in Item #6 to the left.

- 8.** Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the location specified above, and in the number of copies specified in Section L.1., GENERAL INFORMATION, paragraph (a), until **4:30 p.m.** (local time), **May 31, 2005**. Offers must be valid for 120 days. Please specify this period on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043." If your proposal is not received by the Contracting Officer or his/her designee at the place and by the time specified above, then it will be considered late and handled in accordance with HHSAR Clause 352.215-70, entitled "LATE PROPOSALS AND REVISIONS," located in SECTION L.1., paragraph (m) of this solicitation.

- 9.** Offeror must provide full name, address, TIN, and if different, the address to which payment should be mailed. In addition, the Offeror must provide an electronic address (e-mail), DUNS number, and a facsimile number.

- 10.** FOR INFORMATION CALL: Helene Braun, Contract Specialist
 PHONE: 301-496-1813
 E-MAIL: hb106s@nih.gov.
 COLLECT CALLS WILL NOT BE ACCEPTED.

- 11.** Table of Contents on following page.

NOTE: Offerors are responsible for routinely checking either one of the following web sites for any amendments to the solicitation: The FedBizOpps web site is: <http://www.FedBizOpps.gov/>, OR you may refer to the Contracts Management Branch web site at: http://www.ninds.nih.gov/funding/funding_announcements/RFP_all.htm. Individual notifications will not be provided.

DETAILED TABLE OF CONTENTS

PART I - THE SCHEDULE

SECTION A - SOLICITATION/CONTRACT FORM 1
SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS 5
SECTION C - DESCRIPTION/SPECIFICATION/WORK STATEMENT..... 5
SECTION D - PACKAGING, MARKING AND SHIPPING 9
SECTION E - INSPECTION AND ACCEPTANCE.....10
SECTION F - DELIVERIES OR PERFORMANCE 10
SECTION G - CONTRACT ADMINISTRATION DATA 11
SECTION H - SPECIAL CONTRACT REQUIREMENTS 15

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES 19

PART III - LIST OF DOCUMENTS, EXHIBITS, AND OTHER ATTACHMENTS

SECTION J – LIST OF ATTACHMENTS 30

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS AND CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS 30

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS 31

1. GENERAL INFORMATION 31

2. INSTRUCTIONS TO OFFERORS 38

a. GENERAL INSTRUCTIONS..... 38

b. TECHNICAL PROPOSAL INSTRUCTIONS..... 48

c. BUSINESS PROPOSAL INSTRUCTIONS 57

SECTION M - EVALUATION FACTORS FOR AWARD 65

ATTACHMENTS

1. Government Notice for Handling Proposals 71
2. Proposal Intent Response Sheet 72
3. NIH-1688-1, Project Objectives.....73
4. Past Performance Information - NIH Customer Survey of Contractor Performance74
5. Example, Request for Past Performance Information79
6. Summary of Labor and Direct Costs (TECHNICAL PROPOSAL)80
7. Targeted/Planned Enrollment Table..... 81
8. Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption.....82
9. NIH-2043, Proposal Summary and Data Record83
10. Summary of Annual Costs (BUSINESS PROPOSAL)..... 84
11. Summary of Related Activities85
12. SF-LLL, Disclosure of Lobbying Activities 86
13. Small Business Subcontracting Plan89
14. Small Disadvantaged Business (SDB) Participation Factor..... 95
15. Representations and Certifications..... 96
16. Certificate of Current Cost or Pricing Data..... 101

17. NIH(RC)-1, Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts...	102
18. NIH(RC)-4, Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts.....	106
19. NIH(RC)-7, Procurement of Certain Equipment.....	111
20. Inclusion Enrollment Report.....	112
21. NIH 2706, Financial Report of Individual Project/Contract.....	113

PART I - THE SCHEDULE

THE CONTRACT SCHEDULE SET FORTH IN SECTIONS B THROUGH H, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS NOT AN EXACT REPRESENTATION OF THE PROPOSED CONTRACT DOCUMENT. CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (I.E., THOSE RELATING TO THE ORGANIZATIONAL STRUCTURE [E.G., NON-PROFIT, COMMERCIAL] AND SPECIFIC COST AUTHORIZATIONS UNIQUE TO THE OFFEROR'S PROPOSAL AND REQUIRING CONTRACTING OFFICER PRIOR APPROVAL) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. HOWEVER, THE ENCLOSED CONTRACT SCHEDULE PROVIDES ALL THE NECESSARY INFORMATION FOR THE OFFEROR TO UNDERSTAND THE ANTICIPATED TERMS AND CONDITIONS OF ANY RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The objective of this contract is to develop psychometrically robust Executive Function (EF) measurement tools that are accepted by the neurology clinical trials and clinical research communities. The contract will be structured in two phases. Phase I will encompass qualitative research focusing on the identification of content area and the development of EF domain specific tasks. Phase II addresses the formal testing and refining of the final battery of EF tests. It is anticipated that the award from this solicitation will be a cost reimbursement contract.

ARTICLE B.2. PRICES/COSTS

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer for: 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

SECTION C - DESCRIPTION/SPECIFICATION/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

a. Background

Executive Function (EF) refers to a constellation of cognitive abilities that include the ability to plan, organize, and sequence tasks and manage multiple tasks simultaneously. Appropriate EF also includes components of self-monitoring and self-correcting behaviors. These important behaviors are compromised in healthy elders and in people with neurological, mental and age related disorders, leading to disruption of lifestyle and loss of independence. One obstacle for progressive research in this area of cognition is a paucity of valid and reliable tasks that specifically tap domains of EF.

While some research has been ongoing with funding from NIH, the National Science Foundation and the McDonnell Foundation, it has been difficult to establish standard operational definitions of Executive Functions, resolve areas of controversies such as the design and validation of comprehensive neuropsychological tests to assess multiple domains of Executive Function in both basic and clinical research settings. This contract will take advantage of the state of our knowledge on research issues such as: neural pathways associated with executive function; appropriate animal models to study executive function; the nature, extent and rate of change of executive function in pathological states; the characterization – sparing or impairment - of executive function in neurodegenerative diseases; current tasks for assessment of executive function and the development of new tasks; factors that modulate executive function; and feasible behavioral and/or pharmacological interventions.

The development of domain specific tasks of executive function as specified in this contract will be of considerable value to many of NINDS current and future research programs in neurological disorders where dysfunction in cognitive processes are integral components of functional outcomes and quality of life for affected patients. While there are numerous neuropsychological test batteries, their use has been maximized in research settings with little attention paid to adaptability to clinical trials. However, some aspects of “executive function” are being incorporated into many recent or current clinical trials in neurology, usually as secondary outcome measures. Many neuropsychological assessment scales have been developed for use in various disease settings; however, some of the

existing scales have questionable validity and there is no consensus on what methods should be used within or across studies or disease areas. The lack of consensus about the best tools or approaches creates a situation where based on the existing literature, it is not possible to compare the relative burden of various neurological conditions to each other or more importantly, to compare the relative benefits of one treatment over another on the same patient-centered outcome. Supporting a research agenda that will create a battery of domain specific Executive Function tasks would greatly increase the probability for more precise clinical assessment and integration in a large range of basic brain research. Cross-cultural issues are also important; the resulting tool must be applicable to the US Hispanic population and must be available in Spanish.

Advances in cognitive neuroscience research methodology, including computerized adaptive testing and real-world setting (virtual reality), may lead to more efficient, flexible and responsive assessment of Executive Function in a variety of settings. An additional concern for the NINDS is assessment of Executive Function in ethnic and racial minorities, in particular African American and US Hispanic populations. The resulting tasks must be sensitive across cultures and must be available in Spanish.

Goals of the Contract

The overall objective of this contract is to develop psychometrically robust Executive Function measurement tools that are accepted by the neurology clinical trials and clinical research communities. Specific goals of the contract are:

1. To develop a core set of tasks that will address specific domains of Executive Function that is universal to patients with chronic neurological disorders (for example: stroke, traumatic brain injury, neurodegenerative disorders, epilepsy, etc.).
2. To integrate the specific following characteristics in the NINDS Executive Function test battery:
 - o focused on two or more of the following six domains: inhibition (response suppression; interference resolution); working memory (manipulation and maintenance of information; temporal organization (time & place); set shifting (mental flexibility); self monitoring (behavioral awareness, insight); abstraction (rules, categories).
 - o modifiable (depending on individual protocols or paradigms and individual differences)
 - o portable (battery that can be administered in emergency room; physician offices)
 - o programmable; replicable (flexible across laboratories)
 - o usable across age groups
 - o adaptable for clinical trials
 - o utilizes naturalistic situations (virtual reality)
 - o includes functional outcomes (sensitive to treatment, training, drugs)

The NINDS is seeking an innovative approach to Executive Function measurement that will be responsive to the needs of researchers in a variety of neurological disorders and settings, with a particular emphasis on measuring outcomes in clinical trials. Determining criteria for acceptability to the neurology research community prior to specific domain tasks development and evaluating the acceptability to researchers of the final battery will be essential to successful completion of these goals.

b. Technical Specifications

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

The contract will be structured in two phases. Phase I will encompass qualitative research focusing on the identification of content area and the development of EF domain specific tasks. Phase II addresses the formal testing and refining of the final battery of EF tests. Tasks may be performed concurrently or sequentially, as appropriate. It is anticipated that the entire project will be completed in 5 years.

(a) Phase I – Identification of content area and development of test instrument (18 – 24 months)

Phase I tasks include:

- 1) Identification of criteria for acceptance of Executive Function domain specific tasks to the neurology research community
NINDS clinical trials reviewers and clinical research grantees (5-9 individuals per group) including cognitive neuroscientists and neuropsychologists, will be consulted through a focus group format or other method of data collection. The results of this task will inform completion of the remaining tasks.
- 2) Identification of target neurological conditions or groups of similar conditions
Literature on existing cognitive measures and issues regarding measurement for chronic neurological conditions shall be formally reviewed, summarized, and analyzed. Based on the literature review, and with input from the Project Officer, a broad scope of neurological conditions will be identified. Considerations will include prevalence of the disorder and characteristics of the disease (e.g., chronic stable disease, progressive or degenerative disease).
- 3) Identification of initial comprehensive Executive Function domains and tests

Examples of methods to develop a preliminary working set of domains and items include:

- Interviews with clinical experts – i.e., neuropsychologists, physicians, nurses, and/or other clinicians who have experience caring for patients with the target neurological disorders
- Focus group interviews with patients defined by disease subgroup, mixed disease groups

Focus group or other interview subjects should be ethnically diverse and should include both men and women from each functional class level.

- 4) Evaluation and critical analysis of initial sets of Executive Function domains from existing instruments as listed in goals of the contract:

- *Inhibition (response suppression; interference resolution)*
- *Working memory (manipulation and maintenance of information)*
- *Temporal organization (time & place)*
- *Set shifting (mental flexibility)*
- *Self monitoring (behavioral awareness, insight)*
- *Abstraction (rules, categories)*

Examples of methods to critically evaluate this preliminary working set of domains and items include:

- Interviews with clinical experts – i.e., neuropsychologists, cognitive neuroscientists, psychometrics /test development specialists, outcome assessment biostatisticians, physicians, nurses, and/or other clinicians who have experience caring for patients with the target neurological disorders
 - Focus group interviews with developmental cognitive neuroscientists engaged in pre-clinical and clinical studies of Executive Function in order to assess the feasibility of a test battery that could be used in pediatric populations
- 5) Selection of initial sets of items from existing instruments and development of new items
New items will be evaluated for face/content validity; reliability; required training for test administrators; duration; importance of normative data and test interpretation. The cross-cultural equivalence of the items will be evaluated.
 - 6) Translation of items into Spanish
Standard forward/back translation methodology will be used to translate the initial set of items into Spanish. Validation of the Spanish items may be conducted during Phase II testing.

- 7) Development of database, data management system to support Phase I and Phase II tasks.
This database will be used to facilitate scientific communication and collaboration among scientist as well as expand the applicability of Executive Function domain specific core tasks
- 8) Development of a protocol for testing and refinement of the domain specific Executive Function Battery

The Phase II protocol will incorporate at a minimum:

- testing in multiple disease subgroups, including children
- inclusion of ethnic minorities
- inclusion of geographically diverse populations
- evaluation of quality of proxy-reported data
- evaluation of different modes of administration
- evaluation of impact of missing data
- evaluation of longitudinal use of the instrument
- assessment of responsiveness to change

After completion of Phase I tasks, a report of accomplishments and the Phase II protocol shall be submitted to and accepted by the Project Officer before Phase II may begin. The contractor shall not proceed with Phase II activities until receipt of formal authorization to do so from the Project Officer.

- (b) Phase II – Testing and refinement of final NINDS EF battery (3 – 3.5 years)

Phase II tasks include:

- 1) Field testing of battery
The test version of the EF battery will be evaluated in multiple patient samples per disease subgroup as determined through a power analysis. A minimum of 5 sites distributed throughout the US will be identified for the field test.
- 2) Development of final battery
Once a final set of tests is identified, the battery (English and Spanish versions) will be developed. This task includes evaluation of psychometric properties of the instrument; development of scoring program and summary scores; development of user's manual; development of a training program.
- 3) Plans for availability of final battery
The final domain specific EF battery and associated documentation to be developed under this contract will be made available in the public domain. The final EF battery formatted in Microsoft Word and in PDF format, domain specific tests, and computer programs will be provided to NINDS, along with associated documentation (comprehensive user manual; implementation; administration; training materials; scoring guidelines; other supporting data and documentation to establish the validity of the measurement system and aid in the interpretation of study results).

C.2 REPORTING REQUIREMENTS

In addition to the required reports set forth elsewhere in the Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The Contractor shall prepare and deliver the following reports in a manner stated below and in accordance with ARTICLE F.2., DELIVERIES of this contract.

- 1) Quarterly Progress Reports
Quarterly progress reports shall be due within 30 calendar days of the close of each calendar quarter. This report shall describe the progress on the project during the reporting period and shall include the following: an indication of any current problems that may impede performance and proposed corrective action; description of the work to be performed during the subsequent reporting period; and any recommendations.

2) Phase I Report

After completion of Phase I, a report of accomplishments and plans for the next phase of the project shall be submitted for review and approval by the Project Officer. This report is due within 10 days after completion of that phase of the project. The Project Officer will have 20 days to review the report. The Project Officer's written approval will be required before the next phase may be initiated.

3) Draft and Final Reports

The Contractor shall provide the Contracting Officer with copies of the final report in draft form 30 CALENDAR days prior to the delivery date for the final version of the final report. The Project Officer shall review the draft report and provide the Contracting Officer with comments within 15 CALENDAR days after receipt. The final report shall be corrected by the Contractor, if necessary, and the final version delivered in accordance with Section F, Deliveries or Performance, of the contract.

The final report shall include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The final report shall be submitted in accordance with Section F, Deliveries or Performance, of the contract.

4) Final domain specific EF battery

Upon conclusion of the contract, the Contractor shall provide the final EF battery, either as production-ready, formatted questionnaire (hard copy and electronic version), or as a computerized version of the tasks; and all associated documentation, including description of scientific methodology used, scoring algorithm, user's manual, training plan, proposed plan for public access to test battery.

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR CLAUSE 52.227-11, including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040-A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301/435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer at the address listed below. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted prior to closeout of the contract listing all subject inventions or stating that there were none to the following address:

Contracting Officer
National Institutes of Health
National Institute of Neurological Disorders and Stroke
6001 Executive Boulevard, Suite 3287, MSC 9531
Bethesda, Maryland 20892-9531

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (<http://www.i Edison.gov>), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

SECTION D - PACKAGING, MARKING AND SHIPPING

ARTICLE D.1. PACKAGING, MARKING, AND SHIPPING

- a. All deliverables required under this contract shall be packaged, marked, and shipped in accordance with the Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

b. Packaging

1. For the purpose of reports, "immediately usable and acceptable condition" includes securing the pages together in a suitable and reasonable manner to be agreed upon by the Contractor and the NINDS Project Officer.
2. Boxes and/or other types of outer packaging, i.e., containers, wraps, etc., shall be suitable to the type of items being transmitted; and the mode of transportation utilized shall assure that such materials be received in an acceptable condition.

c. Marking

All reports and/or other deliverable items under this contract shall be marked on the cover and cover page with the following identifiers.

1. Project Title: "Domain Specific Tasks of Executive Functions"
2. Contract Number:
3. Name of Contractor:
4. Name of Principal Investigator:

d. Shipping

Shipping shall be accomplished by reasonable and suitable means to be mutually agreed upon by the Contractor and the NINDS Project Officer.

- e. See SECTION F for delivery information.

SECTION E - INSPECTION AND ACCEPTANCE

ARTICLE E.1. INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or a duly authorized representative shall perform inspection and acceptance of all deliverables and services to be provided.
- b. For the purpose of this SECTION, the NINDS Project Officer designated in ARTICLE G.2. is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance of contract work/deliverables shall be performed at the National Institute of Neurological Disorders and Stroke (NINDS), NIH, 6001 Executive Boulevard, Suite 3305, MSC 9531, Bethesda, Maryland 20892-9531, (for courier service: Rockville, MD 20852). Inspection and acceptance shall be performed using quarterly progress reports, other required reports, and the final report. Site visits will also be employed for this purpose. Acceptance of work and/or report deliverables may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within thirty (30) days of receipt.
- d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

**FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:
52.246-9, INSPECTION OF RESEARCH AND DEVELOPMENT (Short Form) (APRIL 1984)**

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF CONTRACT

The period of performance of this contract shall be from _____ through _____.

ARTICLE F.2. DELIVERIES

Satisfactory performance of the work under this contract shall be deemed to occur upon performance of work described in ARTICLE C.1. and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

- a. The items specified below as described in SECTION C, ARTICLE C.2 will be required to be delivered F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below.

<u>Item</u>	<u>Description</u>	<u>Reporting Period</u>	<u>Delivery Schedule</u>
(1)	Quarterly Progress Report	Quarterly	30 days after the reporting period.
(2)	Phase I Report	To be determined	After completion of each task
(3)	Draft and Final Reports	Entire contract period	Draft Report – 30 calendar days prior to delivery of the final report. Final Report – Last day of contract.
(4)	Final Domain Specific EF Battery	-----	Last day of contract.

- b. The above reports shall be addressed and delivered to:
[The specific information will be included in the resultant contract]

ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

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

**FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:
52.242-15, STOP WORK ORDER (AUGUST 1989) WITH ALTERNATE I (APRIL 1984)**

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. KEY PERSONNEL

Pursuant to the Key Personnel Clause incorporated in this contract, the following individual(s) is/are considered to be essential to the work being performed hereunder:

[To be specified prior to award]

The clause cited above contains a requirement for review and approval by the Contracting Officer of written request for change of Key Personnel reasonably in advance of diverting any of these individuals from the contract. The period of time for advance notice shall not be less than thirty (30) days.

ARTICLE G.2. PROJECT OFFICER

The following Project Officer will represent the Government for the purpose of this contract:

[To be specified prior to award]

The Project Officer is responsible for (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance, and recommending to the Contracting Officer changes in requirements; (2) interpreting the Statement of Work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with the authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to (1) direct or negotiate any changes in the Statement of Work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement of any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

- a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts, NIH (RC)-4, are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing requests must be followed to meet the requirements of a "proper payment" request, pursuant to FAR 32.9.

These instructions also provide for the submission of financial and personnel reporting required by HHSAR 342.7002.

1. Invoice/financing requests shall be submitted as follows:

An original and two copies to the following designated billing office:

Contracting Officer
National Institutes of Health
National Institute of Neurological Disorders and Stroke
NeuroScience Center, Suite 3287
6001 Executive Boulevard, MSC 9531
Bethesda, MD 20892-9531

2. Inquiries regarding payment of invoices/financing requests should be directed to the designated billing office, (301) 496-1813.

