SOLICITATION

SECTION A – SOLICITATION/CONTRACT FORM

1. **Request For Proposal (RFP) Number:** NIH-NINDS-01-05	2. **Issue Date:** 06/11/01	3. **Just in Time:** ___ NO _X_ YES See Part IV, Section L.	4. **Set Aside: 100% to Small Business** ___ NO _X_ YES See Part IV, Section L.

5. TITLE: CENTER FOR CLINICAL TRIAL MANAGEMENT RESOURCES

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), **August 10, 2001**. 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 (n) 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), along with a facsimile address.

10. FOR INFORMATION CALL: Desiree Wheeler, Contract Specialist
PHONE: 301-496-1813
E-MAIL: mailto:dw76q@nih.gov
COLLECT CALLS WILL NOT BE ACCEPTED.

11. Table of Contents on following page.

NOTE: Offerors are responsible for routinely checking the Contracts Management Branch's web site (http://www.ninds.nih.gov/funding/currentrfps.htm) for any amendments to the solicitation. Individual notifications will not be provided.

THIS ACQUISITION IS A 100% SMALL BUSINESS SET-ASIDE.

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Information Technology (IT) Security Plan: This requirement will involve the use of an ADP system. Offerors will be required to submit an IT security plan for review by the Institute/Center Information Systems Security Officer. See SECTION L, Technical Proposal Instructions.

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 specific objective of this contract is to establish a center for clinical trial data management, methodology, statistical design, and quality control in support of clinical trials sponsored by the NINDS. It is anticipated that the award from this solicitation will be a Performance-based Cost Plus Award Fee 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

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work, SECTION J, ATTACHMENT No. 1, attached hereto and made a part of this solicitation.

ARTICLE C.2. 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 Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1140A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301/435-1986). In addition, one copy of the 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 within 90 days after contract expiration to the following address:

Contracting Officer
National Institutes of Health
National Institute on 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.iedison.gov), or by contacting the Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH.

ARTICLE C.3. REPORTING REQUIREMENTS

a. Technical Progress Reports

In addition to the required reports set forth elsewhere in this 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 frequency and specific content of these reports will be determined prior to contract award.

For proposal preparation purposes only, it is estimated that 4 copies of these reports will be required as follows:

(1) Semi-Annual Report
The Contractor shall on a semi-annual basis, deliver to the NINDS Project Officer and the Contracting Officer a progress report, electronically as a Microsoft Word document or by mail, which describes the work performed during the period reported and the anticipated work plan for the next period. A progress report is not required for the last six-month period of the contract period.

(2) Final Report - Upon final completion of the contract
The Contractor shall submit a final report by the last day of the contract period. This report shall include a summation of the work performed for the entire contract period.

b. Other Reports/Deliverables

(1) Under Performance Area #1, MONITOR QUALITY ASSURANCE IN CLINICAL TRIALS:
The contractor shall develop within 120 days of the effective date of the contract a draft of the standard operating procedures manual for conducting assessments of quality assurance procedures to monitor compliance with the guidelines. The manual shall include plans for site visits, which will be the contractor's primary method of monitoring quality assurance procedures in NINDS-funded multi-center clinical trials. Each visit will be performed over two days by two clinical trials professionals. It is estimated that about 20 site visits per year will be required. The site visits will be performed in the USA.

The contractor shall conduct the initial, periodic, and final site visits at designated studies to monitor data quality assurance and study integrity procedures, as specified in the manual of standard operating procedures. The report resulting from the initial visit shall assess the study integrity and data quality assurance procedures and will make recommendations for improvements, if needed. The contractor shall be available for consultation to the principal investigator in order to assist him/her in implementing the recommendations for improvements. The report following a periodic follow-up visit shall describe the degree of success in the implementation and effectiveness of the agreed upon plans. The report following the final visit shall evaluate the overall data quality in the study and the integrity of the study overall.

A copy of the reports shall be sent to the Project Officer within 7 days after completion of the site visits, for review and comments. The Project Officer may request additional information or revisions in the reports. The contractor will make the necessary changes in the reports within 7 days following the receipt of Project Officer's comments. The Project Officer will send the final copy of the reports to the Principal Investigator. It is estimated that it will take a total of 8 hours of work by a clinical trials professional to produce both the initial and the final version of each report.

(2) Under Performance Area #2, CLINICAL PROJECT TRACKING:
The contractor shall assist the Clinical Trials Cluster’s Program Analyst in the development and maintenance of a Microsoft Access database system that will identify and track critical elements of all NINDS supported clinical research projects, and will assist the Program Analyst in generating tracking reports created from the database.

As requested, the contractor will also prepare custom reports for members of the Clinical Trials Cluster. A copy of a custom report will be sent to the Project Officer no later than 7 days after a request for a report is made.

ARTICLE C.4. SPECIAL REQUIREMENTS

1. The contract will require that personnel be available for up to 10 hours per week to meet with NINDS staff in Rockville, Maryland, with 24 hours notice. These meetings are for the purpose of reviewing progress and discussing data analysis and quality assurance issues.

2. The Contractor shall have in place or be able to implement procedures necessary to preserve and guard the integrity of the data and any analysis and to protect the privacy of the information provided by the NINDS or any collaborating clinical center. An Information Technology Security Plan is required. Refer to Information Technology System Security Specifications and Confidentiality of Information clauses in Section H.

3. The Contractor must have knowledge and experience in clinical trial management, particularly in data analysis and protocol design and data collection forms.