3. The Contractor agrees to provide with each monthly contract financing request a detailed breakdown of the direct labor/personnel charges claimed, to include: (1) a list of individuals by name; (2) their title/position under the contract; (3) their hourly/annual salary rate; (4) the number of hours worked; and (5) amount claimed for each.

1. Invoices/financing requests must include cumulative expenditures to date, adjusted (as applicable) to show any amounts suspended by the Government.

- b. The Contractor shall include the following certification on every invoice/contract financing request for reimbursable costs incurred with Fiscal Year funds subject to the salary rate limitation provisions as specified in ARTICLE H.6 of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with P.L. [cite the applicable Public Law Number for the applicable Fiscal Year as stated in ARTICLE H.6] of the above referenced contract."

OR

ARTICLE G.4. LETTER OF CREDIT PAYMENT

- a. Advance payments will be provided under Letter of Credit Number _____, in accordance with Alternate V, Advance Payments Without Special Bank Account, of FAR Clause 52.232-12, Advance Payments. This clause is provided in full text in Article I.4. of this contract.

The contractor shall withdraw funds pursuant to Department of Treasury Circular 1075 (31 CFR Part 205, http://www.access.gpo.gov/nara/cfr/waisidx_00/31cfr205_00.html).

1. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts, NIH (RC)-1, are attached and made a part of this contract for the submission of completion and/or final invoices. The invoice instructions and the following directions for the submission of invoices/financing requests must be followed to meet the requirements of a "proper" payment request, pursuant to FAR 32.9. The completion and/or final invoice shall be submitted as follows:

An original and two copies of the completion and/or final invoice shall be submitted to the following designated billing office:

Contracting Officer
National Institutes of Health
National Institute of Neurological Disorders and Stroke
Neuroscience Center, Room 3287
6001 Executive Boulevard, MSC 9531
Bethesda, MD 20892-9531

2. Inquiries regarding payments should be directed to the following office administering advance payments:

Division of Payment Management
11400 Rockville Pike
Rockwall Building #1, Suite 700
Rockville, MD 20852
(<http://www.dpm.psc.gov/> under "Contacts")

ARTICLE G.5. CONTRACT FINANCIAL REPORT (*will be included in any contract with organizations paid under the Payment Management System*)

- a. Financial reports on the attached Form NIH-2706, Financial Report of Individual Project/Contract, shall be submitted by the Contractor in accordance with the Instructions for Completing Form NIH 2706, which accompany the form, in an original and two copies, not later than the thirtieth (30) working day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are discussed in paragraph (e) below. Subsequent changes and/or additions in the line entries shall be made in writing.
- b. Unless otherwise stated in that part of the Instructions for Completing Form NIH-2706 instructions entitled "**Preparation Instructions**," all columns A through J shall be completed for each report submitted.
- c. The first financial report shall cover the period consisting of the *FIRST FULL THREE CALENDAR MONTHS* following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports shall be submitted on a quarterly basis.
- d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

e. The following are examples of expenditure categories which may be reported:

Expenditure Category	Percentage of Effort/Hours
1. Direct Labor (<i>List individuals by name, title/position, level of effort and amount claimed</i>)	
2. Fringe Benefits (<i>Cite rate, base and amount</i>)	
3. Consultants (<i>Identify individuals and amounts</i>)	
4. Subcontracts (<i>Identify subcontractor by name and attach subcontractor invoices</i>)	
5. Materials and Supplies	
6. Accountable Personal Property/Equipment (<i>Identify equipment purchased on form HHS 565 and submit with the invoice</i>)	
7. Other Direct Costs	
8. Total Direct Costs	
9. Indirect Costs/Overhead (<i>Cite rate, base and amount</i>)	
10. General and Administrative Costs (<i>if applicable, cite rate, base and amount</i>)	
11. Total Costs	
12. Fixed Fee (<i>If applicable</i>)	
13. Total Costs [Plus Fixed Fee]	

f. The Government may unilaterally revise the NIH 2706 to reflect the allotment of additional funds.

ARTICLE G.6. INDIRECT COST RATES (will be included in any contract if the successful offeror is a profit making organization)

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7(d)(2), Allowable Cost and Payment incorporated by reference in this contract in Part II, Section I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6100 Building, Room 6B05
6100 Executive Blvd MSC 7540
Bethesda, MD 20892-7540

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.7. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and will incorporate the DHHS Publication (OS) 686, entitled, Contractor's Guide for Control of Government Property, (1990), which can be found at <http://knownet.hhs.gov>

ARTICLE G.8. POST AWARD EVALUATION OF PAST PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluations will be prepared during the contract term to assess ongoing performance.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional

information or a rebutting statement. Any disagreement between the parties regarding an evaluation will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

http://ocm.od.nih.gov/cdmp/cps_contractor.htm

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Contractor should access 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>. The information below is a summary of the NIH Policy Announcement:

The Contractor shall maintain the following information: (1) a list of the names and titles of the Principal Investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational 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.

Prior to any 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.

ARTICLE H.2. RESTRICTION FROM USE OF HUMAN SUBJECTS

Notice: Under governing regulations, Federal funds administered by the Department of Health and Human Services shall not be expended for research involving human subjects, and individuals shall not be enrolled in such research, without prior approval by the Office for Human Research Protections (OHRP), OS, DHHS, of an assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved assurances, whether domestic or foreign, and compliance must be ensured by the awardee.

Prisoners shall not be enrolled in any HHS research activities until all requirements of HHS Regulations at 45 CFR Part 46, Subpart C have been met. If a research subject becomes a prisoner during the period of this contract, 45 CFR Part 46, Subpart C will apply to research involving that individual.

ARTICLE H.3. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

- a. Pursuant to Public Law(s) cited in paragraph b., below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

<u>Public Law and Section No.</u>	<u>Fiscal Year</u>	<u>Period Covered</u>
P.L. 108-447, Title V- General Provisions, Section 509	2005	10/01/2004 – 09/30/2005

ARTICLE H.4. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

- 1) The Small Business Subcontracting Plan, dated _____, is attached hereto and made a part of this contract.
- 2) The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. Subcontracting Reports

(1) Subcontracting Report for Individual Contracts, SF-294

The Contractor shall submit the original and one (1) copy of Subcontracting Report for Individual Contracts, SF-294 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. In addition to the information contained in the General Instructions on the back of this form for Block 17, "Remarks," the Contractor shall provide an explanation **for any** category of small business subcontracting for which there were no dollars reported since the last reporting period.

Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:

April 30th
October 30th

The Report shall be sent to the Contracting Officer at the following address:

National Institute of Neurological Disorders and Stroke
Contracts Management Branch, DER
Neuroscience Center, MSC 9531
6001 Executive Boulevard, Suite 3287
Bethesda, Maryland 20892-9531

(2) Summary Subcontract Report, SF-295

The Contractor shall submit two (2) copies of the Summary Subcontract Report, SF-295 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. Regardless of the effective

date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

One copy of this report shall be sent to the Contracting Officer at the address above. One copy of this Report shall be mailed to the Office of Small Disadvantaged Business Utilization, DHHS at the following address:

Office of Small and Disadvantaged Business Utilization
Department of Health and Human Services
Hubert H. Humphrey Bldg., Room 360G
200 Independence Avenue, S.W.
Washington, D.C. 20201

(3) The Contractor shall also send an "Information Copy" of the SF-295 to the Cognizant Commercial Representative (CMR) at the address provided by the SBA. The Contractor should call SBA Headquarters in Washington, DC at (202) 690-7235 for the correct address if unknown.

ARTICLE H.5. NEEDLE EXCHANGE

a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

<u>Public Law and Section No.</u>	<u>Fiscal Year</u>	<u>Period Covered</u>
P.L. 108-447, Title V- General Provisions, Section 505	2005	10/01/2004 – 09/30/2005

ARTICLE H.6. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to Public Law(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown or the applicable Executive Level for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead, and general and administrative expenses (also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor. The per year salary rate limit also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

<u>Public Law No.</u>	<u>Fiscal Year</u>	<u>Dollar Amount of Salary Limitation</u>
P.L. 108-447	2005	Executive Level I*

c. Payment of direct salaries is limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred.

*For the period 10/1/04 – 12/30/04, the Executive Level I rate is \$175,700. Effective January 1, 2005, the Executive Level I rate increased to \$180,100 and will remain at that rate until it is revised. See the web site listed below for Executive Schedule rates of pay.

FOR FY05 EXECUTIVE LEVEL SALARIES EFFECTIVE JANUARY 1, 2005:

<http://www.opm.gov/oca/05tables/html/ex.asp>

(NOTE: This site shows the CY 05 rates. For previous years, click on "salaries and wages" and then scroll down to the bottom of the page and click on the year to locate the desired Executive Level salary rates).

ARTICLE H.7. PUBLICATION AND PUBLICITY

The Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institute of Neurological Disorders and Stroke, National Institutes of Health, under Contract No. _____."

ARTICLE H.8. PRESS RELEASES

- a. Pursuant to Public Law(s) cited in paragraph (b) below, the Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

b.	<u>Public Law No. and Section No</u> P.L. 108-447, Title V - General Provisions, Section 506	<u>Fiscal Year</u> 2005	<u>Period Covered</u> 10/01/2004 – 09/30/2005
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ARTICLE H.9. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence on fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.10. ANTI -LOBBYING

- a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall only be used for normal and recognized executive-legislative relationships. Contract funds shall not be used, for publicity or propaganda purposes: or for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.
- b. Contract funds shall not be used to pay salary or expenses of the Contractor or any agent acting for the Contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c.	<u>Public Law and Section No.</u> for a., above: P.L. 108-447, Title V- General Provisions, Section 503a	<u>Fiscal Year</u> 2005	<u>Period Covered</u> 10/01/2004 – 09/30/2005
	For b., above: P.L. 108-447, Title V- General Provisions, Section 503b	2005	10/01/2004 – 09/30/2005

ARTICLE H.11. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Sharing Biomedical research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090], concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at: <http://ott.od.nih.gov/NewPages/64FR72090.pdf>. is intended to help Contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

Note: For the purposes of this Article, the terms, "research tools," "research materials," and "research resources" are used interchangeably and have the same meaning.

ARTICLE H.12. SHARING RESEARCH DATA

The Contractor's data sharing plan, dated _____ is hereby incorporated in this contract by reference. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule) at <http://www.hhs.gov/ocr/>). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

SPECIAL NOTE FOR SOLICITATION PURPOSES: This SECTION I uses, as an example, clauses appropriate for the award of a cost-reimbursement research and development type contract. Any resultant contract shall include the clauses applicable to the selected offeror's organization and the type of contract awarded. Any additional clauses required by Public Law, Executive Order, or acquisition regulation in effect at the time of award shall be included in this SECTION I.

A listing of clauses appropriate for the award of other types of contracts will be provided upon request to the Contracting Officer/Contract Specialist identified in the cover letter of this Request for Proposals.

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/>.

FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES/DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATIONS (HHSAR) CLAUSES

Reg	Clause	Date	Clause Title
FAR	52.202-1	Jul 2004	Definitions
FAR	52.203-3	Apr 1984	Gratuities
FAR	52.203-5	Apr 1984	Covenant Against Contingent Fees
FAR	52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government
FAR	52.203-7	Jul 1995	Anti-Kickback Procedures
FAR	52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
FAR	52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity
FAR	52.203-12	Jun 2003	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper
FAR	52.204-7	Oct 2003	Central Contractor Registration
FAR	52.209-6	Jan 2005	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
FAR	52.215-2	Jun 1999	Audit and Records - Negotiation
FAR	52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
FAR	52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
FAR	52.215-12	Oct 1997	Subcontractor Cost or Pricing Data
FAR	52.215-14	Oct 1997	Integrity of Unit Prices
FAR	52.215-15	Oct 2004	Pension Adjustments and Asset Reversions
FAR	52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data – Modifications
FAR	52.216-7	Dec 2002	Allowable Cost and Payment
FAR	52.216-8	Mar 1997	Fixed Fee
FAR	52.219-8	May 2004	Utilization of Small Business Concerns
FAR	52.219-9	Jan 2002	Small Business Subcontracting Plan
FAR	52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan
FAR	52.222-2	Jul 1990	Payment for Overtime Premium (Note: The dollar amount in paragraph (a) of this clause is \$0 unless otherwise specified in the contract.)
FAR	52.222-3	Jun 2003	Convict Labor
FAR	52.222-21	Feb 1999	Prohibition of Segregated Facilities
FAR	52.222-26	Apr 2002	Equal Opportunity
FAR	52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
FAR	52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
FAR	52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-14	Aug 2003	Toxic Chemical Release Reporting
FAR	52.225-1	Jun 2003	Buy American Act – Supplies
FAR	52.225-13	Dec 2003	Restrictions on Certain Foreign Purchases
FAR	52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)

Reg	Clause	Date	Clause Title
FAR	52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	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.
FAR	52.227-14	Jun 1987	Rights in Data – General
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-17	Jun 1996	Interest
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-23	Jan 1986	Assignment of Claims
FAR	52.232-25	Oct 2003	Prompt Payment, ALT I (Feb 2002)
FAR	52.232-33	Oct 2003	Payment by Electronic Funds Transfer--Central Contractor Registration
FAR	52.233-1	Jul 2002	Disputes
FAR	52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	May 2001	Penalties for Unallowable Costs
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
FAR	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.
FAR	52.244-5	Dec 1996	Competition in Subcontracting
FAR	52.244-6	Dec 2004	Subcontracts for Commercial Items
FAR	52.245-5	May 2004	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contracts)
FAR	52.246-23	Feb 1997	Limitation of Liability
FAR	52.249-6	May 2004	Termination (Cost-Reimbursement)
FAR	52.249-14	Apr 1984	Excusable Delays
FAR	52.253-1	Jan 1991	Computer Generated Forms
HHSAR	352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
HHSAR	352.216-72	Oct 1990	Additional Cost Principles
HHSAR	352.228-7	Dec 1991	Insurance - Liability to Third Persons
HHSAR	352.232-9	Apr 1984	Withholding of Contract Payments
HHSAR	352.233-70	Apr 1984	Litigation and Claims
HHSAR	352.242-71	Apr 1984	Final Decisions on Audit Findings
HHSAR	352.270-5	Apr 1984	Key Personnel
HHSAR	352.270-6	Jul 1991	Publications and Publicity
HHSAR	352.270-7	Jan 2001	Paperwork Reduction Act

[END OF GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT 1/05]

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS AND MODIFICATIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations. It is expected that the following clause(s) will be made part of the resultant contract:

FAR clause 52.232-20, LIMITATION OF COSTS, is deleted in its entirety and FAR Clause 52.232-22, LIMITATION OF FUNDS (APRIL 1984) is substituted therefore.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/contractor shall be determined at the time of award. Any contract awarded from this solicitation will contain the following:

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.

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

FAR 52.219-4, Notice Of Price Evaluation Preference For HubZone Small Business Concerns (Oct 2004)

“(c) Waiver of evaluation preference. A HUBZone small business concern may elect to waive the evaluation preference, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of this clause do not apply if the offeror has waived the evaluation preference.”

- Offeror elects to waive the evaluation preference.

FAR 52.219-24, Small Disadvantaged business Participation Program – Targets (OCT 2000)

FAR 52.219-25, Small Disadvantaged Business Participation Program—Disadvantaged Status and Reporting (OCTOBER 1999).

FAR 52.227-14, Rights in Data – General (JUNE 1987), ALT V (JUN 1987). Specific data items that are not subject to paragraph (j) include: None

FAR 52.227-16, Additional Data Requirements (JUNE 1987).

[NOTE TO OFFERORS: One or several of the following clauses pertaining to Cost Accounting Standards may be included in the resultant contract.]

*** (USE IN NEGOTIATED CONTRACTS OVER \$500,000 – FOR FULL CAS COVERAGE [EXCEPT Small Businesses, Educational Institutions and Foreign Contractors – SEE EXCEPTIONS AT 48 CFR CHAPTER 99 [APPENDIX B, FAR LOOSELEAF EDITION], SUBPART 9903.201-1) ***

FAR 52.230-2, Cost Accounting Standards (APRIL 1998).

*** (USE BELOW IN NEGOTIATED CONTRACTS OVER \$500,000 BUT LESS THAN \$25 MILLION, AND THE OFFEROR CERTIFIES THAT IT IS ELIGIBLE FOR AND ELECTS TO USE MODIFIED CAS COVERAGE, EXCEPT Small Businesses, Educational Institutions, and Foreign Contractors – SEE EXCEPTIONS AT 48 CFR CHAPTER 99 [APPENDIX B, FAR LOOSELEAF EDITION], SUBPART 9903.201.1) ***

FAR 52.230-3, Disclosure and Consistency of Cost Accounting Practices (APRIL 1998).

*** (USE BELOW IN NEGOTIATED CONTRACTS THAT ARE EXEMPT FROM CAS REQUIREMENTS SOLELY ON THE BASIS THAT THE CONTRACT IS TO BE AWARDED TO A UNITED KINGDOM CONTRACTOR AND IS TO BE PERFORMED SUBSTANTIALLY IN

THE UNITED KINGDOM – SEE 48 CFR CHAPTER 99 [APPENDIX B, FAR LOOSELEAF EDITION], SUBPART 9903.201-1(B)(2) ***

FAR 52.230-4, Consistency in Cost Accounting Practices (AUGUST 1992).

*** (USE BELOW IN NEGOTIATED CONTRACTS AND SUBCONTRACTS AWARDED TO EDUCATIONAL INSTITUTIONS, WHEN THE CONTRACTOR OR SUBCONTRACT PRICE EXCEEDS \$500,000, UNLESS THE CONTRACT IS EXEMPTED (SEE 48 CFR CHAPTER 99, 9903.201-1), THIS CONTRACT IS TO BE PERFORMED BY AN FFRDC (SEE 9903.201-2 (c)(5), OR THE PROVISION AT 9903.201-2(c)(6)(FAR APPENDIX B) APPLIES.) ***

FAR 52.230-5, Cost Accounting Standards – Educational Institution (APRIL 1998).

*** (USE BELOW IN NEGOTIATED CONTRACTS THAT CONTAIN EITHER THE FORMER FAR CLAUSE 52.230-2, 52,230-3, OR 52.230-5.) ***

FAR 52.230-6, Administration of Cost Accounting Standards (NOV 1999).

FAR 52.242-3, Penalties for Unallowable Costs (MAY 2001).

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

HHSAR 352.270-1 Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities (JANUARY 2001).

HHSAR 352.270-8 Protection of Human Subjects (MARCH 2005)
Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human Subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this clause.

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES

NIH (RC-1) – Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts (Nov 2003)

NIH (RC-4) – Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts (NOV 2003)

NIH (RC)-7 Procurement of Certain Equipment (APRIL 1984) (OMB Bulletin 81-16).

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text.

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

FAR 52.222-39, Notification of Employee Rights Concerning Payment of Union Dues or Fees (DEC 2004)

(a) *Definition.* As used in this clause---

“United States” means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.

(b) Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and

payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).

Notice to Employees

Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.

For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:

National Labor Relations Board
Division of Information
1099 14th Street, N.W.
Washington, DC 20570
1-866-667-6572
1-866-316-6572 (TTY)

To locate the nearest NLRB office, see NLRB's website at <http://www.nlr.gov>.

(c) The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR part 470, and orders of the Secretary of Labor.

(d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B—Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.

(e) The requirement to post the employee notice in paragraph (b) does not apply to ---

- (1) Contractors and subcontractors that employ fewer than 15 persons;
- (2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees.
- (3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;
- (4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements

with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that---

- i. The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and
 - ii. Such a waiver will not interfere with or impede the effectuation of the Executive order; or
- (5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.
- (f) The Department of Labor publishes the official employee notice in two variations; one for Contractors covered by the Railway Labor Act and a second for all other Contractors. The Contractor shall ---
- (1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 20210, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;
 - (2) Download a copy of the poster from the Office of Labor-Management Standards website at <http://www.olms.dol.gov>; or
 - (3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.
- (g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B—Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for non-compliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontract or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States

(End of clause)

ALTERNATE V, ADVANCE PAYMENT WITHOUT SPECIAL ACCOUNT (MAY 2001), ALTERNATE II (MAY 2001), and ALTERNATE IV (APRIL 1984), of FAR Clause 52.232-12, ADVANCE PAYMENTS (MAY 2001).