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 contract. 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: "Center for Clinical Trial Management Resources"
   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 ARTICLE, 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 2215 MSC 9520, Bethesda, Maryland 20892-9520 (for courier service: Rockville, MD 20852). Inspection and acceptance shall be performed using semi-annual 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. DELIVERIES

a. Satisfactory performance of the final contract shall be deemed to occur upon satisfactory or excellent performance of the work described in Article C.1. and delivery and acceptance by the Contracting Officer, or duly authorized representative, of the items specified below. The report deliverables shall be delivered F.O.B. Destination, as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), in accordance with the stated delivery schedule.

Item	Description	Reporting Period	Delivery Schedule
(1)	Semi-annual Progress Reports (refer to ARTICLE C.3.)	January - June July - December	July 10 January 10
(2)	Final Report (refer to ARTICLE C.3.)	Entire contract period	Last day of contract
(3)	Other Reports (refer to ARTICLE C.3.)	As required	As required

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

ARTICLE F.2. STOP WORK ORDER

This contract incorporates the following clause by reference with the same force and effect as if it were given in its full text. Upon request, the Contracting Officer shall make the full text available.

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, Room 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.

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._. 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._.] and ARTICLE H._. of the above referenced contract."

ARTICLE G.4. INDIRECT COST RATES

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.5. 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 incorporate the DHHS Publication (OS) 686, entitled, Contractor's Guide for Control of Government Property, (1990).

ARTICLE G.6. 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, an interim evaluation 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. REIMBURSEMENT OF COSTS FOR INDEPENDENT RESEARCH AND DEVELOPMENT PROJECTS (Commercials Only)

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

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

ARTICLE H.2. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use

by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

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.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**
[Applicable information to be included at award]

ARTICLE H.4. 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.

b. **Public Law and Section No.** **Fiscal Year** **Period Covered**
[Applicable information to be included at award]

ARTICLE H.5. 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 applicable amount shown 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, patent care or other activities. Direct salary (or institutional base salary) excludes any income that an infividual may be permitted to earn outside of duties to the contractor. The per year salary rate limit also applies to individuals proposed under subcontracts. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate exceeds any salary rate ceiling established in future DHHS appropriation acts.

b. **Public Law No.** **Fiscal Year** **Dollar Amount of Salary Limitation***
[Applicable information to be included at award]

** Currently this amount is $161,200 and will remain at this level until such time as the Executive Level I is increased. See the following web site for Executive Level I rates of pay:*

FOR FY-01 EXECUTIVE LEVEL SALARIES: ***http://www3.opm.gov/oca/01tables/execses/html/01execsc.htm***

ARTICLE H.6. CONFIDENTIALITY OF INFORMATION

The following information is covered by HHSAR 352.224-70, Confidentiality of Information (APRIL 1984):

All data obtained, developed, and delivered under this contract are property of the Government.

The Contractor will be required to monitor data quality in designated clinical trials, review data forms information to develop quality assurance guidelines, and archive data. Although the principal investigators at the clinical sites should not supply personal identifiers as data to the NINDS, it is possible that the Contractor may have access to such data while performing required site visits and monitoring data quality. All patient data will be considered confidential.

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 that: (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. **Public Law No. and Section No** **Fiscal Year** **Period Covered**
[Applicable information to be included at award]

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

Information regarding procedural matters is contained in the NIH Manual Chapter 1754, which is available on (http://www1.od.nih.gov/oma/oma.htm).

ARTICLE H.10. YEAR 2000 COMPLIANCE

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause:

a. Service Involving the Use of Information Technology

YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

ARTICLE H.11. INFORMATION TECHNOLOGY SYSTEMS SECURITY SPECIFICATIONS

The Contractor agrees to comply with the Information Technology system security and/or privacy specifications set forth in Section C, the Computer Security Act of 1987 Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems," and the DHHS Automated Information Systems Security Program Handbook (Release 2.0, dated May, 1994). The Contractor further agrees to include this provision in any subcontract awarded pursuant to this prime contract.

NOTE: OMB A-130 is accessible via web site: http://csrc.ncsl.nist.gov/secplcy/a130app3.txt
DHHS Automated Information Systems Security Program Handbook is accessible via web site:
http://wwwoirm.nih.gov/policy/aissp.html

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/.

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

Reg	Clause	Date	Clause Title
FAR	52.202-1	Oct 1995	Definitions
FAR	52.203-3	Apr 1984	Gratuities (Over $100,000)
FAR	52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
FAR	52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over $100,000)
FAR	52.203-7	Jul 1995	Anti-Kickback Procedures(Over $100,000)
FAR	52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
FAR	52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
FAR	52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
FAR	52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
FAR	52.209-6	Jul 1995	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
FAR	52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
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 (Over $500,000)
FAR	52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
FAR	52.215-15	Dec 1998	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	Mar 2000	Allowable Cost and Payment
FAR	52.216-8	Mar 1997	Fixed Fee
FAR	52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)
FAR	52.219-9	Oct 2000	Small Business Subcontracting Plan (Over $500,000)
FAR	52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
FAR	52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar

Reg	Clause	Date	Clause Title
			amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
FAR	52.222-3	Aug 1996	Convict Labor
FAR	52.222-26	Feb 1999	Equal Opportunity
FAR	52.222-35	Apr 1998	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era
FAR	52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
FAR	52.222-37	Jan 1999	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era
FAR	52.223-6	Jan 1997	Drug-Free Workplace
FAR	52.223-14	Oct 2000	Toxic Chemical Release Reporting
FAR	52.225-1	Feb 2000	Buy American Act - Balance of Payments Program - Supplies
FAR	52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
FAR	52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
FAR	52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
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 (Over $100,000)
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-23	Jan 1986	Assignment of Claims
FAR	52.232-25	Jun 1997	Prompt Payment
FAR	52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
FAR	52.233-1	Dec 1998	Disputes
FAR	52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	Oct 1995	Penalties for Unallowable Costs (Over $500,000)
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy (Over $100,000)
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 (Over $100,000)
FAR	52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract)
FAR	52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
FAR	52.249-6	Sep 1996	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	352.228-7	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

Reg	Clause	Date	Clause Title
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 2/20/01]

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 52.219-9, SMALL BUSINESS SUBCONTRACTING PLAN (OCTOBER 2000), and FAR Clause 52.219-16, LIQUIDATED DAMAGES--SUBCONTRACTING PLAN (JANUARY 1999) are deleted in their entirety.

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

FAR 52.219-6, Notice of Total Small Business Set-Aside (JULY 1996)

FAR 52.219-14, Limitations on Subcontracting (DECEMBER 1996)

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

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

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

HHSAR 352.224-70, Confidentiality of Information (APRIL 1984)

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

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

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

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

This contract incorporates the following in full text.

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

FAR Clause 52.244-6, Subcontracts for Commercial Items and Commercial Components (OCTOBER 1998)

a. **Definition**.

Commercial item, as used in this clause, has the meaning contained in the clause at 52.202-1, Definitions.

Subcontract, as used in this clause, includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

b. To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or nondevelopmental items as components of items to be supplied under this contract.

c. Notwithstanding any other clause of this contract, the Contractor is not required to include any FAR provision or clause, other than those listed below to the extent they are applicable and as may be required to establish the reasonableness of prices under Part 15, in a subcontract at any tier for commercial items or commercial components:

1. 52.222-26, Equal Opportunity (E.O. 11246);
2. 52.222-35, Affirmative Action for Special Disabled and Vietnam Era Veterans (38 U.S.C. 4212(a));
3. 52.222-36, Affirmative Action for Handicapped Workers (29 U.S.C. 793); and
4. 52.247-64, Preference for Privately Owned U.S.-Flagged Commercial Vessels (46 U.S.C. 1241)

d. The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

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. Statement of Work, 6 pages.
2. Performance Evaluation and Award Fee Plan, 9 pages.
3. Government Notice for Handling Proposals, 1 page.

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).

4. Summary of Labor & Direct Costs (TECHNICAL PROPOSAL), 1 page.

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

5. NIH-2043, Proposal Summary and Data Record, 2 pages.
6. Summary of Annual Costs (BUSINESS PROPOSAL), 1 page.
7. Summary of Related Activities, 1 page.
8. SF-LLL, Disclosure of Lobbying Activities, 3 pages.

THE FOLLOWING FORMS WILL BE ATTACHED TO ANY CONTRACT RESULTING FROM THIS RFP: (They are included here for informational purposes only).

9. NIH (RC)-7, Procurement of Certain Equipment, (OMB Bulletin 81-16), 1 page.
10. NIH (RC)-4, Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts, 5 pages.

NOTE: Section K - Representations and Certifications - Negotiated Contracts must be completed, signed and included with the Business Proposal. It is available at URL: http://amb.nci.nih.gov/forms/rcneg.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

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

Representations and Certifications - Negotiated Contracts must be accessed electronically from the INTERNET at the following URL:

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

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THESE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM AS PART OF YOUR 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), August 10, 2001. 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 plus 4 copies

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-01-05

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 (May 2001)]**

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

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

(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 travel policy, the annual financial statement, the total compensation plan and certain types of cost/pricing information will only be required to be submitted from those offerors included in the competitive range, or the apparent successful offeror. The special procedures for submission of this documentation are set forth in detail below:

Travel Policy. The offeror's (and any proposed subcontractor's) written travel policy shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a travel policy as a part of their final proposal revision.

Annual Report. The offeror's most recent annual report shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a copy of their most recent annual report as a part of their final proposal revision.

Total Compensation Plan. The offeror's total compensation plan shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a total compensation plan as a part of their final proposal revision.

Cost/Pricing Information. The offeror's business proposal shall include the basic cost/pricing information specified in Section L.4. of this RFP. In addition, the Government may require offerors included in the competitive range to submit additional information substantiating their proposed costs or prices. This additional cost/pricing information will be requested after establishment of the competitive range, and potentially includes payroll documentation, vendor quotes, invoice prices, and/or any other information deemed necessary by the contracting officer to evaluate the reasonableness of the price or to determine cost realism. The information may also include submission and certification of cost or pricing data.

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

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

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

e. **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 541990.
(2) The small business size standard is $5 million.

f. **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 January 25, 2002.

It is anticipated that the award from this solicitation will be a multiple-year performance-based cost plus award fee type contract, with a term of five (5) years. See SECTION J, for the description of the Performance-based Evaluation and Award Fee Plan applicable to this requirement. It is also anticipated that incremental funding will be used for this contract (see Section L.2. (c) - Business Proposal Instructions.

g. **ESTIMATE OF EFFORT**

It is expected that a cost-reimbursement type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the total effort required to complete the RFP objectives to be approximately 29,510 labor hours for the entire contract period. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

You are requested to furnish estimates of personnel and effort based on the requirements of this RFP and the approach you propose to take for achieving the stated objectives.

h. **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.

i. **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.

j. **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.

k. **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.

l. **PREPARATION COSTS**

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

m. **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

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

(End of Provision)

n. **LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70**

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 plus award fee 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. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

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

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

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

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

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

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

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

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

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

-to the Department of Justice as required for litigation.

-to respond to congressional inquiries.