- (a) *Requirements for payment.* Advance payments will be made under this contract (1) upon submission of properly certified invoices or vouchers by the Contractor, and approval by the administering office, Contracts Management Branch, Neuroscience Center, 6001 Executive Blvd., Suite 3287, MSC 9531, Bethesda, MD 20892-9531, or (2) under a letter of credit. The amount of the invoice or voucher submitted plus all advance payments previously approved shall not exceed \$_____ for the base period; and \$_____ for the option period. If a letter of credit is used, the Contractor shall withdraw cash only when needed for disbursements acceptable under this contract and report cash disbursements and balances as required by the administering office. The Contractor shall apply terms similar to this clause to any advance payments to subcontractors.
- (b) *Use of funds.* The Contractor may use advance payment funds only to pay for properly allocable, allowable, and reasonable costs for direct materials, direct labor, and indirect costs. Determinations of whether costs are properly allocable, allowable, and reasonable shall be in accordance with generally

accepted accounting principles, subject to any applicable subparts of Part 31 of the Federal Acquisition Regulation.

- (c) *Repayment to the Government.* At any time, the Contractor may repay all or any part of the funds advanced by the Government. Whenever requested in writing to do so by the administering office, the Contractor shall repay to the Government any part of unliquidated advance payments considered by the administering office to exceed the Contractor's current requirements or the amount specified in paragraph (a) of this clause.
- (d) *Maximum payment.* When the sum of all unliquidated advance payments, unpaid interest charges, and other payments equal the total estimated cost of \$_____ for the base period and \$_____ for the option period (not including fixed-fee, if any) for the work under this contract, the Government shall withhold further payments to the Contractor. Upon completion or termination of the contract, the Government shall deduct from the amount due to the Contractor all unliquidated advance payments and interest charges payable. The Contractor shall pay any deficiency to the Government upon demand. For purposes of this paragraph, the estimated cost shall be considered to be the stated estimated cost, less any subsequent reductions of the estimated cost, plus any increases in the estimated costs that do not, in the aggregate, exceed \$0. The estimated cost shall include, without limitation, any reimbursable cost (as estimated by the Contracting Officer) incident to a termination for the convenience of the Government. Any payments withheld under this paragraph shall be applied to reduce the unliquidated advance payments. If full liquidation has been made, payments under the contract shall resume.
- (e) *Interest.* No interest shall be charged to the prime Contractor for advance payments except for interest charged during a period of default. The terms of this paragraph concerning interest charges for advance payments shall not apply to the prime Contractor.
 - (1) The Contractor shall pay interest to the Government on the daily unliquidated advance payments at the daily rate specified in subparagraph (e)(3) below. Interest shall be computed at the end of each calendar month for the actual number of days involved. For the purpose of computing the interest charge, the following shall be observed:
 - (i) Advance payments shall be considered as increasing the unliquidated balance as of the date of the advance payment check.
 - (ii) Repayments by Contractor check shall be considered as decreasing the unliquidated balance as of the date on which the check is received by the Government authority designated by the Contracting Officer.
 - (iii) Liquidations by deductions from payments to the Contractor shall be considered as decreasing the unliquidated balance as of the dates on which the Contractor presents to the Contracting Officer full and accurate data for the preparation of each voucher. Credits resulting from these deductions shall be made upon the approval of the reimbursement vouchers by the Disbursing Officer, based upon the Contracting Officer's certification of the applicable dates.
 - (2) Interest charges resulting from the monthly computation shall be deducted from any payments on account of the fixed-fee due to the Contractor. If the accrued interest exceeds the payment due, any excess interest shall be carried forward and deducted from subsequent payments of the contract price or fixed-fee. Interest carried forward shall not be compounded. Interest on advance payments shall cease to accrue upon (i) satisfactory completion or (ii) termination of the contract for the convenience of the Government. The Contractor shall charge interest on advance payments to subcontractors in the manner described above and credit the interest to the Government. Interest need not be charged on advance payments to nonprofit educational or research subcontractors for experimental, developmental, or research work.
 - (3) If interest is required under the contract, the Contracting Officer shall determine a daily interest rate based on the rate established by the Secretary of the Treasury under Pub. L. 92-41 (50 U.S.C. App., 1215(b)(2)). The Contracting Officer shall revise the daily interest rate during the contract period in keeping with any changes in the cited interest rate.

- (4) If the full amount of interest charged under this paragraph has not been paid by deduction or otherwise upon completion or termination of this contract, the Contractor shall pay the remaining interest to the Government on demand.
- (f) *Lien on property under contract.* (1) All advance payments under this contract, together with interest charges, shall be secured, when made, by a lien in favor of the Government, paramount to all other liens, on the supplies or other things covered by this contract and on all material and other property acquired for or allocated to the performance of this contract, except to the extent that the Government by virtue of any other terms of this contract, or otherwise, shall have valid title to the supplies, materials, or other property as against other creditors of the Contractor.
- (2) The Contractor shall identify, by marking or segregation, all property that is subject to a lien in favor of the Government by virtue of any terms of this contract in such a way as to indicate that it is subject to a lien and that it has been acquired for or allocated to performing this contract. If, for any reason, the supplies, materials, or other property are not identified by marking or segregation, the Government shall be considered to have a lien to the extent of the Government's interest under this contract on any mass of property with which the supplies, materials, or other property are commingled. The Contractor shall maintain adequate accounting control over the property on its books and records.
- (3) If, at any time during the progress of the work on the contract, it becomes necessary to deliver to a third person any items or materials on which the Government has a lien, the Contractor shall notify the third person of the lien and shall obtain from the third person a receipt in duplicate acknowledging the existence of the lien. The Contractor shall provide a copy of each receipt to the Contracting Officer.
- (4) If, under the termination clause, the Contracting Officer authorizes the Contractor to sell or retain termination inventory, the approval shall constitute a release of the Government's lien to the extent that--
- (i) The termination inventory is sold or retained; and
 - (ii) The sale proceeds or retention credits are applied to reduce any outstanding advance payments.
- (g) *Insurance.* (1) The Contractor shall maintain with responsible insurance carriers--
- (i) Insurance on plant and equipment against fire and other hazards, to the extent that similar properties are usually insured by others operating plants and properties of similar character in the same general locality;
 - (ii) Adequate insurance against liability on account of damage to persons or property; and
 - (iii) Adequate insurance under all applicable workers' compensation laws.
- (2) Until work under this contract has been completed and all advance payments made under the contract have been liquidated, the Contractor shall--
- (i) Maintain this insurance;
 - (ii) Maintain adequate insurance on any materials, parts, assemblies, subassemblies, supplies, equipment, and other property acquired for or allocable to this contract and subject to the Government lien under paragraph (f) of this clause; and
 - (iii) Furnish any evidence with respect to its insurance that the administering office may require.
- (h) *Default.* (1) If any of the following events occur, the Government may, by written notice to the Contractor, withhold further payments on this contract:
- (i) Termination of this contract for a fault of the Contractor.
 - (ii) A finding by the administering office that the Contractor has failed to--
 - (A) Observe any of the conditions of the advance payment terms;

- (B) Comply with any material term of this contract;
 - (C) Make progress or maintain a financial condition adequate for performance of this contract;
 - (D) Limit inventory allocated to this contract to reasonable requirements; or
 - (E) Avoid delinquency in payment of taxes or of the costs of performing this contract in the ordinary course of business.
- (iii) The appointment of a trustee, receiver, or liquidator for all or a substantial part of the Contractor's property, or the institution of proceedings by or against the Contractor for bankruptcy, reorganization, arrangement, or liquidation.
 - (iv) The commission of an act of bankruptcy.
- (2) If any of the events described in subparagraph (h)(1) of this clause continue for 30 days after the written notice to the Contractor, the Government may take any of the following additional actions:
- (i) Charge interest, in the manner prescribed in paragraph (e) of this clause, on outstanding advance payments during the period of any event described in subparagraph (h)(1) of this clause.
 - (ii) Demand immediate repayment by the Contractor of the unliquidated balance of advance payments.
 - (iii) Take possession of and, with or without advertisement, sell at public or private sale all or any part of the property on which the Government has a lien under this contract and, after deducting any expenses incident to the sale, apply the net proceeds of the sale to reduce the unliquidated balance of advance payments or other Government claims against the Contractor.
- (3) The Government may take any of the actions described in subparagraphs (h)(1) and (h)(2) of this clause it considers appropriate at its discretion and without limiting any other rights of the Government.
- (i) *Prohibition against assignment.* Notwithstanding any other terms of this contract, the Contractor shall not assign this contract, any interest therein, or any claim under the contract to any party.
 - (j) *Information and access to records.* The Contractor shall furnish to the administering office (1) monthly or at other intervals as required, signed or certified balance sheets and profit and loss statements, and, (2) if requested, other information concerning the operation of the Contractor's business. The Contractor shall provide the authorized Government representatives proper facilities for inspection of the Contractor's books, records, and accounts.
 - (k) *Other security.* The terms of this contract are considered to provide adequate security to the Government for advance payments; however, if the administering office considers the security inadequate, the Contractor shall furnish additional security satisfactory to the administering office, to the extent that the security is available.
 - (l) *Representations.* The Contractor represents the following:
 - (1) The balance sheet, the profit and loss statement, and any other supporting financial statements furnished to the administering office fairly reflect the financial condition of the Contractor at the date shown or the period covered, and there has been no subsequent materially adverse change in the financial condition of the Contractor.
 - (2) No litigation or proceedings are presently pending or threatened against the Contractor, except as shown in the financial statements.
 - (3) The Contractor has disclosed all contingent liabilities, except for liability resulting from the renegotiation of defense production contracts, in the financial statements furnished to the administering office.
 - (4) None of the terms in this clause conflict with the authority under which the Contractor is doing business or with the provision of any existing indenture or agreement of the Contractor.

- (5) The Contractor has the power to enter into this contract and accept advance payments, and has taken all necessary action to authorize the acceptance under the terms of this contract.
 - (6) The assets of the Contractor are not subject to any lien or encumbrance of any character except for current taxes not delinquent, and except as shown in the financial statements furnished by the Contractor. There is no current assignment of claims under any contract affected by these advance payment provisions.
 - (7) All information furnished by the Contractor to the administering office in connection with each request for advance payments is true and correct.
 - (8) These representations shall be continuing and shall be considered to have been repeated by the submission of each invoice for advance payments.
- (m) *Covenants.* To the extent the Government considers it necessary while any advance payments made under this contract remain outstanding, the Contractor, without the prior written consent of the administering office, shall not--
- (1) Mortgage, pledge, or otherwise encumber or allow to be encumbered, any of the assets of the Contractor now owned or subsequently acquired, or permit any preexisting mortgages, liens, or other encumbrances to remain on or attach to any assets of the Contractor which are allocated to performing this contract and with respect to which the Government has a lien under this contract;
 - (2) Sell, assign, transfer, or otherwise dispose of accounts receivable, notes, or claims for money due or to become due;
 - (3) Declare or pay any dividends, except dividends payable in stock of the corporation, or make any other distribution on account of any shares of its capital stock, or purchase, redeem, or otherwise acquire for value any of its stock, except as required by sinking fund or redemption arrangements reported to the administering office incident to the establishment of these advance payment provisions;
 - (4) Sell, convey, or lease all or a substantial part of its assets;
 - (5) Acquire for value the stock or other securities of any corporation, municipality, or Governmental authority, except direct obligations of the United States;
 - (6) Make any advance or loan or incur any liability as guarantor, surety, or accommodation endorser for any party;
 - (7) Permit a writ of attachment or any similar process to be issued against its property without getting a release or bonding the property within 30 days after the entry of the writ of attachment or other process;
 - (8) Pay any remuneration in any form to its directors, officers, or key employees higher than rates provided in existing agreements of which notice has been given to the administering office, accrue excess remuneration without first obtaining an agreement subordinating it to all claims of the Government, or employ any person at a rate of compensation over \$ N/A a year;
 - (9) Change substantially the management, ownership, or control of the corporation;
 - (10) Merge or consolidate with any other firm or corporation, change the type of business, or engage in any transaction outside the ordinary course of the Contractor's business as presently conducted;
 - (11) Deposit any of its funds except in a bank or trust company insured by the Federal Deposit Insurance Corporation or a credit union insured by the National Credit Union Administration;

- (12) Create or incur indebtedness for advances, other than advances to be made under the terms of this contract, or for borrowings;
- (13) Make or covenant for capital expenditures exceeding \$ N/A in total;
- (14) Permit its net current assets, computed in accordance with generally accepted accounting principles, to become less than \$ N/A; or
- (15) Make any payments on account of the obligations listed below, except in the manner and to the extent provided in this contract:

[List the pertinent obligations]

PART III - LIST OF DOCUMENTS, EXHIBITS, AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this RFP:

1. Government Notice for Handling Proposals.
2. Proposal Intent Response Sheet.
3. NIH Form 1688-1, Project Objectives.
4. National Institutes of Health Customer Survey of Contractor Performance.
5. Example, Request for Past Performance Information.

THE FOLLOWING FORM MUST BE COMPLETED AND SUBMITTED WITH EACH TECHNICAL PROPOSAL: (A copy of each form shall be included with the original and every copy of the technical proposal).

6. Summary of Labor & Direct Costs (TECHNICAL PROPOSAL).
7. Targeted/Planned Enrollment Table

THE FOLLOWING FORMS MUST BE COMPLETED AND SUBMITTED WITH EACH BUSINESS PROPOSAL:

8. Protection of Human Subjects Assurance Identification /IRB Certification/Declaration of Exemption
9. NIH-2043, Proposal Summary and Data Record.
10. Summary of Annual Costs (BUSINESS PROPOSAL).
11. Summary of Related Activities.
12. SF-LLL, Disclosure of Lobbying Activities.
13. Small Business Subcontracting Plan .
14. Small Disadvantaged Business (SDB) Participation Factor.
15. Representations and Certifications
16. Certificate of Current Cost and Pricing Data

THE FOLLOWING FORMS MAY BE MADE A PART OF ANY CONTRACT RESULTING FROM THIS RFP. These are included here for informational purposes.

17. NIH (RC-1), Invoice/Financing Request for NIH Cost-Reimbursement Type Contracts.
18. NIH (RC)-4, Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts.
19. NIH (RC)-7, Procurement of Certain Equipment, (OMB Bulletin 81-16).
20. Inclusion Enrollment Report.
21. NIH 2706, Financial Report of Individual Project/Contract.

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS AND CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS

Beginning January 1, 2005, the Federal Acquisition Regulation (FAR) requires the use of the Online Representations and Certifications Application (ORCA) in Federal solicitations as a part of the proposal submission process. With ORCA, you now have the ability to enter and maintain your representation and certification information, at your convenience, via the Internet at <http://orca.bpn.gov>. In addition to the on-line representations and certifications, it is recognized that other representations and certifications are required on a case by case basis and are not covered by the on-line documentation. For this RFP, in addition to the on-line representations and certifications, offerors are required to complete the representations and certifications listed in Attachment #15 under Section J, and to submit a completed copy as a part of their original business proposal.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. PACKAGING AND DELIVERY OF PROPOSAL

Your proposal shall be organized as specified in SECTION L.2., INSTRUCTIONS TO OFFERORS.

Proposals for furnishing the supplies and/or services in the SCHEDULE will be accepted at the location specified in (3) below, and in the number of copies specified in (1) below, **until 4:30 p.m. (local time), May 31, 2005**. Delivery and marking of proposals shall be as indicated below:

1. Number of Copies: The number of copies required of each part of your proposal are as follows:

Technical Proposal: Original plus 10 copies

Business Proposal: Original and 4 copies, **plus a yearly and cumulative summary of proposed costs on a CD in Microsoft Excel® format.**

2. External Package Marking

In addition to the address cited below, the outside of each package should be marked with the following information:

RFP No. NIH-NINDS-05-02

3. Address

If hand-delivered or sending your proposal via an overnight delivery service, e.g., Federal Express, DHL, etc, your proposal must be delivered to the following address:

Contracts Management Branch, DER
National Institute of Neurological Disorders and Stroke, NIH
NeuroScience Center Building
6001 Executive Boulevard, Suite 3287
Rockville, Maryland 20852

If mailing your proposal through the U.S. Postal Service your proposal must be sent to the following address:

Contracts Management Branch, DER
National Institute of Neurological Disorders and Stroke, NIH
NeuroScience Center Building, MSC 9531

6001 Executive Boulevard, Suite 3287
Bethesda, Maryland 20892-9531

b. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Clause 52.215-1 (Jan 2004)]**

(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*", "*writing*", or "*written*" means any worded or numbered expression that 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, and (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).

[Note: In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.]

- (e) *Restriction on disclosure and use of data.* (1) The proposal submitted in response to this request 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. The legend reads:

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 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).

- (2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

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

- (3) Offerors are cautioned that proposals submitted with 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.
- (f) *Contract award.* (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.
- (2) The Government may reject any or all proposals if such action is in the Government's interest.
 - (3) The Government may waive informalities and minor irregularities in proposals received.
 - (4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines

them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

- (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.
- (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.
- (7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.
- (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.
- (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
- (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.
- (11) If a post-award debriefing is given to requesting offeror's, the Government shall disclose the following information, if applicable:
 - (i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
 - (ii) The overall evaluated cost or price and technical rating of the successful and the debriefed offeror and past performance information on the debriefed offeror.
 - (iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection.
 - (iv) A summary of the rationale for award.
 - (v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.
 - (vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

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.

(End of Provision)

c. **"JUST IN TIME"**

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information needed during the initial evaluation of proposals. Certain documents will no longer be required to be submitted with initial proposals, but will be requested at a later stage in the competitive process. Specifically, the offeror's travel policy, annual financial statement, total compensation plan and small business subcontracting plan will only be required to be submitted as part of any revised proposal and/or Final Proposal Revision (FPR) submission.

d. **NAICS 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 North American Industry Classification System (NAICS) code for this acquisition is **541710**.
- (2) The small business size standard is 500 employees.

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

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

It is anticipated that ONE (1) AWARD may be made from this solicitation and that the award may be made on/about September 30, 2005. Depending upon the type of organization selected for contract award, it is anticipated that the award from this solicitation will be a cost reimbursement type contract for a period of five (5) years. It is expected that a completion type contract will be awarded as a result of this RFP.

f. **ESTIMATE OF EFFORT**

To assist you in the preparation of your proposal, the Government considers the estimated effort for this project as follows: see the table below. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

*Offerors are required to furnish their own estimates of effort as related to their own technical approach.

Labor Category	Percentage of Effort				
	YR 1	YR 2	YR 3	YR 4	YR 5
Professional	100%	125%	125%	125%	140%
Other:					
Professional Support	250%	400%	400%	400%	275%

g. **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 acquisition. Any other commitment, either explicit or implied, is invalid.

h. **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.

i. **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.

j. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that the most important award selection factor shall be the technical evaluation of proposals. The technical proposal will receive paramount consideration in the selection of the Contractor for this acquisition. All evaluation factors, other than cost or price, when combined are significantly more important than cost or price. The relative importance of the award selection factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the offeror whose proposal provides the best overall value to the Government, cost and other factors considered.

k. **PREPARATION COSTS**

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

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

- (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:

Contracting Officer*
Contracts Management Branch, DER
National Institute of Neurological Disorders and Stroke
NeuroScience Center, MSC 9531
6001 Executive Boulevard, Suite 3287
BETHESDA MD 20892-9531

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

*Complete address and contact information can be found in the SECTION A SOLICITATION/CONTRACT FORM page of the specific RFP.