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

(10) 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 panel may suggest that the Contracting Officer request clarifying information from an offeror.

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

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

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

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

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

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

While it is 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 finalization of 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 process will take into consideration the results of the technical evaluation, evaluation of cost and past performance.

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 in the Commerce Business Daily.

(11) 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.

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

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

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

(13) Salary Rate Limitation in Fiscal Year 2001*

Offerors are advised that pursuant to P.L. 106-554, no NIH Fiscal Year 2001 (October 1, 2000 - September 30, 2001) funds may be used to pay the direct 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). This does not preclude the offeror from absorbing that portion of an employee's 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. 106-554 applies only to Fiscal Year 2001 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 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. P.L. 106-554 states in pertinent part:

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

***This rate may change periodically. For your information, the rate can be found at: http://www.opm.gov/oca/01tables/execses/html/01execsc.htm .**

*****Note: FY-2002 Public Law and Salary Rate information will replace this and be inserted into the contract upon passage of DHHS FY-2002 appropriation legislation.***

(14) 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.

(e) 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.

(15) Past Performance Information

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. Standard Industrial Code

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

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

(a) 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) Facilities Capital Cost of Money, FAR Clause 52.215-16 (October 1997)

(d) 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.

- The contract will require that personnel be available for up to 10 hours per week to meet with NINDS staff in Rockville, Maryland, with 24 hours notice. These meetings are for the purpose of reviewing progress and discussing data analysis and quality assurance issues.

- The Contractor shall have in place or be able to implement procedures necessary to preserve and guard the integrity of the data and any analysis and to protect the privacy of the information provided by the NINDS or any collaborating clinical center. An Information Technology Security Plan is required. Refer to Information Technology System Security Specifications and Confidentiality of Information clauses in Section H and see #5 below.

- The Contractor must have knowledge and experience in clinical trial management, particularly in data analysis and protocol design and data collection forms.

(1) Technical Discussions

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

a) **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.

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.

b) **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

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) Information Technology Systems Security

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

NOTE: OMB A-130 is accessible via web site: http://www.whitehouse.gov/omb/circulars

c. BUSINESS PROPOSAL INSTRUCTIONS

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

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

It is anticipated that the award from this solicitation will be a performance-based cost plus award fee type contract, with a term of five (5) years. See SECTION J, Attachment #2, for the description of the Performance-based Evaluation and Award Fee Plan applicable to this requirement.

(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 rational 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.

i) **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.

ii) **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.

iii) **Subcontracted Items**

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only

to the prime contract. For each subcontract over $500,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.806.

iv) **Raw Materials**

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

v) **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.).

vi) **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.

vii) **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.

viii) **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.

ix) **Travel**

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

x) **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(l), 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.(4) 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) **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. **Past Performance information (see Section L.2.a.15 of this RFP) must be submitted with the Business Proposal.**

(6) **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)**

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

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

d) **Financial Capacity**

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

e) **Incremental Funding**

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

> Sufficient funds are not presently available to cover the total cost of the complete multiple year project described in this solicitation. However, it is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled "Limitation of Funds." Under that clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover an initial period of performance. Additional funds are intended to be allotted from time to time, to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

The "Limitation of Funds" clause to be included in the resultant contract shall supersede the "Limitation of Cost" clause found in the General Clauses.

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

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

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

(7) **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.

(8) **Proposer's Annual Financial Report**

All offerors included in the competitive range will be required to submit a copy of the organization's most recent annual financial report.

(9) **Representations and Certifications**

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(10) **Travel Costs/Travel Policy**

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 included in the competitive range will be required to submit a copy of their written travel policy. A written travel policy for any proposed subcontractors shall also be submitted at that time. 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 three factors. The factors in order of importance are: technical, cost, and past performance. Although technical factors are of paramount consideration in the award of the contract, cost and past performance are also important to the overall contract award decision. All evaluation factors other than cost, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award to that offeror whose proposal provides the best overall value to the Government.

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 evaluation of cost and past performance will not be conducted on any proposal determined to be "technically unacceptable" as a result of the initial technical review. In addition, evaluation of past performance will not be conducted on any proposal not included in the competitive range on the basis of the evaluation of factors other than past performance.

B. TECHNICAL EVALUATION CRITERIA

The following evaluation criteria shall be used by the technical review panel for the evaluation of technical proposals. The relative importance of these criteria is as indicated by the assigned point weights. The maximum total score possible is 100 points. Proposals will be judged solely on the written material provided by the offeror.

1. Expertise of Personnel **Total: 40 points**

a. The reviewers will evaluate: 1) The combined level and breadth of clinical trials expertise of the offeror's professional team, in areas such as clinical trials design, methodology, statistics, data processing, project management, quality control, and auditing. 2) The level of clinical trials expertise demonstrated by the proposed Project Director, especially in such areas as designing, evaluating, managing, coordinating, or auditing clinical trials. (30 points)

b. The reviewers will evaluate evidence of adaptability and flexibility in staffing required to expand personnel (either through hiring or subcontracting) in response to the changing work requirements within the scope of the contract. (5 points)

c. In addition, the reviewers will assess the adequacy of administrative and management personnel to support the Statement of Work. (5 points)

2. Previous Experience **Total: 40 points**

The reviewers will evaluate previous experience in the performance areas outlined in the SOW:

a. Monitoring quality assurance in clinical trials. (25 points)
b. Clinical project tracking, and especially creation and modification of relational databases. (5 points)
c. Development of classification systems of research projects. (5 points)
d. Statistical and methodological consultation (5 points)

3. Technical Approach **Total: 15 points**

Reviewers will evaluate: 1) Understanding of the purpose of this contract and of the requirements outlined in the Statement of Work. 2) An overall approach which reflects clarity, conciseness, general responsiveness, and the ability to comply with the requirements of the Statement of Work. 3) The extent to which the proposal is consistent with the stated goals and objectives and demonstrates the feasibility of successfully accomplishing requirements.