(End of Provision)

m. **LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70 (NOVEMBER 1986)**

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, a proposal received after the date specified for

receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

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

(1) Contract Type and General Clauses

It is contemplated that a cost reimbursement type contract will be awarded. 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 addressees, and marked as indicated in Section L.1.a. 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, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm (120 days minimum) and the designation of those personnel authorized to conduct negotiations. (See Section J, Attachment #9 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 labor-categories, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment #6 entitled, 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 and separate cost estimates provided.

(6) Evaluation of Proposals

The Government will evaluate technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

(7) 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.

(8) 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 procurements, 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.

(9) Privacy Act – Treatment of Proposal Information

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.

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.

(10) Obtaining and Disseminating Biomedical Research Resources

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH Contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: <http://ott.od.nih.gov/NewPages/64FR72090.pdf>

(11) Sharing Research Data

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:

<http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>

(12) Selection of Offerors

- a) The acceptability of the technical portion of each research contract proposal will be evaluated by a technical review panel. The panel will evaluate each technical proposal in strict conformity with the technical evaluation criteria of the RFP, utilizing point scores and written critiques. The technical strengths and weaknesses of each proposal will be addressed by the reviewers and written recommendations provided to the Contracting Officer. Each proposal will be rated as either technically acceptable or unacceptable. Proposals rated technically unacceptable will not be considered further. The panel may suggest that the Contracting Officer request clarifying information from an offeror.
- b) A separate and independent review of the business proposal will be made by Institute staff and will be subjected to a cost realism analysis, and if applicable, a cost analysis.
- 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 NINDS' policy to conduct discussions with all offerors in the competitive range, NINDS 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 subsequent limited negotiations to finalize details with the selected source in accordance with HHSAR 315.370.

- 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 permits tradeoffs among cost or price and non cost factors and allows the Government to accept other than the lowest price proposal.

- f) The NINDS 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 NINDS' requirements. Synopses of awards exceeding \$25,000 will be published on the FedBizOpps web site.

(13) Small Business Subcontracting Plan

****** This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.c. of this RFP. ******

(This document is not required with submission of the initial proposal).

If the proposed contract exceeds a total estimated cost of \$500,000 for the entire period of performance, the 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, Attachment #13 to this RFP is 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 Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses and Service Disabled Veteran-Owned Small Businesses 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, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Businesses,

and Service Disabled Veteran-Owned Small Businesses Concerns 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, HUBZone, Veteran-Owned Small Business, and Service Disabled Veteran-Owned 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, HUBZone, Veteran-Owned Small Business, and Service Disabled Veteran-Owned Concerns as subcontractors.
- (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, HUBZone, Veteran-Owned Small Business, and Service Disabled Veteran-Owned Concerns as subcontractors.
- (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, HUBZone, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Concerns as subcontractors.
- (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, HUBZone, Veteran-Owned Small Business, and Service Disabled Veteran-Owned Concerns as subcontractors 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 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 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, HUBZone, Veteran-Owned Small Business, and Service Disabled Veteran-Owned Concerns as subcontractors and award subcontracts to them.

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

(14) HUBZone Small Business Concerns

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

(15) Extent of Small Disadvantaged Business Participation

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors 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 Section M shall be used for evaluation purposes.

Offerors shall include with their offers, SDB participation targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is 541710, as specified in Section L.1.(d). A total target for SDB participation by the prime contractor, including joint ventures and team arrangements*, 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. **SDB Participation Plan information may be provided by using Attachment 14, entitled "Small Disadvantaged Business Participation Factor" or in a format developed by the offeror. 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 SDB evaluation factor in Section M includes a subfactor that considers the extent to which SDB concerns must be specifically identified in the participation plan, 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 – NAICS Subsector 223

	SDB Percentage of Total Contract Value	SDB Dollars
Total Contract Value – \$1,000,000	25%	\$250,000
SDB Participation by Prime (Includes joint venture partners and team arrangements)*	10%	\$100,000
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.

(16) Salary Rate Limitation in Fiscal Year 2005

Offerors are advised that pursuant to P.L. 108-447, no NIH Fiscal Year 2005 (October 1, 2004 - September 30, 2005) 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 I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor.

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 I*. The salary rate limitation set by P.L. 108-447 applies only to Fiscal Year 2005 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 I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 108-447 states in pertinent part:

"None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, 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 I*."

LINK TO EXECUTIVE SCHEDULE SALARIES:

<http://www.opm.gov/oca/05tables/html/ex.asp>

*Note to Offerors: The current Fiscal Year Executive Level I Salary Rate should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award will be required to be in compliance with the current Fiscal Year 2005 Executive Level I Salary rates.

(17) 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.

(18) 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.

(19) Past Performance Information

Offerors shall mail the Past Performance Information Survey to at least five previous clients (see Section J, Attachment #4 using the criterion below for selection of clients. In addition, offeror's shall submit the following information in their proposal (for both the offeror and for each proposed major subcontractor).

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

A list of the last 5 contracts completed during the past three years and all contracts currently in process that, are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

Include the following information for each contract or subcontract:

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

The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort. For the purpose of this solicitation, a "major subcontract" is defined as a subcontract that exceeds \$500,000.

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

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

(21) Electronic and Information Technology Accessibility

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L. 105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that:

- a. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and
- b. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards.

Further information about Section 508 is available via the Internet at:

<http://www.section508.gov>

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

This solicitation incorporates the following 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) Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).
- (a) Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
- (b) Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).
- (c) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8 (October 1997)

b. TECHNICAL PROPOSAL INSTRUCTIONS

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

1. **Technical Discussions**

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

(a) **Project Objectives, NIH-1688-1**

The offeror shall insert a completed NIH Form 1688-1, Project Objectives, as provided in Section J, Attachment #3, behind the Title Page of each copy of the proposal, along with the "Government Notice for Handling Proposals." The NIH Form 1688-1 is to be completed as follows:

- For an **Institution of Higher Education**: The form MUST be completed in its entirety.
- For **OTHER** than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank.

The information required under the "Summary of Objectives" portion of the form **MUST** meet the requirements set forth in the section of the form entitled, "**INSTRUCTIONS:**"

(b) **Statement of Work**

i) 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.

ii) 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.

iii) 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. The tasks listed in the Statement of Work are stated in broad terms. The offeror shall propose specific procedures to accomplish the stated tasks.

iv) 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.

(c) **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.

The following specific information must be provided by the offeror pertaining to the Project Director, Principal Investigator, and each of any other proposed key professional individuals designated for performance under any resultant contract. **The offeror shall provide a separate “Summary of Related Activities” form, Attachment #11, for each key professional individual proposed for work under the project.**

i) 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.

ii) Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss their 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.

iii) 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 must be indicated and the anticipated sources must 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.

iv) 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 Criteria (Section M).

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. **Human Subjects**

IMPORTANT NOTE TO OFFERORS: The following 11 paragraphs (5 through 10) shall be addressed in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

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

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (MARCH 2005)

- 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 Protections (OHRP), Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.
- b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or 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 OpDiv 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 consultation with OHRP, telephone: 301-496-7005), 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. The Contracting Officer will direct the offeror/Contractor to the OHRP IRB Registration and Assurance Filing website, found at <http://www.hhs.gov/ohrp/> or to the physical address if the offeror/Contractor cannot access the Internet. HHS regulations for the protection of human subjects may be found at: http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html

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. (End of Provision)

6. **Instructions to Offerors Regarding Protection of Human Subjects**

Offerors must address the following human subjects protections issues if this contract will be for research involving human subject (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

(a) Risks to the subjects

Human Subjects Involvement and Characteristics:

- Describe the proposed involvement of human subjects in response to the solicitation.

- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.

- Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.

Sources of Materials:

- Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks:

- Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.

- Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

- Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the Contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the Contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

Protection Against Risk:

- Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
- Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.
- In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

(c) Potential Benefits of the Proposed Research to the Subjects and Others

- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to those provided to the participants by the proposed research, where appropriate.
- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

(d) Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Note: If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

Collaborating Site(s)

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

7. **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](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html) 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/>. You may download the information at this site at no cost and modify it, if desired. The University of Rochester has made its training program available for individual investigators. 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_prof_protect.html. If an institution already has developed educational programs on the protection of research participants, completion of these programs also will 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 Contracting Officer with the title of the education program and a one sentence description of the program that the replacement has completed.

8. **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is NIH policy that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an Institute/Center Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43), **and applies to research subjects of all ages.**

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

http://www.grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research (<http://www.nih.gov/news/crp/97report/execsum.htm>).

Information Required for ALL Clinical Research Proposals

This solicitation contains a review criterion addressing the adequacy of: (1) the offeror's plans for inclusion of women and minorities in the research proposed; or (2) the offeror's justification(s) for exclusion of one or both groups from the research proposed.

Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic groups and provide a rationale for selection of such subjects in response to the requirements of the solicitation. The description may include (but is not limited to) information on the population characteristics of the disease or condition being studied in the planned research, and/or described in the statement of work, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned research.

The proposal must include the following information:

- A description of the subject selection criteria
- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group
- The proposed sample composition using the "Targeted/Planned Enrollment Table" (see Section J, Attachments)

NOTE 1: For all proposals, use the ethnic and racial categories and complete the "Targeted/Planned Enrollment Table in accordance with the Office of Management and Budget (OMB) Directive No. 15, which may be found at <http://www.whitehouse.gov/OMB/fedreg/ombdir15.html>

Standards for Collecting Data. When you, as a Contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in OMB Directive No. 15. The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When you collect race and ethnicity separately, you must collect ethnicity first. You shall offer respondents the option of selecting one or more racial designations. When you collect data on race and ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple responses, you shall make available, at a minimum, the total number of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

Use the form in Section J, Attachments, entitled, "Targeted/Planned Enrollment Table," when preparing your response to the solicitation requirements for inclusion of women and minorities.

Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

Use the format for the Annual Technical Progress Report for Clinical Research Study Populations (See Section J – List of Documents, Exhibits and Other Attachments of the RFP) entitled, "Inclusion Enrollment Report," for reporting in the resultant contract.

9. **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 *clear and compelling* reasons not to include them. (See examples of Justification for Exclusion of Children below). 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.

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

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. The “Human Subjects” section of your technical proposal 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. This solicitation contains a review criterion addressing the adequacy of: (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

When children are included, the plan also must include a description of: (1) the expertise of the investigative team for dealing with children at the ages included; (2) the appropriateness of the available facilities to accommodate the children; and, (3) the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation.

Justification for Exclusion of Children

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

- The objective of the solicitation is not relevant to children.
- There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.
- The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.
- A separate, age-specific study in children is warranted and preferable. Examples include:
 - The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
 - The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
 - Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or
 - Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be in the initial group to be involved in research studies, in some

instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or

- Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);

- Other special cases justified by the offeror and found acceptable to the review group and the Institute Director

Definition of a Child

For the purpose of this solicitation, a child is defined as an individual under the age of 21 years. The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a “child,” and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of “child” for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

10. Research Involving Prisoners as Subjects

a. HHS Regulations at 45 CFR Part 46, Subpart C provide additional protections pertaining to biomedical and behavioral research involving prisoners or those individuals who, during the period of the contract become prisoners, as subjects. These regulations also set forth the duties of the Institutional Review Board (IRB) where prisoners are involved in the research. HHS-funded research involving prisoners as subjects may not proceed until the Office for Human Research Protections (OHRP) issues approval, in writing, as required by 45 CFR 46.306(a)(2). In addition, OHRP Guidance on the Involvement of Prisoners in Research may be found at: <http://www.hhs.gov/ohrp/humansubjects/guidance/prisoner.pdf>

b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

On June 20, 2003 the Secretary of HHS waived the applicability of certain provisions of Subpart C of 45 CFR Part 46, (Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects) to specific types of epidemiological research involving prisoners as subjects.

The applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain epidemiological research conducted or funded by DHHS is waived when:

1. The sole purposes are:

- a) to describe the prevalence or incidence of a disease by identifying all cases, or
- b) to study potential risk factor associations for a disease, and

2. The Institution responsible for the conduct of the research certifies to the OHRP that the Institutional Review Board (IRB) approved the research and fulfilled its duties under 45 CFR 46.305(a)(2-7) and determined and documented that:

- a) the research presents no more than minimal risk, and
- b) no more than inconvenience to the prisoner-subjects, and
- c) prisoners are not a particular focus of the research.

For more information about this Waiver see <http://www.hhs.gov/ohrp/special/prisoners/Prisoner%20waiver%206-20-03.pdf>

c. **BUSINESS PROPOSAL INSTRUCTIONS**

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

The business proposal must contain sufficient information to allow the Government to perform a basic cost realism analysis of the proposed cost or price of the work. This information shall include payroll documentation, vendor quotes, invoice prices and/or any other information deemed necessary to evaluate the reasonableness of the price or to determine cost realism for all of the basic cost elements. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, and, if applicable, fee and profit.

(2) **Proposal Cover Sheet**

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

- (a) Solicitation, contract, and/or modification number;
- (b) Name and address of Offeror;
- (c) Name and telephone number of point of contact;
- (d) Name, address, and telephone number of Contract Administration Office, (if available);
- (e) Name, address, and telephone number of Audit Office (if available);
- (f) Proposed cost and/or price; profit or fee (as applicable); and total;
- (g) 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.
- (h) Date of submission; and
- (i) 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 with the initial proposal 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.

The attached "Summary of Annual Costs" shall be used as the yearly and cumulative summary of proposed costs. This budget summary shall be presented directly behind the business proposal cover page.

(3) **Information Other than Cost or Pricing Data**

- (a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the cost estimate/price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the cost estimate/price proposed. Support any information provided by explanations or supporting rationale as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

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

1) **Direct Labor**

Provide a breakdown, by individual or labor class, of labor hours and rates. Identify and list all key personnel and all others who will be directly involved in work under the project. Provide a written narrative justifying the basis of the labor effort proposed for all persons.

2) **Materials**

Provide a summary listing and/or bill of materials for all individual material types and quantities and the basis for the line item cost/pricing estimate. This information should be supported with documentation such as current vendor quotes, invoices based on recent purchases, catalog price lists/schedules, etc.

3) **Subcontracted Items**

The offeror shall include parts, components, assemblies, and services that are to be produced or performed by others in accordance with the offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over \$550,000, 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 15.404-3.

4) **Raw Materials**

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

5) **Purchased Parts**

Includes items not covered above. Provide priced quantities of items required for the proposal. Provide a list for all purchase parts and quantities and the basis for the line item cost/pricing estimate. This information should be supported with documentation such as current vendor quotes, invoices based on recent purchases, catalog price lists/schedules, etc.).

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 you have computed and applied your 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**

List any equipment proposed as a direct cost, including description, price, quantity, total price, results of purchase or lease analysis, and the basis for the cost/pricing estimate.

9) **Travel**

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

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.

(4) **Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)]**

- (a) Exceptions from cost or pricing data.

- (1) In lieu of submitting cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.
 - (i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.
 - (ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--
 - (A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;
 - (B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;
 - (C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.
 - (2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.
- (b) Requirements for cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:
- (1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.
 - (2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.
- (End of provision)

Alternate I (October 1997). As prescribed in 15.408(1), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

- (b)(1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.c.(3) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

(5) Total Compensation Plan - Instructions

******This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.c. of this RFP. ******

- a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts.
- b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
- c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

(6) Total Compensation Plan – Evaluation

- a) Total Compensation Plan (Professional Employees)

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

- b) Cost (Professional Compensation)

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

- c) Other (Labor Relations)

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

- d) Federal Acquisition Regulation Clauses Incorporated by Reference

(7) **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.

(8) **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, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) Royalties

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

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

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

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

d) Financial Capacity

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

e) Incremental Funding

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

HHSAR 352.232-75, Incremental Funding (January 2001)

- a. 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 the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted 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.
- b. The "Limitation of Funds" clause to be included in the resultant contract shall supersede the "Limitation of Cost" clause found in the General Provisions.

(End of provision)

f) FAR 52.215-16, Facilities Capital Cost of Money (JUNE 2003)

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

- (1) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(b) met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.
- (2) 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.

(9) 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.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

<http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm>

(10) Offeror's Annual Financial Report

****** This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.c. of this RFP. ******

All offerors who are requested to submit a final proposal revision will be required to submit a copy of the organization's most recent annual financial report.

(11) Representations and Certifications

Beginning January 1, 2005, the Federal Acquisition Regulation (FAR) requires the use of the Online Representations and Certifications Application (ORCA) in Federal solicitations as a part of the proposal submission process. With ORCA, you now have the ability to enter and maintain your representation and certification information, at your convenience, via the Internet at <http://orca.bpn.gov>. In addition to the on-line representations and certifications, it is recognized that other representations and certifications are required on a case by case basis and are not covered by the on-line documentation. For this RFP, in addition to the on-line representations and certifications, offerors are required to complete the representations and certifications listed in Attachment #15 under Section J, and to submit a completed copy as a part of their original business proposal. In addition, the above instructions would apply for any proposed subcontractor.

(12) Travel Costs/Travel Policy

****** This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1.c. of this RFP. ******

(This document is not required with submission of the initial proposal).

a) Travel Costs - Commercial

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

All offerors who are requested to submit a final proposal revision will be required to submit a copy of the organization's most recent travel policy. If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

A. GENERAL INFORMATION REGARDING EVALUATION FACTORS FOR AWARD

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors are: technical, past performance, cost/price, and small disadvantaged business participation factor. The technical proposal will receive paramount consideration in the selection of the Contractor for this acquisition. The technical evaluation is more important than past performance, and past performance is more important than cost/price, and cost/price is more important than the Small Disadvantaged Business (SDB) Participation Factor. All evaluation factors other than cost/price, when combined, are significantly more important than cost/price. In any event, the Government reserves the right to make an award to that offeror whose proposal provides the best overall value for the Government. The trade-off process described in FAR 15.101-1 shall be employed.

An initial technical review will be conducted to evaluate technical proposals against the technical evaluation criteria specified below. Offerors must submit sufficient information to allow evaluation of their proposals based on the research objectives specified in the Statement of Work and the technical evaluation criteria listed below. Failure to provide any of the information required to evaluate the proposal may result in less than a favorable evaluation.

The estimated cost of a proposal must be reasonable for the work to be performed. The business proposal will be subjected to a cost realism analysis and, if applicable, a cost analysis.

If a proposal is received from a foreign source, the technical review group will address the need or appropriateness of accomplishing the work outside the United States.

B. TECHNICAL EVALUATION CRITERIA

Technical proposals shall be evaluated in accordance with the following technical evaluation criteria that are listed and weighted by their relative importance with a maximum total score of 100 points. **Proposals will be judged solely on the written material provided by the offeror.**

CRITERIA

POINTS

1. Understanding the Requirement and Technical Approach

45 maximum points

The proposal must demonstrate a thorough understanding of the requirements of the Statement of Work and describe an approach for each specified task that will demonstrate the achievement of timely and acceptable performance. The proposal shall present a comprehensive statement of the problem, scope, and purpose of the project to demonstrate an understanding of the requirements from a management and technical standpoint.

Although worth a total of 45 maximum points, this criteria will be evaluated and scored according to the following subfactors:

The proposal shall provide evidence of the quality of the following:

- Methods for conducting and evaluating each component of the research; methods for assessing acceptability of measures to the neurology clinical trials community **(0-10)**.
- Plans for providing expertise, infrastructure, resources and facilities for conducting the research and developing final instruments **(0-15)**.
- Plans to collaborate with appropriate subject-matter experts **(0-10)**.
- The adequacy of the offeror's proposed plan and approach for making the battery available in the public domain in a format that is both user friendly and accessible. **(1-10)**

2. Qualifications and Availability of Proposed Personnel

45 maximum points

Demonstrated evidence of the qualifications, experience, and availability of professional and technical personnel comprising the offeror's proposed investigative team.

Although worth a total of 45 maximum points, this criteria will be evaluated and scored according to the following subfactors:

The proposal shall document the offeror's knowledge of and actual experience in the field of cognitive neuroscience and outcomes research. The offeror will be evaluated on the basis of proven and demonstrated competence, creativity, and leadership, as documented by an extensive record of achievement and publication history in cognitive neuroscience research, as well as documented experience in clinical trials research and understanding of clinical trials methodology **(0-25)**.