4. Equipment and Facilities **Total: 5 points**

Reviewers will evaluate evidence of adequate computer equipment and support, office space, communications, storage capabilities, and compatibility with NINDS computer systems, such as the availablity of the latest version of MS Office for PC.

C. PAST PERFORMANCE

An evaluation of offeror's past performance information will be conducted subsequent to the technical evaluation. 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.

The assessment of performance risk is not intended to be the product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers all available and relevant information. When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

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

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

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

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

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

0 None - No past performance history identifiable.

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

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

STATEMENT OF WORK

INTRODUCTION AND BACKGROUND

To address the present and anticipated future needs of the National Institute of Neurological Disorders and Stroke (NINDS), National Institutes of Health, the NINDS Clinical Trials Cluster is requesting proposals to establish and manage a Center for Clinical Trial Management Resources. The overall purpose of the Center is to provide support for the management, tracking, and oversight of clinical trials sponsored by the Institute.

NINDS ranks fourth among NIH Institutes and Centers in the number of ongoing recruiting clinical trials. The NINDS spent in FY 2000 $849 million dollars on 3,423 research projects; of this amount $284 million dollars (33%) was spent on 769 (22%) projects that required human subjects approvals from an IRG. Of these grants, 46 were designated as clinical trials, pilot clinical trials, or planning grants for phase III clinical trials.

The Clinical Trials Cluster at NINDS is charged with ensuring the highest quality of each NINDS-funded clinical research project and compliance with DHHS/NIH/NINDS regulations regarding human subjects protections and safety monitoring. To carry out this responsibility, the Cluster requires clinical trial-related scientific and management resources of the proposed Center.

GENERAL REQUIREMENT

Independently, and not as an agent of the Government, the Contractor shall exert its best efforts to furnish the necessary services, qualified personnel, material, equipment and facilities required to serve as a Center for Clinical Trial Management Resources that accomplishes the work described below. In general terms, the contractor shall provide scientific resources and services necessary to support a broad range of activities required to effectively manage the NINDS clinical research program. This includes multiple activities requiring advanced expertise level in the design, conduct, and oversight of clinical trials. Although five distinct performance areas have been identified (see Specific Requirements), it is impossible to anticipate every need of the Clinical Trials Cluster, both because the future clinical trials and their associated unique demands are unknown, and because of possible unanticipated NINDS and NIH policy changes. The contractor shall provide clinical trials professionals with broad enough expertise to handle such unanticipated needs. Examples of such possible needs include: preparation of the scientific background information needed to develop new scientific initiatives involving clinical trials; review and refinement of Clinical Trials Cluster policy statements; dissemination and translation of results from clinical trials to the clinical community (patient and physician education).

SPECIFIC REQUIREMENTS

The NINDS has identified five specific performance areas comprising the scope of the contract.

I. PERFORMANCE AREA #1: MONITOR QUALITY ASSURANCE IN CLINICAL TRIALS

Quality assurance in NINDS-funded clinical trials is the responsibility of the principal investigator and his/her staff. However, the extent of investigators' experience and skill in developing and applying effective quality assurance procedures varies, and some investigators stand to benefit from assistance and guidance received from experts in quality assurance in clinical trials. The overall objective of the quality assurance performance area is to ensure that the data resulting from a trial are of highest quality and are considered valid and credible within the scientific and clinical community.
To assist the investigators in meeting this objective, the contractor will be asked to use its scientific resources to review, monitor, and correct (if needed) quality assurance procedures in NINDS-funded clinical trials. Specifically, the contractor will be asked to:

1. Develop guidelines for investigators, specifying the procedures that the investigator should develop and implement to assure data quality and integrity;

2. Provide technical assistance to investigators to facilitate the interpretation and implementation of the data quality assurance guidelines;

3. Develop in cooperation with the NINDS Clinical Trials Cluster written procedures for use by the contractor for conducting site visits to review, assess, and correct (if needed) data quality assurance procedures (the initial site visit) and to monitor, assess, and correct (if needed) the implementation and effectiveness of data quality assurance procedures throughout the trial (periodic site visits and the final site visit);

4. Conduct site visits as specified in the procedures document developed in 3).

Note of clarification to the Offeror: The development and the implementation of quality assurance procedures is the Clinical Trial Investigator's, not the contractor's responsibility. The contractor will only be responsible for reviewing, assessing, and correcting quality assurance procedures in clinical trials, monitoring their implementation and effectiveness, and correcting data quality procedures, if needed.

The four elements of the quality assurance performance area are described in greater detail below.

A. Develop guidelines for Clinical Trial investigators to ensure data quality and integrity for NINDS-funded multi-center clinical trials.

The contractor shall develop guidelines for data quality and integrity for NINDS-funded multi-center clinical trials. The guidelines will specify the procedures that the investigator should develop and implement to prevent, detect, and to correct data quality and integrity problems. Examples of aspects of a clinical trial that should be reviewed, assessed, and corrected to ensure *prevention* of data quality problems include, but are not limited to: the clarity and completeness of the protocol, of the manual of operations, of the data forms; and of the description of study procedures; plans for pretesting data forms and procedures; plans for training and certification of study staff to ensure reliability of the outcome measures. The guidelines should also address assurance of data integrity, such as procedures for blinding; procedures for preventing conflict of interest; procedures for reviewing manuscripts; and procedures for protecting patient safety.