Personnel proposed to be assigned and available for work under the project shall be evaluated on their demonstrated, documented, and relevant expertise, education, availability, and experience, highlighting that which was obtained within the past three years. It is anticipated that successful completion of the work will require the participation of a multidisciplinary team of investigators. Experts in the following areas are likely to be required: cognitive neuroscience, developmental neuroscience, neurology psychometrics, neuropsychology, clinical and rehabilitation medicine, statistics, health services and outcomes research, and database design and management **(0-20)**.

3. Availability and utilization of proposed facilities and equipment **10 maximum points**

Although worth a total of 10 maximum points, this criteria will be evaluated and scored according to the following subfactors:

Offerors shall describe the availability and proposed utilization of appropriate facilities and equipment required to successfully perform the work requirements **(0-5)**.

The Contractor must provide computing facilities and adequate support resources to complete the work. The computing system should be state-of-the-art, secure and able to handle large quantities of data and complex analysis. When possible, available software technology will be used, although specific applications may be developed as needed **(0-5)**.

C. PAST PERFORMANCE

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

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

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

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to 1) quality of product or service (the offeror's record of performing according to the contract requirements, including standards of good workmanship); 2) cost control (the offeror's record of controlling and forecasting costs); 3) timeliness of performance (the offeror's adherence to contract schedules, including the administrative aspects of performance); and 4) business relations (the offeror's reputation for reasonable and cooperative behavior).

Each of the above factors will be evaluated by using a point scale based on the following ratings: unsatisfactory, poor, fair, good, excellent and outstanding.

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

D. SMALL DISADVANTAGED BUSINESS PARTICIPATION FACTOR NON-SCORED

In accordance with FAR Part 15.304(c) 4, the Small Disadvantaged Business (SDB) targets expressed in dollars and percentages in performance of the contract shall be evaluated independent of the technical merit review. Offerors shall submit information on planned SDB participation in one clearly marked section of your business proposal. **Please note that the SDB Participation Factor is separate from the requirement to provide a Small Business Subcontracting Plan.** The SDB Participation Factor describes the extent of participation of SDB concerns in performance of the contract. This can include joint ventures, teaming arrangements, subcontracts and participation in performance of the contract expected to be performed by SDB concerns at the prime contract level.

Evaluation of the SDB Participation Factor will be assessed based on consideration of the information presented in the offeror's proposal and will be evaluated prior to determining the competitive range. We request that offeror's provide the "Participation Factor" information on the attached form "Small Disadvantaged Business (SDB) Participation Factor", see Attachment #14 to the RFP. 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.

The offeror's SDB Participation Factor will be evaluated by the following:

Offerors shall provide targets expressed in dollars and percentages of the total contract value in each applicable authorized NAICS Industry Subsectors and a total SDB participation target for SDB participation by the Contractor and subcontractor.

All targets will be incorporated into and become part of any resulting contract.

The offeror's Small Disadvantaged Business Participation Factor will be evaluated before determination of the competitive range.

OTHER NON-SCORED FACTORS

1. Evaluation of Data Sharing Plan

In addition to the four factors above, the NINDS will also evaluate the offeror's plan for the sharing of final research data, or, if data sharing is not possible, the offeror's rationale for its inability to share research data, shall be assessed for appropriateness and adequacy; and the offeror's proposal addressing the protection of human subjects from research risks. Note: The plan or documentation as to the rationale for not providing a plan shall be evaluated by NINDS program and contracts staff and shall not be scored. Any identified weaknesses in a plan or in the rationale for not permitting the sharing of research data may be part of any subsequent discussions with the offeror. The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy.

If your proposal does not include a plan or if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range, you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

2. Human Subject Evaluation

This research project involves human subjects. NIH Policy requires:

a. Protection of Human Subjects from Research Risks

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by NINDS that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated “unacceptable” (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or “acceptable”. If the reviewers find that this portion of the proposal is “unacceptable” they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range, you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the protection of human subjects from research risks is still found to be unacceptable, then your proposal may not be considered further for award.

b. Women and Minorities

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will consider the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:
 - the purpose of the research constrains the offeror’s selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
 - overriding factors dictate selection of subjects); or
 - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.
- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
 - inclusion of those groups would be inappropriate with respect to their health; or
 - inclusion of those groups would be inappropriate with respect to the purpose of the research.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research.

Based on the evaluation of the response to this criterion, this section of the proposal may be rated “unacceptable” (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or “acceptable.” See Section L of the solicitation for the requirements of women/minorities inclusion. If the reviewers find that this portion of the proposal is “unacceptable” they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range, you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the protection of human subjects from research risks is still found to be unacceptable, then your proposal may not be considered further for award.

c. Children

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them.

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers’ narrative evaluation of the offeror’s response to this evaluation criterion, this section of the proposal may be rated “unacceptable” (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror’s response regarding the inclusion of children; or the plan is not in accordance with NIH policy guidelines) or “acceptable.” If the reviewers find that this portion of the proposal is “unacceptable” they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range, you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the protection of human subjects from research risks is still found to be unacceptable, then your proposal may not be considered further for award.

GOVERNMENT NOTICE FOR HANDLING PROPOSALS

This proposal shall be used and disclosed for evaluation purposes only, and a copy of this Government notice shall be applied to any reproduction or abstract thereof. Any authorized restrictive notices which the submitter places on this proposal shall be strictly complied with. Disclosure of this proposal outside the Government for evaluation purposes shall be made only to the extent authorized by, and in accordance with, the procedures in HHSAR paragraph 315.608-72.

- (f) If authorized in agency implementing regulations, agencies may release proposals outside the Government for evaluation, consistent with the following:
 - (1) Decisions to release proposals outside the Government for evaluation purposes shall be made by the agency head or designee;
 - (2) Written agreement must be obtained from the evaluator that the information (data) contained in the proposal will be used only for evaluation purposes and will not be further disclosed;
 - (3) Any authorized restrictive legends placed on the proposal by the prospective Contractor or subcontractor or by the Government shall be applied to any reproduction or abstracted information made by the evaluator;
 - (4) Upon completing the evaluation, all copies of the proposal, as well as any abstracts thereof, shall be returned to the Government office which initially furnished them for evaluation; and
 - (5) All determinations to release the proposal outside the Government take into consideration requirements for avoiding organizational conflicts of interest and the competitive relationship, if any, between the prospective Contractor or subcontractor and the prospective outside evaluator.
- (g) The submitter of any proposal shall be provided notice adequate to afford an opportunity to take appropriate action before release of any information (data) contained therein pursuant to a request under the Freedom of Information Act (5 U.S.C. 552); and, time permitting, the submitter should be consulted to obtain assistance in determining the eligibility of the information (data) in question as an exemption under the Act. (See also Subpart 24.2, Freedom of Information Act.)

PROPOSAL INTENT RESPONSE SHEET

RFP No. NIH-NINDS-05-02

PLEASE REVIEW THE ATTACHED REQUEST FOR PROPOSAL. FURNISH THE INFORMATION REQUESTED BELOW AND RETURN THIS PAGE BY THE EARLIEST PRACTICABLE DATE. YOUR EXPRESSION OF INTENT IS NOT BINDING BUT WILL GREATLY ASSIST US IN PLANNING FOR PROPOSAL EVALUATION.

=====

- DO INTEND TO SUBMIT A PROPOSAL

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

COMPANY/INSTITUTION NAME:

AUTHORIZED SIGNATURE:

TYPED NAME AND TITLE:

DATE:

=====

RETURN TO:

National Institutes of Health
National Institute of Neurological Disorders and Stroke
Contracts Management Branch, DER
NeuroScience Center, MSC 9531
6001 Executive Boulevard, Suite 3287
Bethesda, Maryland 20892-9531

DEPARTMENT OF HEALTH AND HUMAN SERVICES
NATIONAL INSTITUTES OF HEALTH

PROJECT OBJECTIVES, FORM NIH-1688-1

SOLICITATION NUMBER: _____

CONTRACT NUMBER: (TO BE INSERTED BY THE CONTRACTING OFFICER): _____

OFFEROR NAME AND ADDRESS:

OFFEROR PHONE NUMBER (WITH AREA CODE) _____

***DEPARTMENT, SERVICE, LABORATORY OR EQUIVALENT (i.e., Department Name):**

***MAJOR SUBDIVISION (i.e., "Dental School", "Medical School", etc., or Major Component Code, if known):** _____

RFP TITLE: _____

PRINCIPAL INVESTIGATOR: _____

SUMMARY OF OBJECTIVES:

INSTRUCTIONS: The information supplied on this form MUST meet the following requirements: The summary of objectives MUST fit in the space provided. The height of the letters must not be smaller than 10 point; Helvetica or Arial 12 point is the NIH-suggested font. Type density, including characters and spaces, must be no more than 15 characters per inch (cpi). For proportional spacing, the average for any representative section of text must not exceed 15 cpi. No more than 6 lines of type within a vertical inch. Margins, in all directions, must be at least ½ inch.

THIS FORM MUST BE PLACED BEHIND THE TITLE PAGE OF EACH COPY OF THE TECHNICAL PROPOSAL ALONG WITH THE "GOVERNMENT NOTICE FOR HANDLING PROPOSALS."

***The insertion of the DEPARTMENT, SERVICE, LABORATORY OR EQUIVALENT (i.e., the Department Name) and MAJOR SUBDIVISION (i.e., "Dental School", "Medical School," etc., or the Major Component Code, if known) is required ONLY for INSTITUTIONS OF HIGHER EDUCATION.**

**PAST PERFORMANCE INFORMATION
NATIONAL INSTITUTES OF HEALTH CUSTOMER SURVEY OF CONTRACTOR PERFORMANCE**

Please complete the following questionnaire and return via regular mail or fax to the attention of:

_____ by (Date) _____
(Name)

(Address)

(Fax Number)

This survey pertains to: _____

Department/Component: _____

Contract Number: _____ Date of Survey: _____

Name of Person Completing Survey: _____

Signature of Person Completing Survey: _____

Your Company/Agency: _____

Your Role in this Contract (circle one): Contracting Officer Contract Specialist Project Officer
Other _____

Contract Value (including options) : \$ _____

Period of Performance (including option periods) : _____

Type of Contract: _____

Approximate percentage of work being performed (or completed) by subcontractor (s) : _____%

**PAST PERFORMANCE INFORMATION
NATIONAL INSTITUTES OF HEALTH CUSTOMER SURVEY OF CONTRACTOR PERFORMANCE**

Information on subcontractor(s) (where more than _____ % of work was completed by the subcontractor) :

_____	_____	_____
Subcontractor	Program Manager	Phone
_____	_____	_____
Subcontractor	Program Manager	Phone
_____	_____	_____
Subcontractor	Program Manager	Phone

General description of products / services required under the contract:

RATINGS

Please answer each of the following questions with a rating that is based on objective measurable performance indicators to the maximum extent possible. Commentary to support rating may be noted on page 5.

Assign each area a rating of 0 (unsatisfactory) , 1 (Poor) , 2 (Fair) , 3 (Good) , 4 (Excellent) , or 5 (Outstanding) . Use the attached Rating Guidelines as guidance in making these evaluations. Circle the appropriate rating. If you do not have enough personal knowledge or feedback from internal customers who directly received products and services from the contractor to make a determination on any of the performance criteria below, please circle "N/A" (not applicable / no opinion).

QUALITY OF SERVICE

-
1. Compliance with contract requirements
0 1 2 3 4 5 N/A
 2. Accuracy of reports
0 1 2 3 4 5 N/A
 3. Effectiveness of personnel
0 1 2 3 4 5 N/A
 4. Technical Excellence
0 1 2 3 4 5 N/A

PAST PERFORMANCE INFORMATION
NATIONAL INSTITUTES OF HEALTH CUSTOMER SURVEY OF CONTRACTOR PERFORMANCE

COST CONTROL

1. Record of forecasting and controlling target costs
0 1 2 3 4 5 N/A
2. Current, accurate and complete billings
0 1 2 3 4 5 N/A
3. Relationship of negotiated costs to actuals
0 1 2 3 4 5 N/A
4. Cost efficienciese
0 1 2 3 4 5 N/A

TIMELINESS OF PERFORMANCE

1. Met interim milestones
0 1 2 3 4 5 N/A
2. Reliability
0 1 2 3 4 5 N/A
3. Responsive to technical directions
0 1 2 3 4 5 N/A
4. Completed on time including wrap-up and contract administration
0 1 2 3 4 5 N/A
5. Met delivery schedules
0 1 2 3 4 5 N/A
6. Liquidated damages assessed: Yes No (circle one)

BUSINESS RELATIONS

1. Effective management, including management of subcontracts
0 1 2 3 4 5 N/A
2. Reasonable/cooperative behavior
0 1 2 3 4 5 N/A
3. Responsive to contract requirements
0 1 2 3 4 5 N/A
4. Notification of problems
0 1 2 3 4 5 N/A
5. Flexibility
0 1 2 3 4 5 N/A
6. Pro-active vs reactive
0 1 2 3 4 5 N/A

PAST PERFORMANCE INFORMATION
NATIONAL INSTITUTES OF HEALTH CUSTOMER SURVEY OF CONTRACTOR PERFORMANCE

SMALL BUSINESS AND SMALL DISADVANTAGED BUSINESS GOALS

The contractor met the goals set forth in its Subcontracting Plan. (See FAR 19.7 and FAR 15.305(a)(2)(v))
Yes No (circle one)

Comments: (optional) _____

The contractor met Small Disadvantaged Business Participation goals. (See 15.305(a)(2)(v) and FAR 19.1202)
Yes No (circle one)

Comments: (optional) _____

CUSTOMER SATISFACTION

1. The contractor is committed to customer satisfaction.
Yes No (circle one)

2. Would you recommend selection of this firm again?
Yes No (circle one)

ADDITIONAL COMMENTS

PAST PERFORMANCE INFORMATION
NATIONAL INSTITUTES OF HEALTH CUSTOMER SURVEY OF CONTRACTOR PERFORMANCE

	QUALITY OF PRODUCT OR SERVICE	COST CONTROL	TIMELINESS OF PERFORMANCE	BUSINESS RELATIONS
0- UNSATISFACTORY	Contractor is not in compliance and is jeopardizing achievement of contract objectives	Contractor is unable to manage costs effectively	Contractor delays are jeopardizing performance of contract objectives	Response to inquiries, technical/ service/ administrative issues is not effective
1-Poor	Major problems have been encountered	Contractor is having major difficulty in managing costs effectively	Contractor is having major difficulty meeting milestones and delivery schedule	Response to inquiries, technical/ service/ administrative issues is marginally effective
2-Fair	Some problems have been encountered	Contractor is having some problems in managing costs effectively	Contractor is having some problems meeting milestones and delivery schedule	Response to inquiries, technical/ service/ administrative issues is somewhat effective
3-Good	Minor inefficiencies/ errors have been identified	Contractor is usually effective in managing costs	Contractor is usually effective in meeting milestones and delivery schedule	Response to inquiries, technical/ service/ administrative issues is usually effective
4-Excellent	Contractor is in compliance with contract requirements and/ or delivers quality products / services	Contractor is effective in managing costs and submits current, accurate, and complete billings	Contractor is effective in meeting milestones and delivery schedule	Response to inquiries, technical/ service/ administrative issues is effective
5-Outstanding: The contractor has demonstrated an outstanding performance level in any of the above four categories that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances when contractor performance clearly exceeds the performance levels described as "Excellent."				

EXAMPLE, REQUEST FOR PAST PERFORMANCE INFORMATION

Date:

Dear Client:

We are currently responding to the DHHS/NIH/NINDS RFP-05-02 entitled: Domain Specific Tasks of Executive Function in Neurological Disorders. The Government is placing increased emphasis in their procurements on past performance as a source selection factor and is requiring that clients of firms responding to NINDS solicitations be identified and their participation in the evaluation process be requested.

Therefore, enclosed is a past performance questionnaire for your completion. We are requesting that you complete the questionnaire and return it to the undersigned by _____, as this information must be submitted along with our business proposal.

We thank you for your prompt response in this matter.

Sincerely,

(To be signed by offeror)

Attachment

(SUBMIT WITH TECHNICAL PROPOSAL)

SUMMARY OF LABOR AND DIRECT COSTS

<u>COST ELEMENTS</u>	<u>YEAR 01</u>	<u>YEAR 02</u>	<u>YEAR 03</u>	<u>YEAR 04</u>	<u>YEAR 05</u>	<u>TOTAL</u>
<u>DIRECT LABOR</u> (List individuals by name / labor category. Indicate hours or % effort for each.) _____ _____ _____ _____						
<u>TOTAL LABOR COSTS</u>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
<u>MATERIALS/SUPPLIES</u> (Specify items and cost for each.)	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
<u>TRAVEL COSTS</u> (Specify trips and costs.)	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
<u>EQUIPMENT</u> (List separately)	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
<u>CONSULTANTS</u> (Identify name & amount)	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
<u>SUBCONTRACTS</u> (Identify name & amount)	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
<u>OTHER DIRECT COST</u> (Specify items & costs for all elements)	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
<u>TOTAL DIRECT COST</u>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____

Specific Instructions:

1. Enter dollar totals for each person/labor category under Direct Labor. Hours or other effort estimates must be indicated.
2. DO NOT include salary rates under Direct Labor.
3. Total Labor Costs should include fringe benefit cost estimates in this total.
4. DO NOT include any Indirect Costs or Fixed-Fee.
5. DO NOT show the total proposal amount offered.
6. This form must be included with the TECHNICAL PROPOSAL.

Targeted/Planned Enrollment Table

This report format should NOT be used for data collection from study participants.

Study Title:

Total Planned Enrollment:

TARGETED/PLANNED ENROLLMENT: Number of Subjects			
<u>Ethnic Category</u>	<u>Sex/Gender</u>		
	<u>Females</u>	<u>Males</u>	<u>Total</u>
Hispanic or Latino			
Not Hispanic or Latino			
Ethnic Category Total of All Subjects*			
<u>Racial Categories</u>			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
Racial Categories: Total of All Subjects*			

*The "Ethnic Category Total of All Subjects" must be equal to the "Racial Categories Total of All Subjects."

**Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)**

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule.

Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type <input type="checkbox"/> ORIGINAL <input type="checkbox"/> CONTINUATION <input type="checkbox"/> EXEMPTION	2. Type of Mechanism <input type="checkbox"/> GRANT <input type="checkbox"/> CONTRACT <input type="checkbox"/> FELLOWSHIP <input type="checkbox"/> COOPERATIVE AGREEMENT <input type="checkbox"/> OTHER:	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
4. Title of Application or Activity		5. Name of Principal Investigator, Program Director, Fellow, or Other

6. Assurance Status of this Project (*Respond to one of the following*)

- This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No. _____, the expiration date _____ IRB Registration No. _____
- This Assurance, on file with (*agency/dept*) _____, covers this activity.
Assurance No. _____, the expiration date _____ IRB Registration/Identification No. _____ (*if applicable*)
- No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.
- Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph _____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

- This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: Full IRB Review on (date of IRB meeting) _____ or Expedited Review on (date) _____
 If less than one year approval, provide expiration date _____
- This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the common rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.	10. Name and Address of Institution	
11. Phone No. (<i>with area code</i>) 12. Fax No. (<i>with area code</i>) 13. Email:	15. Title	
14. Name of Official		
16. Signature	17. Date	

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Public reporting burden for this collection of information is estimated to average less than an hour per response. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: OS Reports Clearance Officer, Room 503 200 Independence Avenue, SW., Washington, DC 20201. Do not return the completed form to this address.

NIH 2043. PROPOSAL SUMMARY AND DATA RECORD

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH PROPOSAL SUMMARY AND DATA RECORD PROJECT TITLE (Title or Solicitation or Contract Proposal)	Solicitation/CONTRACT NUMBER		
LEGAL NAME AND ADDRESS OF OFFEROR	PLACE OF PERFORMANCE (Full address including ZIP)		
TYPE OF CONTRACT PROPOSED COST-REIMBURSEMENT FIXED PRICE COST-PLUS-FIXED-FEE OTHER			
ESTIMATED TIME REQUIRED TO COMPLETE PROJECT			
ESTIMATED DIRECT COSTS IN PROPOSED YEAR (From Budget)	PROPOSED STARTING DATE		
DOES THIS PROPOSAL INCLUDE A SUBCONTRACT YES NO (If yes, please furnish name and location of organization, description of services, basis for selection, responsible person employed by subcontractor and cost information.)			
NAME AND TITLE OF PRINCIPAL INVESTIGATOR	SOCIAL SECURITY NO.	EST. HOURS WEEKLY	AREA CODE/TEL.NO.
NAME AND TITLE OF CO-INVESTIGATOR (Use attachment if necessary.)			
NAME AND TITLE OF INDIVIDUAL(S) AUTHORIZED TO NEGOTIATE CONTRACTS	AREA CODE/TELEPHONE NUMBER		
NAME AND TITLE OF INDIVIDUAL(S) AUTHORIZED TO EXECUTE CONTRACTS	AREA CODE/TELEPHONE NUMBER		
DOES THIS PROPOSAL INVOLVE EXPERIMENTS WITH HUMAN SUBJECTS Institution's General Assurance re: Human Subjects Institution's Review Board's Approval of this Proposal An example of the informed consent for this study is enclosed A Clinical Protocol is enclosed		YES NO DATE APPROVED _____ DATE APPROVED _____ YES NO YES NO	PENDING PENDING
OFFEROR'S ACKNOWLEDGMENT OF AMENDMENTS TO THE Solicitation (Use attachment if necessary)			
ERRATA NUMBER	DATE	ERRATA NUMBER	DATE
NAME, ADDRESS, AND PHONE NUMBER OF COGNIZANT GOVERNMENT AUDIT AGENCY		NUMBER OF EMPLOYEES CURRENTLY EMPLOYED	
		DOLLAR VOLUME OF BUSINESS PER ANNUM	
		THIS OFFER EXPIRES _____ DAYS FROM THE DATE OF THIS OFFER (120 days if not specified)	
FOR THE INSTITUTION			
SIGNATURE OF PRINCIPAL INVESTIGATOR		SIGNATURE OF BUSINESS REPRESENTATIVE	
TYPED NAME AND TITLE		TYPED NAME AND TITLE	
EMPLOYER IDENTIFICATION NUMBER		DATE OF OFFER	

Provision of the Social Security Number is voluntary. Social Security Numbers are requested for the purpose of accurate and efficient identification, review, and management of NIH Extramural Programs. Authority for requesting this information is provided by Title III, Section 301, and Title IV of the Public Health Service Act, as amended.

SUMMARY OF ANNUAL COSTS

<u>COST ELEMENTS</u>	<u>YEAR 01</u>	<u>YEAR 02</u>	<u>YEAR 03</u>	<u>YEAR 04</u>	<u>YEAR 05</u>	<u>TOTAL</u>
<u>DIRECT LABOR</u> (List individuals by name / labor category. Indicate hours, % effort, and rates for each. _____ _____ _____ _____ _____ _____						
<u>TOTAL LABOR COSTS</u>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
<u>FRINGE BENEFITS</u>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
<u>MATERIALS/SUPPLIES</u>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
<u>TRAVEL COSTS</u>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
<u>EQUIPMENT</u>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
<u>CONSULTANTS</u>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
<u>SUBCONTRACTS</u>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
<u>OTHER DIRECT COST</u>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
<u>TOTAL DIRECT COST</u>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
<u>OVERHEAD (%)*</u>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
<u>G&A EXPENSE (%)*</u>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
<u>TOTAL EST. COST</u>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
<u>FEE (If applicable)</u>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____
<u>TOTAL COST PLUS FEE</u>	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____	\$ _____

Specific Instructions:

1. Enter dollar totals for each person/labor category under Direct Labor. Hours or other effort estimates must be indicated as well as salary/wage rates for each.
2. For * specify applicable base.
3. This form must be included with the BUSINESS PROPOSAL.

SUMMARY OF RELATED ACTIVITIES

The following specific information must be provided by the offeror pertaining to the Project Director, Principal Investigator, and each of any other proposed key professional individuals designated for performance under any resulting contract.

- a. Identify the total amount of all presently active federal contracts/cooperative agreements/grants and commercial agreements citing the committed levels of effort for those projects for each of the key individuals* in this proposal.

Professional's Name and Title/Position: _____

<u>Identifying Number</u>	<u>Agency</u>	<u>Total Effort Committed</u>
---------------------------	---------------	-------------------------------

- 1.
- 2.
- 3.
- 4.

*If an individual has no obligation(s), so state.

- b. Provide the total number of outstanding proposals, exclusive of the instant proposal, having been submitted by your organization, not presently accepted but in an anticipatory stage, which will commit levels of effort by the proposed professional individuals*.

Professional's Name and Title/Position: _____

<u>Identifying Number</u>	<u>Agency</u>	<u>Total Effort Committed</u>
---------------------------	---------------	-------------------------------

- 1.
- 2.
- 3.
- 4.

*If no commitment of effort is intended, so state.

- c. Provide a statement of the level of effort to be dedicated to any resultant contract awarded to your organization for those individuals designated and cited in this proposal.

<u>Name</u>	<u>Title/Position</u>	<u>Total Proposed Effort</u>
-------------	-----------------------	------------------------------

- 1.
- 2.
- 3.
- 4.

DISCLOSURE OF LOBBYING ACTIVITIES
CONTINUATION SHEET

Approved by OMB
0348-0046

Reporting Entity: _____ Page _____ of _____

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee of prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.
2. Identify the status of the covered Federal action.
3. Identify the appropriate classification of this report. If this is a follow-up report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.
4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.
5. If the organization filing the report in item 4 checks "Subawardee," then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.
6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.
7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.
8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (Solicitation) number, Invitation for Bid (IFB) number, grant announcement number, the contract, grant, or loan award number, the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "Solicitation-DE-90-001."
9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.
10.
 - (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.
 - (b) Enter the full names of the individual(s) performing services, and include full address if different from 10(a); Enter Last Name, First Name, and Middle Initial (MI).
11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material charge report, enter the cumulative amount of payment made or planned to be made.
12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.
13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.
14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s), employee(s), or Member(s) of Congress that were contacted.
15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.
16. The certifying official shall sign and date the form, print his/her name, title and telephone number.

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, D.C. 20503.

SMALL BUSINESS SUBCONTRACTING PLAN

DATE OF PLAN: _____
CONTRACTOR: _____
ADDRESS: _____

DUNN & BRADSTREET NUMBER: _____
SOLICITATION OR CONTRACT NUMBER: _____
ITEM/SERVICE (Description): _____

TOTAL CONTRACT AMOUNT: \$ _____
Total contract or Base-Year, if options
\$ _____ \$ _____ \$ _____ \$ _____

Option #1 Option #2 Option #3 Option #4
(if applicable) (if applicable) (if applicable) (if applicable)
TOTAL MODIFICATION AMOUNT, IF APPLICABLE \$ _____
TOTAL TASK ORDER AMOUNT, IF APPLICABLE \$ _____

PERIOD OF CONTRACT PERFORMANCE (Month, Day & Year): _____

The following outline meets the minimum requirements of section 8(d) of the Small Business Act, as amended, and implemented by Federal Acquisition Regulations (FAR) Subpart 19.7. While this outline has been designed to be consistent with statutory and regulatory requirements, other formats of a subcontracting plan may be acceptable. It is not intended to replace any existing corporate plan that is more extensive. Failure to include the essential information of FAR Subpart 19.7 may be cause for either a delay in acceptance or the rejection of a bid or offer when a subcontracting plan is required. "SUBCONTRACT," as used in this clause, 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 performance of the contract or subcontract. **If assistance is needed to locate small business sources, contact the Office of Small and Disadvantaged Business Utilization (OSDBU) at (202) 690-7300 or the OPDIV Small Business Specialist at _____.** Sources may also be obtained from SBA's PRO-Net website.

The offeror is required to include an explanation for a category that has zero as a goal.

NOTE TO CONTRACTORS: Please provide your CCR number with your Dunn & Bradstreet number.
Small Business Subcontracting Plan Page 1
March, 2003

1. Type of Plan (check one)

Individual plan (all elements developed specifically for this contract and applicable for the full term of this contract).

Master plan (goals developed for this contract) all other elements standardized and approved by a lead agency Federal Official; must be renewed every three years and contractor must provide copy of lead agency approval.

Commercial products/service plan This plan is used when the contractor sells products and services customarily used for non-government purposes. Plan/goals are negotiated with the initial agency on a company-wide basis rather than for individual contracts. The plan is effective only during the year approved. The contractor must provide a copy of the initial agency approval, and must submit an annual SF 295 to HHS with a breakout of subcontracting prorated for HHS (with an OPDIV breakdown, if possible).

2. Goals

State separate dollar and percentage goals for Small Business (SB), Small Disadvantaged Business (SDB), Woman-owned Small Business (WOSB), Historically Underutilized Business Zone (HUBZone) Small Business, Veteran-owned Small Business (VOSB), Service-Disabled Veteran-owned Small Business (SDVOSB) and "Other than small business" (Other) as subcontractors, for the base year and each option year, as specified in FAR 19.704. (Break out and append option year goals, if the contract contains option years or project annual subcontracting base and goals under commercial plans.)

a. Total estimated dollar value of ALL planned subcontracting, i.e., with ALL types of concerns under this contract is \$ _____ (b + h = a) (Base Year)

FY-____ (1st Option) FY-____ (2nd Option) FY-____ (3rd Option) FY-____ (4th Option)
\$ _____ & ____% \$ _____ & ____% \$ _____ & ____% \$ _____ & ____%

b. Total estimated dollar value and percent of planned subcontracting with SMALL BUSINESSES (including SDB, WOSB, HUBZone, SDVOSB and VOSB): (% of "a") \$ _____ and _____% (Base Year)

FY-____ (1st Option) FY-____ (2nd Option) FY-____ (3rd Option) FY-____ (4th Option)

\$ _____ & ____% \$ _____ & ____% \$ _____ & ____% \$ _____ & ____%

c. Total estimated dollar value and percent of planned subcontracting with SMALL DISADVANTAGED BUSINESSES: (% of "a") \$ _____ and _____% (Base Year)
 FY-____ (1st Option) FY-____ (2nd Option) FY-____ (3rd Option) FY-____ (4th Option)
 \$ _____ & ____% \$ _____ & ____% \$ _____ & ____% \$ _____ & ____%

d. Total estimated dollar value and percent of planned subcontracting with WOMAN-OWNED SMALL BUSINESSES: (% of "a") \$ _____ and _____% (Base Year)
 FY-____ (1st Option) FY-____ (2nd Option) FY-____ (3rd Option) FY-____ (4th Option)
 \$ _____ & ____% \$ _____ & ____% \$ _____ & ____% \$ _____ & ____%

e. Total estimated dollar and percent of planned subcontracting with HUBZone SMALL BUSINESSES: (% of "a") \$ _____ and _____% (Base Year)
 FY-____ (1st Option) FY-____ (2nd Option) FY-____ (3rd Option) FY-____ (4th Option)
 \$ _____ & ____% \$ _____ & ____% \$ _____ & ____% \$ _____ & ____%

Small Business Subcontracting Plan Page 2

March, 2003

f. Total estimated dollar and percent of planned subcontracting with VETERAN-OWNED SMALL BUSINESSES: (% of "a") \$ _____ and _____% (Base Year)
 FY-____ (1st Option) FY-____ (2nd Option) FY-____ (3rd Option) FY-____ (4th Option)
 \$ _____ & ____% \$ _____ & ____% \$ _____ & ____% \$ _____ & ____%

g. Total estimated dollar and percent of planned subcontracting with SERVICE-DISABLED VETERANOWNED SMALL BUSINESSES: (% of "a") \$ _____ and _____% (Base Year)
 FY-____ (1st Option) FY-____ (2nd Option) FY-____ (3rd Option) FY-____ (4th Option)
 \$ _____ & ____% \$ _____ & ____% \$ _____ & ____% \$ _____ & ____%

h. Total estimated dollar and percent of planned subcontracting with "OTHER THAN SMALL BUSINESSES": (% of "a") \$ _____ and _____% (Base Year)
 FY-____ (1st Option) FY-____ (2nd Option) FY-____ (3rd Option) FY-____ (4th Option)
 \$ _____ & ____% \$ _____ & ____% \$ _____ & ____% \$ _____ & ____%

Notes: 1. Federal prime contract goals are:
 SB equals 23%; SDB equals 5%; HUBZone equals 3%, WOSB equals 5% and SDVOSB equals 3%, VOSB equals 3% and can serve as objectives for subcontracting goal development.

2. SDB, WOSB, HUBZone, SDVOSB and VOSB goals are subsets of SB and should be counted and reported in multiple categories, as appropriate.
 3. If any contract has more than four options, please attach additional sheets showing dollar amounts and percentages.

i. Provide a description of ALL the products and/or services to be subcontracted under this contract, and indicate the size and type of business supplying them (check all that apply).

- Product/Service
- Other
- SB
- SDB
- WOSB
- HUBZone
- VOSB
- SDVOSB

Small Business Subcontracting Plan Page 3

March, 2003

j. Provide a description of the method used to develop the subcontracting goals for SB, SDB, WOSB, HUBZone, and VOSB concerns. Address efforts made to ensure that maximum practicable subcontracting opportunities have been made available for those concerns and explain the method used to identify potential sources for solicitation purposes. Explain the method and state the quantitative basis (in dollars) used to establish the percentage goals. Also, explain how the areas to be subcontracted to SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns were determined, how the capabilities of these concerns were considered for contract opportunities and how such data comports with the cost proposal. Identify any source lists or other resources used in the determination process. (Attach additional sheets, if necessary.)

k. Indirect costs have, have not been included in the dollar and percentage subcontracting goals above (check one).

l. If indirect costs have been included, explain the method used to determine the proportionate share of such costs to be allocated as subcontracts to SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns.

3. Program Administrator:

NAME/TITLE:

ADDRESS:

TELEPHONE/E-MAIL:

Duties: Does the individual named above have general overall responsibility for the company's subcontracting program, i.e., developing, preparing, and executing subcontracting plans and monitoring performance relative to the requirements of those subcontracting plans and perform the following duties?

yes no

(If NO is checked, please indicate who in the company performs those duties, or indicate why the duties are not performed in your company.)

a. Develops and promotes company-wide policy initiatives that demonstrate the company's support for awarding contracts and subcontracts to SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns; and assures that these concerns are included on the source lists for solicitations for products and services they are capable of providing; yes no

b. Develops and maintains bidder source lists of SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns from all possible sources; yes no

c. Ensures periodic rotation of potential subcontractors on bidder's lists; yes no

d. Ensures that SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB businesses are included on the bidders' list for every subcontract solicitation for products and services that they are capable of providing; yes no

Small Business Subcontracting Plan Page 4

March, 2003

e. Ensures that Requests for Proposals (RFPs) are designed to permit the maximum practicable participation of SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns; yes no

f. Reviews subcontract solicitations to remove statements, clauses, etc., which might tend to restrict or prohibit SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB participation; yes no

g. Accesses various sources for the identification of SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns to include the SBA's PRO-Net and SUB-Net Systems, (<http://www.sba.gov>), the National Minority Purchasing Council Vendor Information Service, the Office of Minority Business Data Center in the Department of Commerce, local small business and minority associations, contact with local chambers of commerce and Federal agencies' Small Business Offices; yes no

h. Establishes and maintains contract and subcontract award records; yes no

i. Participates in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, Procurement Conferences, etc; yes no

j. Ensures that SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company; yes no

k. Conducts or arranges for the conduct of training for purchasing personnel regarding the intent and impact of Section 8(d) of the Small Business Act, as amended; yes no

l. Monitors the company's subcontracting program performance and makes any adjustments necessary to achieve the subcontract plan goals; yes no

m. Prepares and submits timely, required subcontract reports; yes no

n. Coordinates the company's activities during the conduct of compliance reviews by Federal agencies; yes no; and

o. Other duties: _____

4. Equitable Opportunity

Describe efforts the offeror will make to ensure that SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB concerns will have an equitable opportunity to compete for subcontracts. These efforts include, but are not

limited to, the following activities:

a. Outreach efforts to obtain sources:

1. Contacting minority and small business trade associations; 2) contacting business development organizations and local chambers of commerce; 3) attending SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB procurement conferences and trade fairs; 4) requesting sources from the Small Business Administrations (SBA) PRO-Net and SUB-Net Systems, (<http://www.sba.gov/>) and other SBA and Federal agency resources. Contractors may also conduct market surveys to identify new sources, to include, accessing the NIH e-Portals in Commerce, (e-PIC), (<http://epic.od.nih.gov/>). The NIH e-Portals in Commerce is not a mandatory source and may be used at the offeror's discretion.

b. Internal efforts to guide and encourage purchasing personnel:

1. Conducting workshops, seminars, and training programs;
2. Establishing, maintaining, and utilizing SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB source lists, guides, and other data for soliciting subcontractors; and
3. Monitoring activities to evaluate compliance with the subcontracting plan.

Small Business Subcontracting Plan Page 5

March, 2003

c. Additional efforts:

5. Flow Down Clause

The contractor agrees to include the provisions under FAR 52.219-8, "Utilization of Small Business Concerns," in all acquisitions exceeding the simplified acquisition threshold that offers further subcontracting opportunities. All subcontractors, except small business concerns, that receive subcontracts in excess of \$500,000 (\$1,000,000 for construction) must adopt and comply with a plan similar to the plan required by FAR 52.219-9, "Small Business Subcontracting Plan." (Flow down is not applicable for commercial items/services as described in 52.212-5(e) and 52.244-6(c).)

6. Reporting and Cooperation

The contractor gives assurance of (1) cooperation in any studies or surveys that may be required; (2) submission of periodic reports which show compliance with the subcontracting plan; (3) submission of Standard Form (SF) 294, "Subcontracting Report for Individual Contracts," and attendant Optional Form 312, SDB Participation Report, if applicable, (*required only for contracts containing the clause 52.219-25*) and SF 295, "Summary Subcontract Report," in accordance with the instructions on the forms; and (4) ensuring that subcontractors agree to submit Standard Forms 294 and 295.

Reporting Period Report Due Due Date

Oct 1 - Mar 31 SF 294 4/30

Apr 1 - Sept 30 SF 294 10/30

Oct 1 - Sept 30 SF 295 10/30

Contract Completion OF 312 30 days after completion

Special instructions for commercial plan: SF 295 Report is due on 10/30 each year for the previous fiscal year ending 9/30.

a. Submit SF 294 to cognizant Awarding Contracting Officer.

b. Submit Optional Form 312, (OF 312), if applicable, to cognizant Awarding Contracting Officer.

c. Submit SF 295 to cognizant Awarding Contracting Officer and to the:

Office of Small and Disadvantaged Business Utilization

Department of Health and Human Services

200 Independence Avenue, SW

Humphrey H. Building, Room 517-D

Washington, D.C. 20201

d. Submit "information" copy of the SF 295 and the SF 294 upon request to the SBA Commercial Market Representative (CMR); visit the SBA at <http://www.sba.gov/gc> and click on assistance directory to locate your nearest CMR.