Examples of topics related to *detection* of data quality problems that should be covered in the guidelines include, but are not limited to: procedures for detecting protocol violations; procedures for checking data forms for completeness, accuracy, and internal consistency; using software programs for data cleaning; procedures for comparing data forms or summary information with source documents; plans for site audits.

Finally, the discussion of actions to be taken to *correct* a data quality problem (if detected) should include topics such as: plans for correcting individual data items and documenting corrections; plans for correcting systematic errors; plans for using feedback and education to prevent recurrence of problems; plans for correcting and preventing recurrence of protocol violations.
A draft copy of the guidelines shall be submitted to the NINDS Project Officer within 90 days of the effective day of the contract, for review and comments. The Project Officer will return comments to the contractor within 30 days. The contractor will then incorporate the comments and will prepare the final version of the guidelines within 30 days following receipt of written comments from the NINDS Project Officer.

The NINDS Project Officer will disseminate the guidelines by posting the document on the NINDS website. All new NINDS grantees receiving funds for clinical trials will be required to follow these guidelines to ensure high quality data. In addition, current Principal Investigators for NINDS-funded clinical trials will be required to review their operations in light of the guidelines.

It is estimated that the development of the guidelines will require approximately 80 hours of work by clinical trials professional. Ongoing discussion with the staff of the Clinical Trials Cluster will be necessary throughout this process.

B. Provide technical and administrative assistance for interpretation and implementation of the guidelines for specific clinical trials.

The contractor shall be available through the NINDS Clinical Trials Cluster to NINDS grantees to provide telephone or written consultation in the implementation of the data quality assurance guidelines (in addition, consultation will be provided during site visits - see below). These consultations will be closely coordinated with the Clinical Trials Cluster. It is anticipated that new grantees will require the greatest amount of assistance. However, an existing study may require intensive consultation as well, especially if a site visit reveals significant problems. It is estimated that the telephone and mail consultation will require approximately 10 hours per week by a clinical trials professional.

C. Develop standard operating procedures manual for conducting assessments of quality assurance procedures in NINDS-funded multi-center clinical trials.

The contractor shall develop within 120 days of the effective date of the contract a draft of the standard operating procedures manual for conducting assessments of quality assurance procedures to monitor compliance with the guidelines. The Project Officer will return comments to the contractor within 30 days. The contractor will then incorporate the comments and will prepare the final version of the manual within 30 days following receipt of written comments from the NINDS Project Officer.

The manual shall include plans for site visits, which will be the contractor's primary method of monitoring quality assurance procedures in NINDS-funded multi-center clinical trials. The manual should separately describe operating procedures for the initial visit, periodic follow-up visits, and the final visit. The Project Officer will select the studies that require site visits. The number of periodic follow-up visits will depend on the needs of any particular trial and will be determined by the Project Officer. The choice of the location of the site visit for a designated study (e.g., the Data Coordinating Center, specific clinical centers) will depend on the needs of each particular study and will be determined by the Project Officer, in collaboration with the contractor.

After each site visit, the contractor shall prepare a brief report describing the main findings and recommendations. A copy of the report will be sent to the Project Officer within 7 days after completion of the site visit, for review and comments. The Project Officer may request additional information or revisions in the report. The contractor will make the necessary changes in the report within 7 days following the receipt of Project Officer's comments. The Project Officer will send the final copy of the report to the Principal Investigator.

The manual shall specify procedures for the initial visit, the follow-up visits, and the final visit. The initial visit will focus on the review, assessment, and correction (if needed) of the study's planned procedures for preventing, detecting, and correcting data quality and trial integrity problems. The follow-up visits will be designed to evaluate the degree of success in the implementation and the effectiveness of the data quality assurance and trial integrity procedures that were assessed during the initial (or the last) visit - either in their original form, if no improvements were required, or procedures that were modified according to the contractor's recommendations. In cases when a problem is detected, the contractor shall aim to identify the source of the problem and make recommendations for correcting the problem. A follow-up visit may require a direct data audit as part of the assessment of the degree of success in the implementation of the quality assurance procedures. Future follow-up visits will include evaluation of the extent to which problems have been dealt with and how successful these attempts have been. The final site visits shall provide overall assessment of the quality of data: their reliability, validity, accuracy, and completeness.

It is estimated that the development of the manual of operations will require approximately 80 hours of work by clinical trials professional. Ongoing discussion with the staff of the Clinical Trials Cluster will be necessary throughout this process.

D. Conduct site visits to monitor data quality in designated clinical trials.

The contractor shall conduct the initial, periodic, and final site visits at designated studies to monitor data quality assurance and study integrity procedures, as specified in the manual of standard operating procedures. Each site visit will be followed by a report, as specified above. The report resulting from the initial visit shall assess the study integrity and data quality assurance procedures and will make recommendations for improvements, if needed. The contractor shall be available for consultation to the

principal investigator in order to assist him/her in implementing the recommendations for improvements. The report following a periodic follow-up visit shall describe the degree of success in the implementation and effectiveness of the agreed upon plans. The report following the final visit shall evaluate the overall data quality in the study and the integrity of the study overall.

Each visit will take two days spent at the site. Counting the two visit days and time needed for preparations for a visit and preparation of a report after a visit, it is estimated that each site visit will require 24 hours of work by a clinical trials professional and 16 hours of work by a clinical trials manager. It is estimated that about 20 site visits per year will be required.