7. Record keeping

In accordance with FAR 19.704(a)(11), the following is a recitation of the types of records the contractor will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. These records will include, but not be limited to, the following:

Small Business Subcontracting Plan Page 6

March, 2003

- a. SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB source lists, guides and other data identifying such vendors;
 - b. Organizations contacted in an attempt to locate SB, SDB, WOSB, HUBZone, VOSB, and SDVOSB sources;
 - c. On a contract-by-contract basis, records on all subcontract solicitations over \$100,000, which indicate for each solicitation (1) whether SB, SDB, WOSB, HUBZone, VOSB, and/or SDVOSB concerns were solicited, if not, why not and the reasons solicited concerns did not receive subcontract awards.
 - d. Records to support other outreach efforts, e.g., contacts with minority and small business trade associations, attendance at small and minority business procurement conferences and trade fairs;
 - e. Records to support internal guidance and encouragement provided to buyers through (1) workshops, seminars, training programs, incentive awards; and (2) monitoring performance to evaluate compliance with the program and requirements; and
 - f. On a contract-by-contract basis, records to support subcontract award data including the name, address, and business type and size of each subcontractor. (This item is not required on a *contract-by-contract basis* for company or division-wide commercial plans.)
 - g. Other records to support your compliance with the subcontracting plan: (Please describe)
-
-
-

8. Timely Payments to Subcontractors

FAR 19.702 requires your company to establish and use procedures to ensure the timely payment of amounts due pursuant to the terms of your subcontracts with small business concerns, small disadvantaged small business concerns, women-owned small business concerns, HUBZone small business concerns, veteran-owned small business concerns, and service-disabled veteran-owned small business concerns. Your company has established and uses such procedures: [] yes [] no

9. Description of Good Faith Effort

Maximum practicable utilization of small, small disadvantaged, women-owned, HUBZone, veteran-owned, and service-disabled veteran-owned small business concerns as subcontractors in Government contracts is a matter of national interest with both social and economic benefits. **When a contractor fails to make a good faith effort to comply with a subcontracting plan, these objectives are not achieved, and 15 U.S.C. 637(d) (4) (F) directs that liquidated damages shall be paid by the contractor.** In order to demonstrate your compliance with a good faith effort to achieve the small, small disadvantaged, womenowned, HUBZone, veteran-owned, and service-disabled veteran-owned small business subcontracting goals, outline the steps your company plans to take. These steps will be negotiated with the contracting officer prior to approval of the plan.

SIGNATURE PAGE

Signatures Required:

This subcontracting plan was submitted by:

Signature: _____

Typed Name: _____

Title: _____

Date: _____

This plan was reviewed by:

Signature: _____

Typed Name: _____

Title: _____ **Contracting Officer** _____

Date: _____

This plan was reviewed by:

Signature: _____

Typed Name: _____

Title: _____ **Small Business Specialist** _____

Date: _____

This plan was reviewed by:

Signature: _____

Typed Name: _____

Title: _____ **SBA Procurement Center Representative** _____

Date: _____

And Is Accepted By:

Signature: _____

Typed Name: _____

Title: _____

Date: _____

REPRESENTATIONS AND CERTIFICATIONS

This attachment is made up of six (6) separate representations and certifications, which are listed below in full text and are, in addition to, the on-line representations and certifications that offerors are required to complete on an annual basis. Offerors must complete and submit the following representations and certifications and submit these as a part of your business proposal. By submission of your signed offer, the offeror makes the following representation and certifications.

1. ANNUAL REPRESENTATIONS AND CERTIFICATIONS (JAN 2005), FAR Provision 52.204-8

- (a) (1) If the clause at 52.204-7, Central Contractor Registration, is included in this solicitation, paragraph (b) of this provision applies.
- (2) If the clause at 52.204-7 is not included in this solicitation, and the offeror is currently registered in CCR, and has completed the ORCA electronically, the offeror may choose to use paragraph (b) of this provision instead of completing the corresponding individual representations and certifications in the solicitation. The offeror shall indicate which option applies by checking one of the following boxes:
- (i) Paragraph (b) applies.
 - (ii) Paragraph (b) does not apply and the offeror has completed the individual **representations and certifications** in the solicitation.
- (b) The offeror has completed the annual representative and certifications electronically via the Online Representations and Certifications Application (ORCA) website at <http://orca.bpn.gov>. After reviewing the ORCA database information, the offeror verifies by submission of the offer that the representations and certifications currently posted electronically have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code reference (see FAR 4.1201); except for the changes identified below [*offeror to insert changes, identifying change by clause number, title, date*]. These amended representation (s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR Clause #	Title	Date	Change

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on ORCA.

(End of Provision)

2. COST ACCOUNTING STANDARDS NOTICES AND CERTIFICATION (JUN 2000), FAR Provision 52.230-1

Note: *This notice does not apply to small businesses or foreign governments. This notice is in three parts, identified by Roman numerals I through III.*

Offerors shall examine each part and provide the requested information in order to determine Cost Accounting Standards (CAS) requirements applicable to any resultant contract.

If the offeror is an educational institution, Part II does not apply unless the contemplated contract will be subject to full or modified CAS-coverage pursuant to 48 CFR 9903.201-2(C)(5) or 9903.201-2(c)(6), respectively.

I. Disclosure Statement – Cost Accounting Practices and Certification

- (a) Any contract in excess of \$500,000 resulting from this solicitation will be subject to the requirements of the Cost Accounting Standards Board (48 CFR Chapter 99), except for those contract which are exempt as specified in 9903.201-1.
- (b) Any offeror submitting a proposal which, if accepted, will result in a contract subject to the requirements of 48 CFR Chapter 99 must, as a condition of contracting, submit a Disclosure Statement as required by 9903.202. When required, the Disclosure Statement must be submitted as a part of the offeror’s proposal under this solicitation unless the offeror has already submitted a Disclosure Statement disclosing the practices used in connection with the pricing of this proposal. If an applicable Disclosure Statement has already been submitted, the offeror may satisfy the requirement for submission by providing the information requested in paragraph (c) of Part I of this provision.

CAUTION: In the absence of specific regulations or agreement, a practice disclosed in a Disclosure Statement shall not, by virtue of such disclosure, be deemed to be a proper, approved, or agreed-to practice for pricing proposals or accumulating and reporting contract performance cost data.

(c) Check the appropriate box below:

(1) **Certificate of Concurrent Submission of Disclosure Statement.**

The offeror hereby certifies that, as part of the offer, copies of the Disclosure Statement have been submitted as follows:

- (i) original and one copy to the cognizant Administrative Contracting Officer (ACO), or cognizant Federal agency official authorized to act in that capacity (Federal official), as applicable, and;
- (ii) one copy to the cognizant Federal auditor.

(Disclosure must be on Form No. CASB DS-1 or CASB DS-2, as applicable. Forms may be obtained from the cognizant ACO or Federal official and/or from the loose-leaf version of the Federal Acquisition Regulation).

Date of Disclosure Statement:	
Name and Address of Cognizant ACO or Federal Official Where Filed:	

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the Disclosure Statement.

(2) **Certificate of Previously Submitted Disclosure Statement.**

The offeror hereby certifies that the required Disclosure Statement was filed as follows:

Date of Disclosure Statement:	
Name and Address of Cognizant ACO or Federal Official Where Filed:	

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the applicable Disclosure Statement.

(3) **Certificate of Monetary Exemption.**

The offeror hereby certifies that the offeror together with all divisions, subsidiaries, and affiliates under common control, did not receive net awards of negotiated prime contracts and subcontracts subject to CAS totaling more than \$50 million or more in the cost accounting period immediately preceding the period in which this proposal was submitted. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

(4) **Certificate of Interim Exemption.**

The offeror hereby certifies that:

- (i) the offeror first exceeded the monetary exemption for disclosure, as defined in (3) of this subsection, in the cost accounting period immediately preceding the period in which this offer was submitted, and;
- (ii) in accordance with 48 CFR 9903.202-1, the offeror is not yet required to submit a Disclosure Statement. The offeror further certifies that if an award resulting from this proposal has not been made within 90 days after the end of that period the offeror will immediately submit a revised certificate to the Contracting Officer, in the form specified under subparagraph (c)(1) or (c) (2) of Part I of this provision, as appropriate, to verify submission of a completed Disclosure Statement.

CAUTION: Offerors currently required to disclose because they were awarded a CAS-covered prime contract or subcontract of \$50 million or more in the current cost accounting period may not claim this exemption (4). Further, the exemption applies only in connection with proposals submitted before expiration of the 90-day period following the cost accounting period in which the monetary exemption was exceeded.

(5) **Certificate of Disclosure Statement Due Date by Educational Institution.**
(ALTERNATE I – APRIL 1996)

If the offeror is an educational institution that, under the transition provisions of 48 CFR 9903-202-1(f), is or will be required to submit a Disclosure Statement after receipt of this award, the offeror hereby certifies that (**check one and** complete):

- (i) A Disclosure Statement filing Due Date of _____ has been established with the cognizant Federal agency.
- (ii) The Disclosure Statement will be submitted within the 6-month period ending _____ months after receipt of this award.

Name and Address of Cognizant ACO or Federal Official Where Disclosure Statement is to be Filed:

II. Cost Accounting Standards – eligibility for Modified Contract Coverage

If the offeror is eligible to use the modified provisions of 48 CFR 9903.201-2(b) and elects to do so, the offeror shall indicate by checking the box below. Checking the box below shall mean that the resultant contract is subject to the Disclosure and Consistency of Cost Accounting Practices clause in lieu of the Cost Accounting Standards clause.

- The offeror hereby claims an exemption from the Cost Accounting Standards clause under the provisions of 48 CFR 9903.201-2(b) and certifies that the offeror is eligible for use of the Disclosure and Consistency of Cost Accounting Practices clause because during the cost accounting period immediately preceding the period in which this proposal was submitted, the offeror received less than \$50 million in awards of CAS-covered prime contracts and subcontracts. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

CAUTION: An offeror may not claim the above eligibility for modified contract coverage if this proposal is expected to result in the award of a CAS-covered contract of \$50 million or more or if, during its current cost accounting period, the offeror has been awarded a single CAS-covered prime contract or subcontract of \$50 million or more.

III. Additional Cost Accounting Standards Applicable to Existing Contracts

The offeror shall indicate below whether award of the contemplated contract would, in accordance with subparagraph (a)(3) of the Cost Accounting Standards Clause, require a change in established cost accounting practices affecting existing contracts and subcontracts.

YES NO

3. CERTIFICATION REGARDING ENVIRONMENTAL TABACCO SMOKE (DEC 1994)

[Note: This certification applies only to those contract which contain provisions for children's services. The offeror's signature on their business proposal constitutes certification that the submitting organization of its compliance with the Act.]

Public Law 103-227, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted fro an entity and used routinely or regularly for the provision of health, day care, early childhood development services, education or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law also applies to children's services that are provided in indoor facilities that are constructed, operated, or maintained with such federal funds. The law does not apply to children's service provided in private residences; portions of facilities used for inpatient drug or alcohol treatment; service providers whose sole source of applicable federal funds in Medicare or Medicaid; or facilities where WIC coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to \$1,000 for each violation and/or the imposition of an administrative compliance order on the responsible entity.

By submission of its signed offer, the offeror/contractor (for acquisitions) or applicant/grantee (for grants) certifies that the submitting organization will comply with the requirements of the Act and will not allow smoking within any portion of any indoor facility used for the provision of services for children as defined by the Act.

The submitting organization agrees that it will require that the language of this certification be included in any subawards which contain provisions for children's services and that all subrecipients shall certify accordingly.

4. CERTIFICATION OF INSTITUTIONAL POLICY ON CONFLICT OF FINANCIAL INTEREST (OCT 1995)

Note: This certification is applicable to Research and Development (R&D) Contracts. However, this certification does not apply to SBIR-Phase I contractors.

By submission of its signed offer, the offeror certifies that:

- (1) A written and enforced administrative process to identify and manage, reduce or eliminate conflicting financial interest with respect to all research projects for which funding is sought from the NIH is, is not currently in effect.

- (2) Should a process not be in effect at the time of the submission of its offer, the offeror certifies that it will, no later than 30 days subsequent to submission of its offer or prior to award, whichever is earlier, notify the Contracting Officer of the establishment of a written and enforced financial conflict of interest policy.

5. ROYALTY INFORMATION (APRIL 1984), FAR Provision 52.227-6

- (a) **Cost or charges for royalties.** When the response to this solicitation contains costs or charges for royalties totaling more than \$250, the following information shall be included in the response relating to each separate item of royalty or license fee:
 - (1) Name and address of licensor.
 - (2) Date of license agreement.
 - (3) Patent numbers, patent application serial numbers or other basis on which the royalty is payable.
 - (4) Brief description, including any part or model numbers of each contract item or component on which the royalty is payable.
 - (5) Percentage or dollar rate of royalty per unit.
 - (6) Unit price of contract item.
 - (7) Number of units.
 - (8) Total dollar amount of royalties.
- (b) **Copies of current licenses.** In addition, if specifically requested by the Contracting Officer before execution of the contract, the offeror shall furnish a copy of the current license agreement and an identification of applicable claims of specific patents.

6. REPRESENTATION OF LIMITED RIGHTS DATA AND RESTRICTED COMPUTER SOFTWARE (MAY 1999), FAR provision 52.227-15

This solicitation sets forth the work to be performed if a contract award results, and the Government's known delivery requirements for data (as defined in FAR 27.401). Any resulting contract may also provide the Government the option to order additional data under the Additional Data Requirements clause at 52.227-16 of the FAR, if included in the contract. Any data delivered under the resulting contract will be subject to the Rights in Data-General clause at 52.227-14 that is to be included in this contract. Under the latter clause, a Contractor may withhold from delivery data that qualify as limited rights data or restricted computer software, and deliver form, fit, and function data in lieu thereof. The latter clause also may be used with its Alternates II and/or III to obtain delivery of limited rights data or restricted computer software, marked with limited rights or restricted rights notices, as appropriate. In addition, use of Alternate V with this latter clause provides the Government the right to inspect such data at the Contractor's facility.

As an aid in determining the Government's need to include Alternate II or Alternate III in the clause at 52.227-14, Rights in Data-General, the offeror shall complete paragraph (c) of this provision to either state that none of the data qualify as limited rights data or restricted computer software, or identify, to the extent feasible, which of the data qualifies as limited rights data or restricted computer software. Any identification of limited rights data or restricted computer software in the offeror's response is not determinative of the status of such data should a contract be awarded to the offeror.

The offeror has reviewed the requirements for the delivery of data or software and states [*offeror check appropriate block*]-

[]	None of the data proposed for fulfilling such requirements qualifies as limited rights data or restricted computer software.
[]	Data proposed for fulfilling such requirements qualify as limited rights data or restricted computer software and are identified as follows:

NOTE: "Limited rights data" and "Restricted computer software" are defined in the contract clause entitled "Rights in Data-

CERTIFICATE OF CURRENT COST OR PRICING DATA (FAR 15.406-2)

(When cost or pricing data are required in accordance with FAR 15.406-2, the Contracting Officer will request that the offeror complete, execute, and submit to the Contracting Officer a certification in the format shown in the following Certificate of Current Cost or Pricing Data. The certification shall be submitted only at the time negotiations are concluded. Offerors should complete the certificate and return it when requested by the Contracting Officer.)

This is to certify that, to the best of my knowledge and belief, the cost or pricing data (as defined in section 15.401 of the Federal Acquisition Regulation (FAR) and required under FAR subsection 15.403-4) Submitted, either actually or by specific identification in writing, to the Contracting Officer or to the Contracting Officer's representative in support of _____* are accurate, complete, and current as of _____**.

This certification includes the cost or pricing data supporting any advance agreements and forward pricing rate agreements between the offeror and the Government that are part of the proposal.

Firm	
Signature	
Name	
Title	
Date of execution***	
*	Identify the proposal, request for price adjustment, or other submission involved, giving the appropriate identifying number (e.g., RFP No.)
**	Insert the day, month, and year when price negotiations were concluded and price agreement was reached, or if applicable, an earlier date agreed upon between the parties that is as close as practicable to the date of agreement on price.
***	Insert the day, month, and year of signing, which should be as close as practicable to the date when the price negotiations were concluded and the contract price was agreed to.

(End of Certificate)

INVOICE/FINANCING REQUEST INSTRUCTIONS
FOR NIH COST-REIMBURSEMENT TYPE CONTRACTS, NIH(RC)-1

General: The contractor shall submit claims for reimbursement in the manner and format described herein and as illustrated in the sample invoice/financing request.

Format: Standard Form 1034, "Public Voucher for Purchases and Services Other Than Personal," and Standard Form 1035, "Public Voucher for Purchases and Services Other Than Personal-- Continuation Sheet," or reproduced copies of such forms marked ORIGINAL should be used to submit claims for reimbursement. In lieu of SF-1034 and SF-1035, claims may be submitted on the payee's letter-head or self-designed form provided that it contains the information shown on the sample invoice/financing request.

Number of Copies: As indicated in the Invoice Submission Clause in the contract.

Frequency: Invoices/financing requests submitted in accordance with the Payment Clause shall be submitted monthly unless otherwise authorized by the contracting officer.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by precontract cost provisions.

Billing of Costs Incurred: If billed costs include: (1) costs of a prior billing period, but not previously billed; or (2) costs incurred during the contract period and claimed after the contract period has expired, the amount and month(s) in which such costs were incurred shall be cited.

Contractor's Fiscal Year: Invoices/financing requests shall be prepared in such a manner that costs claimed can be identified with the contractor's fiscal year.

Currency: All NIH contracts are expressed in United States dollars. When payments are made in a currency other than United States dollars, billings on the contract shall be expressed, and payment by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Costs Requiring Prior Approval: Costs requiring the contracting officer's approval, which are not set forth in an Advance Understanding in the contract shall be so identified and reference the Contracting Officer's Authorization (COA) Number. In addition, any cost set forth in an Advance Understanding shall be shown as a separate line item on the request.

Invoice/Financing Request Identification: Each invoice/financing request shall be identified as either:

- (a) **Interim Invoice/Contract Financing Request** — These are interim payment requests submitted during the contract performance period.
- (b) **Completion Invoice** — The completion invoice is submitted promptly upon completion of the work; but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which this contract is physically complete (whichever date is later). The completion invoice should be submitted when all costs have been assigned to the contract and all performance provisions have been completed.
- (c) **Final Invoice** — A final invoice may be required after the amounts owed have been settled between the Government and the contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The contractor shall furnish the information set forth in the explanatory notes below. These notes are keyed to the entries on the sample invoice/financing request.

- (a) **Designated Billing Office Name and Address** — Enter the designated billing office name and address, identified in the Invoice Submission Clause of the contract, on all copies of the invoice/financing request.
- (b) **Invoice/Financing Request Number** — Insert the appropriate serial number of the invoice/financing request.
- (c) **Date Invoice/Financing Request Prepared** — Insert the date the invoice/financing request is prepared.
- (d) **Contract Number, ADB Number and Date** — Insert both the contract number and the ADB number (which appears in the upper left hand corner of the face page of the contract), and the effective date of the contract.
- (e) **Payee's Name and Address** — Show the contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the contractor, or a different payee has been designated, then insert the name and address of the payee instead of the contractor.
- (f) **Total Estimated Cost of Contract** — Insert the total estimated cost of the contract, exclusive of fixed-fee. For incrementally funded contracts, enter the amount currently obligated and available for payment.
- (g) **Total Fixed-Fee** — Insert the total fixed-fee (where applicable). For incrementally funded contracts, enter the amount currently obligated and available for payment.
- (h) **Billing Period** — Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.
- (i) **Amount Billed for Current Period** — Insert the amount billed for the major cost elements, adjustments, and adjusted amounts for the period.
- (j) **Cumulative Amount from Inception** — Insert the cumulative amounts billed for the major cost elements and adjusted amounts claimed during this contract.
- (k) **Direct Costs** — Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.
- (l) **Direct Labor** — Include salaries and wages paid (or accrued) for direct performance of the contract.
- (2) **Fringe Benefits** — List any fringe benefits applicable to direct labor and billed as a direct cost. Fringe benefits included in indirect costs should not be identified here.
- (3) **Accountable Personal Property** — Include permanent research equipment and general purpose equipment having a unit acquisition cost of \$1,000 or more and having an expected service life of more than two years, and sensitive property regardless of cost (see the DHHS *Contractor's Guide for Control of Government Property*). Show permanent research equipment separate from general purpose equipment. Prepare and attach the NIH Form entitled, "Report of Government Owned, Contractor Held Property," in accordance with the following instructions:

List each item for which reimbursement is requested. A reference shall be made to the following (as applicable):

- The item number for the specific piece of equipment listed in the Property Schedule.
- The COA letter and number, if the equipment is not covered by the Property Schedule.
- An asterisk (*) shall precede the item if the equipment is below the approval level.