II. PERFORMANCE AREA #2: CLINICAL PROJECT TRACKING

In order to ensure the highest quality clinical research studies and compliance with DHHS/NIH/NINDS regulations regarding human subjects protections and safety monitoring, the NINDS Clinical Trials Cluster must have accurate and up-to-date information on the status of all clinical research projects supported by NINDS. To facilitate the oversight process, the contractor shall assist the Clinical Trials Program Analyst in the ongoing development and maintenance of a tracking system for all clinical research project grants. The purpose of this system is to identify and track clinical research projects through their various stages, from initial concept development through grant and cooperative agreement application, evaluation and award phases. This readily accessible database will provide rapid reporting of all clinical research projects supported by NINDS. The contractor's responsibilities for developing and maintaining this system shall include:

1. The contractor shall assist the Clinical Trials Cluster's Program Analyst in the development and modification of a Microsoft Access database that will identify and track critical elements of all NINDS supported clinical research projects. Critical elements included in the tracking process will include (but will not limited to): project summary, IRB approval and/or concerns, presence of Data Safety Monitoring Board (DSMB), organization of the DSMB, progress of participant recruitment, minority and gender recruitment, and reporting of adverse events.

2. The contractor shall provide a computer programmer with Microsoft ACCESS database proficiency to assist in the developmental link of the tracking system to other relational databases, including the NINDS Scientific Research Project Database and the NIH IMPAC2 database. Use of the programming language of Microsoft ACCESS to generate procedures that create, modify, or respond to documents or messages in Microsoft OUTLOOK, WORD, and EXCEL documents will be required.

3. The contractor shall assist the Program Analyst in identifying and updating tracking elements for individual clinical research projects as they change during the course of the clinical project. Responsibilities of the contractor will also include entering data into the tracking database.

4. The Contractor will assist in the definition of a validation mechanism to ensure the accuracy of the data that is entered into this database.

5. The contractor will assist the Program Analyst in generating tracking reports created from the database.

6. As requested, the contractor will prepare custom reports for members of the Clinical Trials Cluster.

It is estimated that this performance area will require an initial 100 hours of an ACCESS programmer effort, to build the database. After that, the programmer's work will be required approximately 2.5 hours per week on an on-going basis, to maintain the database and to generate reports. In addition, about 2.5 hours a week of a clinical trials manager will be required to identify information for input into the data base.

III. PERFORMANCE AREA #3: SUPPORT FOR NINDS STAFF'S DEVELOPMENT OF A CLASSIFICATION SYSTEM OF RESEARCH PROJECTS

The contractor shall assist the NINDS Clinical Trials Cluster staff in developing a classification system for categorizing ongoing funded research projects in clinical and basic science related to the development of neurological therapies. The contractor responsibilities include:

1. Acquiring research protocols, research reports in the scientific literature, and unpublished reports obtained through personal requests for the NINDS staff and use this information to help NINDS staff develop a classification system.

2. Using above classification system to perform an analysis of currently active NINDS grants, and under NINDS staff guidance, classify grants by type of research and evaluate them for the need for monitoring, auditing and compliance to human subject protection.

It is estimated that the development and maintenance of the clinical trial classification system will require a 2.5 hours per week effort by a clinical trials professional, and about 10 hours a week by clinical trials managers. An initial ACCESS programmer's effort will be required for approximately 30 days.

IV. PERFORMANCE AREA #4: STATISTICAL AND METHODOLOGICAL SUPPORT

The contractor shall provide support and consultation to the Clinical Trials Cluster in the area of statistics and clinical research methodology. Specifically, assistance will be required in the development of statistical and methodological guidelines for prospective applicants and for reviewers; statistical consultation will be needed in evaluating requests to submit applications for large clinical projects; expert advice will be needed to help solve methodological problems in ongoing clinical projects; and occasionally, statistical services will be required to conduct statistical analyses. The rationale and specific requirements for each subtask area is described below.

1. Develop statistical and methodological guidelines for prospective applicants and reviewers

One of the major activities of the professional staff within the Clinical Trial Group is to provide assistance to grant applicants seeking NINDS support for large clinical research projects, clinical trials, pilot studies, and planning grants. Because of the diversity of neurological diseases, each clinical community has developed somewhat independently with its own view of appropriate trial design. When the applications are reviewed, however, there are some common expectations of reviewers regardless of subspecialty differences. As part of providing information to applicants, documents may be prepared describing different methodologies for clinical research. Sharing these documents with reviewers will provide a common basis for communication and provide a basis for continuing improvement in clinical research methodology. The contractor will be expected to assist the NINDS Clinical Trial staff in preparation of these documents. For instance, a discussion of different organizational structures may be presented; considerations for including or not including a futility analysis may be presented; different monitoring boundaries may be chosen; an equivalence or superiority design may be preferred; statistical modeling may be proposed, one or two tailed tests may be chosen. The goal is to encourage applicants and reviewers to go beyond traditional and standard methodology and its limitations in order to fit the study design more closely to the circumstances of the trial. The issues concerning the design of Phase I and Phase II trials are particularly numerous and ambiguous. Expectations of applicants and reviewers are likely to be widely divergent unless some common ground rules are established. Other reasons to provide guidelines include: more efficient trial design, resulting in greater patient safety due to smaller sample sizes; an opportunity for the NINDS to provide leadership to the field by establishing high standards of quality for statistical design and trial methodology.

Another aspect of assisting the NINDS staff in preparation of guidelines and instructions will be reviewing previous trials to serve as examples of particular methodology. For instance, the completeness of follow-up of patients for a variety of different trials may be examined. Analysis of the completeness of follow-up may establish expectations and set goals for newly proposed and funded trials.