Further itemization of invoices/financing requests shall only be required for items having specific limitations set forth in the contract.

- (4) **Materials and Supplies** — Include equipment with unit costs of less than \$1,000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.
- (5) **Premium Pay** — List remuneration in excess of the basic hourly rate.
- (6) **Consultant Fee** — List fees paid to consultants. Identify consultant by name or category as set forth in the contract's advance understanding or in the COA letter, as well as the effort (i.e., number of hours, days, etc.) and rate being billed.
- (7) **Travel** — Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.
- (8) **Subcontract Costs** — List subcontractor(s) by name and amount billed.
- (9) **Other** — List all other direct costs in total unless exceeding \$1,000 in amount. If over \$1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.
- (l) **Cost of Money (COM)** — Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.
- (m) **Indirect Costs--Overhead** — Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.
- (n) **Fixed-Fee Earned** — Cite the formula or method of computation for the fixed-fee (if any). The fixed-fee must be claimed as provided for by the contract.
- (o) **Total Amounts Claimed** — Insert the total amounts claimed for the current and cumulative periods.
- (p) **Adjustments** — Include amounts conceded by the contractor, outstanding suspensions, and/or disapprovals subject to appeal.
- (q) **Grand Totals**

The contracting officer may require the contractor to submit detailed support for costs claimed on one or more interim invoices/financing requests.

SAMPLE INVOICE/FINANCING REQUEST

- (a) Billing Office Name and Address
 NATIONAL INSTITUTES OF HEALTH
 National Cancer Institute, RCB
 EPS, Room _____
 6120 EXECUTIVE BLVD MSC
 Bethesda, MD 20892-____
- (b) Invoice/Financing Request No.
- (c) Date Invoice Prepared
- (d) Contract No., ADB No., and Effective Date
- (e) Payee's Name and Address
 ABC CORPORATION
 100 Main Street
 Anywhere, U.S.A. zip code
- (f) Total Estimated Cost of Contract
- (g) Total Fixed Fee

Attention: Name, Title, and Phone Number
of Official to Whom Payment is Sent

(h) This invoice/financing request represents reimbursable costs from Aug. 1, 2003 through Aug. 31, 2003

	(i) Amount Billed for Current Period	(j) Cumulative Amount From Inception
(k) Direct Costs		
(1) Direct Labor	\$ 3,400	\$ 6,800
(2) Fringe Benefits	600	1,200
(3) Accountable Personal Property (Attach Form HHS-565)		
Permanent Research	3,000	6,000
General Purpose	2,000	2,000
(4) Materials and Supplies	2,000	4,000
(5) Premium Pay	100	150
(6) Consultant Fee-Dr. Jones 1 day @ 100 (COA #3)	100	100
(7) Travel (Domestic)	200	200
(Foreign)	200	200
(8) Subcontract Costs	-0-	-0-
(9) Other	<u>-0-</u>	<u>-0-</u>
Total Direct Costs	\$11,600	\$20,650
(l) Cost of Money (Factor) of (Appropriate Base)	2,400	3,600
(m) Indirect Costs -- Overhead _____ % of Direct Labor or Other Base (Formula)	4,000	6,000
(n) Fixed-Fee Earned (Formula)	<u>700</u>	<u>1,400</u>
(o) Total Amount Claimed	\$18,700	\$31,650
(p) Adjustments		
Outstanding Suspensions		<u>(1,700)</u>
(q) Grand Totals	\$18,700	\$29,950

"I certify that all payments requested are for appropriate purposes and in accordance with the contract."

 Name of Official)

INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING
INSTRUCTIONS FOR NIH COST-REIMBURSEMENT CONTRACTS, NIH(RC)-4

General: The contractor shall submit claims for reimbursement in the manner and format described herein and as illustrated in the sample invoice/financing request.

Format: Standard Form 1034, "Public Voucher for Purchases and Services Other Than Personal," and Standard Form 1035, "Public Voucher for Purchases and Services Other Than Personal-- Continuation Sheet," or reproduced copies of such forms marked ORIGINAL should be used to submit claims for reimbursement. In lieu of SF-1034 and SF-1035, claims may be submitted on the payee's letter-head or self-designed form provided that it contains the information shown on the sample invoice/financing request.

Number of Copies: As indicated in the Invoice Submission Clause in the contract.

Frequency: Invoices/financing requests submitted in accordance with the Payment Clause shall be submitted monthly unless otherwise authorized by the contracting officer.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by precontract cost provisions.

Billing of Costs Incurred: If billed costs include: (1) costs of a prior billing period, but not previously billed; or (2) costs incurred during the contract period and claimed after the contract period has expired, the amount and month(s) in which such costs were incurred shall be cited.

Contractor's Fiscal Year: Invoices/financing requests shall be prepared in such a manner that costs claimed can be identified with the contractor's fiscal year.

Currency: All NIH contracts are expressed in United States dollars. When payments are made in a currency other than United States dollars, billings on the contract shall be expressed, and payment by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Costs Requiring Prior Approval: Costs requiring the contracting officer's approval, which are not set forth in an Advance Understanding in the contract shall be so identified and reference the Contracting Officer's Authorization (COA) Number. In addition, any cost set forth in an Advance Understanding shall be shown as a separate line item on the request.

Invoice/Financing Request Identification: Each invoice/financing request shall be identified as either:

- (a) **Interim Invoice/Contract Financing Request** — These are interim payment requests submitted during the contract performance period.
- (b) **Completion Invoice** — The completion invoice is submitted promptly upon completion of the work; but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which this contract is physically complete (whichever date is later). The completion invoice should be submitted when all costs have been assigned to the contract and all performance provisions have been completed.
- (c) **Final Invoice** — A final invoice may be required after the amounts owed have been settled between the Government and the contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The contractor shall furnish the information set forth in the explanatory notes below. These notes are keyed to the entries on the sample invoice/financing request.

- (a) **Designated Billing Office Name and Address** — Enter the designated billing office and address, identified in the Invoice Submission Clause of the contract, on all copies of the invoice/financing request.
- (b) **Invoice/Financing Request Number** — Insert the appropriate serial number of the invoice/financing request.
- (c) **Date Invoice/Financing Request Prepared** — Insert the date the invoice/financing request is prepared.
- (d) **Contract Number, ADB Number and Date** — Insert both the contract number and the ADB number (which appears in the upper left hand corner of the face page of the contract), and the effective date of the contract.
- (e) **Payee's Name and Address** — Show the contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the contractor, or a different payee has been designated, then insert the name and address of the payee instead of the contractor.
- (f) **Total Estimated Cost of Contract** — Insert the total estimated cost of the contract, exclusive of fixed-fee. For incrementally funded contracts, enter the amount currently obligated and available for payment.
- (g) **Total Fixed-Fee** — Insert the total fixed-fee (where applicable). For incrementally funded contracts, enter the amount currently obligated and available for payment.
- (h) **Billing Period** — Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.
- (i) **Incurred Cost - Current** — Insert the amount billed for the major cost elements, adjustments, and adjusted amounts for the current period.
- (j) **Incurred Cost - Cumulative** — Insert the cumulative amounts billed for the major cost elements and adjusted amounts claimed during this contract.
- (k) **Direct Costs** — Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.
 - (l) **Direct Labor** — Include salaries and wages paid (or accrued) for direct performance of the contract. For Key Personnel, list each employee on a separate line. List other employees as one amount unless otherwise required by the contract.
 - (2) **Fringe Benefits** — List any fringe benefits applicable to direct labor and billed as a direct cost. Fringe benefits included in indirect costs should not be identified here.
 - (3) **Accountable Personal Property** — Include permanent research equipment and general purpose equipment having a unit acquisition cost of \$1,000 or more and having an expected service life of more than two years, and sensitive property regardless of cost (see the DHHS *Contractor's Guide for Control of Government Property*). Show permanent research equipment separate from general purpose equipment. Prepare and attach the NIH Form entitled, Report of Government Owned, Contractor Held Property," in accordance with the following instructions:

List each item for which reimbursement is requested. A reference shall be made to the following (as applicable):

- The item number for the specific piece of equipment listed in the Property Schedule.
 - The Contracting Officer's Authorization letter and number, if the equipment is not covered by the Property Schedule.
 - An asterisk (*) shall precede the item if the equipment is below the approval level.
- (4) **Materials and Supplies** — Include equipment with unit costs of less than \$1,000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.
 - (5) **Premium Pay** — List remuneration in excess of the basic hourly rate.
 - (6) **Consultant Fee** — List fees paid to consultants. Identify consultant by name or category as set forth in the contract's Advance Understanding or in the COA letter, as well as the effort (i.e., number of hours, days, etc.) and rate being billed.
 - (7) **Travel** — Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.
 - (8) **Subcontract Costs** — List subcontractor(s) by name and amount billed.
 - (9) **Other** — List all other direct costs in total unless exceeding \$1,000 in amount. If over \$1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.
 - (l) **Cost of Money (COM)** — Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.
 - (m) **Indirect Costs--Overhead** — Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.
 - (n) **Fixed-Fee Earned** — Cite the formula or method of computation for the fixed-fee (if any). The fixed-fee must be claimed as provided for by the contract.
 - (o) **Total Amounts Claimed** — Insert the total amounts claimed for the current and cumulative periods.
 - (p) **Adjustments** — Include amounts conceded by the contractor, outstanding suspensions, and/or disapprovals subject to appeal.
 - (q) **Grand Totals**

The contracting officer may require the contractor to submit detailed support for costs claimed on one or more interim invoices/financing requests.

FINANCIAL REPORTING INSTRUCTIONS:

These instructions are keyed to the Columns on the sample invoice/financing request.

Column A--Expenditure Category - Enter the expenditure categories required by the contract.

Column B--Cumulative Percentage of Effort/Hrs.-Negotiated - Enter the percentage of effort or number of hours agreed to doing contract negotiations for each employee or labor category listed in Column A.

Column C--Cumulative Percentage of Effort/Hrs.-Actual - Enter the percentage of effort or number of hours worked by each employee or labor category listed in Column A.

Column D--Incurred Cost-Current - Enter the costs, which were incurred during the current period.

Column E--Incurred Cost-Cumulative - Enter the cumulative cost to date.

Column F--Cost at Completion - Enter data only when the contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column G-- Contract Amount - Enter the costs agreed to during contract negotiations for all expenditure categories listed in Column A.

Column H--Variance (Over or Under) - Show the difference between the estimated costs at completion (Column F) and negotiated costs (Column G) when entries have been made in Column F. This column need not be filled in when Column F is blank. When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column F by Column G, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) Clause of the contract.

Modifications: Any modification in the amount negotiated for an item since the preceding report should be listed in the appropriate cost category.

Expenditures Not Negotiated: An expenditure for an item for which no amount was negotiated (e.g., at the discretion of the contractor in performance of its contract) should be listed in the appropriate cost category and all columns filled in, except for G. Column H will of course show a 100 percent variance and will be explained along with those identified under H above.

SAMPLE INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

<p>(a) Billing Office Name and Address</p> <p>NATIONAL INSTITUTES OF HEALTH National Cancer Institute, RCB EPS, Room 6120 EXECUTIVE BLVD MSC Bethesda, MD 20892-</p> <p>(e) Payee's Name and Address</p> <p>ABC CORPORATION 100 Main Street Anywhere, USA zip code</p> <p>Attn: Name, Title, & Phone Number of Official to Whom Payment is Sent</p>	<p>(b) Invoice/Financing Request No. _____</p> <p>(c) Date Invoice Prepared _____</p> <p>(d) Contract No. _____ ADB No. _____ Effective Date _____</p> <p>(f) Total Estimated Cost _____</p> <p>(g) Total Fixed Fee _____</p>
---	---

(h) This invoice/financing request represents reimbursable costs for the period from _____ to _____

Expenditure Category* A	Cumulative Percentage of Effort/Hrs.		Incurred Cost		Cost at Completi on F	Contract Amount G	Variance H
	Negotiated B	Actual C	(i) Current D	(j) Cumulative E			
(k) Direct Costs:							
(1) Direct Labor							
(2) Fringe Benefits							
(3) Accountable Property (attach HHS-565)							
(4) Materials & Supplies							
(5) Premium Pay							
(6) Consultant Fees							
(7) Travel							
(8) Subcontracts							
(9) Other							
Total Direct Costs							
(l) Cost of Money							
(m) Overhead							
G&A							
(n) Fixed Fee							
(o) Total Amount Claimed							
(p) Adjustments							
(q) Grand Totals							

I certify that all payments are for appropriate purposes and in accordance with the contract.

(Name of Official)

(Title)

* Attach details as specified in the contract

PROCUREMENT OF CERTAIN EQUIPMENT

Notwithstanding any other clause in this contract, the Contractor will not be reimbursed for the purchase, lease, or rental of any item of equipment listed in the following Federal Supply Groups, regardless of the dollar value, without the prior written approval of the Contracting Officer.

- 67 - Photographic Equipment
- 69 - Training Aids and Devices
- 70 - General Purpose ADP Equipment, Software, Supplies and Support (Excluding 7045 - ADP Supplies and Support Equipment.)
- 71 - Furniture
- 72 - Household and Commercial Furnishings and Appliances
- 74 - Office Machines and Visible Record Equipment
- 77 - Musical Instruments, Phonographs, and Home-type Radios
- 78 - Recreational and Athletic Equipment

When equipment in these Federal Supply Groups is requested by the Contractor and determined essential by the Contracting Officer, the Government will endeavor to fulfill the requirement with equipment available from its excess personal property sources, provided the request is made under a cost-reimbursement contract. Extensions or renewals of approved existing leases or rentals for equipment in these Federal Supply Groups are excluded from the provisions of this article.

INCLUSION ENROLLMENT REPORT

Study Title:	
Total Enrollment:	Protocol Number:
Contract Number:	

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino				
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				

Racial Categories

American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				

*These totals must agree
 **These totals must agree

INSTRUCTIONS FOR COMPLETING FORM NIH 2706 "FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT"

GENERAL INFORMATION

Purpose. Form NIH 2706 is designed to: (1) provide a management tool for use by be NIH in monitoring the application of financial and personnel resources to the NIH contracts; (2) provide contractors with financial and personnel management data which is usable in their management processes; (3) promptly indicate potential areas of contract underruns or overruns by making possible comparisons of actual performance and projections with prior estimates on individual elements of cost and personnel; and (4) obtain contractor's analysis of cause and effect of significant variations between actual and prior estimates of financial and personnel performance.

REPORTING REQUIREMENTS

Scope. The specific cost and personnel elements to be reported shall be established by mutual agreement prior to award. The Government may require the contractor to provide detailed documentation to support any element(s) on one or more financial reports.

Number of Copies and Mailing Address. An original and two (2) copies of the report(s) shall be sent to the contracting officer at the address shown on the face page of the contract, no later than 30 working days after the end of the period reported. However, the contract may provide for one of the copies to be sent directly to the project officer.

REPORTING STATISTICS

A modification which extends the period of performance of an existing contract will not require reporting on a separate Form NIH 2706, except where it is determined by the contracting officer that separate reporting is necessary. Furthermore, when incrementally funded contracts are involved, each separate allotment is not considered a separate contract entity (only a funding action). Therefore, the statistics under incrementally funded contracts should be reported cumulatively from the inception of the contract through completion.

Definitions and Instructions for Completing Form NIH 2706. For the purpose of establishing expenditure categories in Column A, the following definitions and instructions will be utilized. Each contract will specify the categories to be reported.

- (1) **Key Personnel.** Include key personnel regardless of annual salary rates. All such individuals should be listed by names and job titles on a separate line including those whose salary is not directly charged to the contract but whose effort is directly associated with the contract. The listing must be kept up to date.
- (2) **Personnel--Other.** List as one amount unless otherwise required by the contract.
- (3) **Fringe Benefits.** Include allowances and services provided by the contractor to employees as compensation in addition to regular salaries and wages. If a fringe benefit rate(s) has been established, identify the base, rate, and amount billed for each category. If a rate has not been established, the various fringe benefit costs may be required to be shown separately. Fringe benefits which are included in the indirect cost rate should not be shown here.
- (4) **Accountable Personal Property.** Include nonexpendable personal property with an acquisition cost of \$1,000 or more and with an expected useful life of two or more years, and sensitive items regardless of cost. Form HHS 565, "Report of Accountable Property," must accompany the contractor's public voucher (SF 1034/SF 1035) or this report if not previously submitted. See "Contractor's Guide for Control of Government Property."

- (5) **Supplies.** Include the cost of supplies and material and equipment charged directly to the contract, but excludes the cost of nonexpendable equipment as defined in (4) above.
- (6) **Inpatient Care.** Include costs associated with a subject while occupying a bed in a patient care setting. It normally includes both routine and ancillary costs.
- (7) **Outpatient Care.** Include costs associated with a subject while not occupying a bed. It normally includes ancillary costs only.
- (8) **Travel.** Include all direct costs of travel, including transportation, subsistence and miscellaneous expenses. Travel for staff and consultants shall be shown separately. Identify foreign and domestic travel separately. If required by the contract, the following information shall be submitted: (i) Name of traveler and purpose of trip; (ii) Place of departure, destination and return, including time and dates; and (iii) Total cost of trip.
- (9) **Consultant Fee.** Include fees paid to consultant(s). Identify each consultant with effort expended, billing rate, and amount billed.
- (10) **Premium Pay.** Include the amount of salaries and wages over and above the basic rate of pay.
- (11) **Subcontracts.** List each subcontract by name and amount billed.
- (12) **Other Costs.** Include any expenditure categories for which the Government does not require individual line item reporting. It may include some of the above categories.
- (13) **Overhead/Indirect Costs.** Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.
- (14) **General and Administrative Expense.** Cite the rate and the base. In the case of nonprofit organizations, this item will usually be included in the indirect cost.
- (15) **Fee.** Cite the fee earned, if any.
- (16) **Total Costs to the Government.**

PREPARATION INSTRUCTIONS

These instructions are keyed to the Columns on Form NIH 2706.

Column A--Expenditure Category. Enter the expenditure categories required by the contract.

Column B--Percentage of Effort/Hours Negotiated. Enter the percentage of effort or number of hours agreed to during contract negotiations for each labor category listed in Column A.

Column C--Percentage of Effort/Hours-Actual. Enter the cumulative percentage of effort or number of hours worked by each employee or group of employees listed in Column A.

Column D--Cumulative Incurred Cost at End of Prior Period. Enter the cumulative incurred costs up to the end of the prior reporting period. This column will be blank at the time of the submission of the initial report.

Column E--Incurred Cost-Current Period. Enter the costs which were incurred during the current period.

Column F--Cumulative Incurred Cost to Date. Enter the combined total of Columns D and E.

Column G--Estimated Cost to Complete. Make entries only when the contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column H--Estimated Costs at Completion. Complete only if an entry is made in Column G.

Column I--Negotiated Contract Amount. Enter in this column the costs agreed to during contract negotiations for all expenditure categories listed in Column A.

Column J--Variance (Over or Under). Complete only if an entry is made in Column H. When entries have been made in Column H, this column should show the difference between the estimated costs at completion (Column H) and negotiated costs (Column I). When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column J by Column I, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) Clause of the contract.

Modifications. List any modification in the amount negotiated for an item since the preceding report in the appropriate cost category.

Expenditures Not Negotiated. List any expenditure for an item for which no amount was negotiated (e.g., at the discretion of the contractor in performance of its contract) in the appropriate cost category and complete all columns except for I. Column J will of course show a 100 percent variance and will be explained along with those identified under J above.