Increasingly, the NINDS is seeing studies for large genetic projects to identify genes and there is urgency to study disease states with complex genetics. Capability to draw up guidelines and evaluate different methodologies for genetic studies may be requested.

2. Provide statistical and methodological consultation to Clinical Trials Cluster staff

From time to time, NINDS staff will be evaluating a request to submit a large clinical research project. Unusual methodology or particularly creative methods may be proposed. The contractor may be asked to serve as a resource for NINDS staff by providing a list of advantages and disadvantages of the proposed methods.

NINDS staff face a wide variety of methodological questions and problems during the conduct of a trial or its oversight by a monitoring committee. Creative and original solutions are often required. The contractor will be requested to propose solutions to problems in ongoing clinical trials. Often, the perfect solution is not available and an imperfect but workable solution must be selected.

3. Conduct statistical analyses

The NINDS has data from several clinical trials that have been completed. From time to time, NINDS staff will want to provide analysis of the data for NINDS staff in order to assist them in carrying out there duties or to test scientific hypotheses from different investigators. A broad range of statistical expertise and experience with different data architectures will be required.

The statistical and methodological support performance area is estimated to require the availability of either an in-house or a consultant statistician experienced in clinical trial design and data analyses. It is estimated that the statistician(s) will work for 120 hours to develop the statistical and methodological guidelines, will provide statistical and methodological consultation to NINDS staff approximately 5 hours a week, and will perform statistical analyses about 2.5 hours per week The analyses will be supported by a programmer from the Offeror's organization approximately 5 hours a week.

V. PERFORMANCE AREA #5: CLINICAL DATA ACQUISITION AND ARCHIVING

The contractor shall provide consultation and services in the area of data acquisition and archiving. After the termination of clinical research projects, investigators must decide which study materials will be retained or discarded. For stored study materials, storage site, maintenance of confidentiality, and length of storage must be determined. The contractor will aid the NINDS Clinical Trials Cluster staff in developing information for investigators about archiving data after closure of a clinical trial.

For some past contracts, data currently owned by NINDS requires archival and analysis. The contractor shall provide services necessary to acquire the data and to store them in an electronic form.
The contractor will provide computer equipment and software capable of acquiring and processing SAS data files stored on CDs. The estimated memory requirement for these data is 5 gigabytes. In addition, the contractor will provide shelf space (about 3 shelves) to store the dataset documentation.

This performance area will require the availability of a programmer skilled in clinical data management. It is estimated that an initial effort of 60 hours of services and consultation from the data management programmer will be needed. Throughout the duration of the contract, one hour per week effort by a clinical trials professional, and 5 hours a week of effort by an assistant will be required.

PERFORMANCE EVALUATION
AND AWARD FEE PLAN

FOR

CENTER FOR CLINICAL TRIAL MANAGEMENT RESOURCES

Plan Dated _____

Prepared by: Raina Cervantes
Contracts Management Branch, NINDS

TABLE OF CONTENTS

ATTACHMENTS

I. INTRODUCTION

The purpose of this document is to establish a proposed procedure for evaluating a Contractor's performance in providing clinical trial quality assurance and data acquisition support services for the National Institute of Neurological Disorders and Stroke. This Performance Based Cost-Plus Award-Fee (PBCPAF) type of contracting is utilized to provide a strong incentive for the Contractor to achieve excellent performance. It allows the Contractor flexibility in performing the work and promotes maximum cooperation between the Contractor and the Government.

The objectives of this Performance Evaluation and Award Fee Plan are to: (1) motivate the Contractor to improve performance in the rated areas, but not at the expense of minimally acceptable performance in all other areas and, (2) emphasize to the Contractor key areas of management focus. This plan provides the basis for the evaluation of the Contractor's performance and for presenting an assessment of that performance to the Contracting Officer (Fee Determining Official). The specific criteria and procedures used to assess the Contractor's performance and to determine the amount of award fee earned are described herein.

II. ORGANIZATION / RESPONSIBILITIES

The award fee organization consists of the Fee Determining Official and a Performance Evaluation Group (PEG).

A. Fee Determining Official

The Fee Determining Official is the Government Contracting Officer (CO) and is responsible for:

1. Approving this award fee plan and any significant revisions to it.
2. Reviewing recommendations of the PEG, considering all pertinent data and determining the earned award fee for each evaluation period.
3. Notifying the Contractor in writing of the amount of the award fee awarded for the evaluation period.

B. Performance Evaluation Group (PEG)

The PEG will be established after contract award. It will consist of the Project Officer and other NINDS Program staff who will monitor performance under the resultant contract. The PEG shall evaluate the Contractor's performance and recommend earned award fee amount to the CO. They may also recommend changes to this plan. Each member is responsible for:

1. Monitoring, evaluating, and reporting Contractor performance.
2. Submitting monthly Performance Evaluation Reports (Attachment C) to the CO for documenting and reporting Contractor performance. These reports shall include details of strengths, weaknesses, and any areas where the Contractor does not meet contract requirements. Criticism should be constructive in all points, and should be directed toward improvement of operations in conformance with Government objectives and requirements.
3. Preparing End-of-period Evaluation Reports for Award Fee (Attachment D).
4. Meeting with the Contractor to discuss performance results.

III. PERFORMANCE EVALUATION PROCESS

A. Award Fee Allocation

Award fee pool will be set after contract award based on Contractor input. The base fee included in the award will be 0. The maximum award fee that the contractor may earn shall be determined in accordance with FAR 16.405-2(a)(2).

The total award fee pool will be broken out by evaluation periods as shown in Attachment B. A percentage of the maximum available fee for each period will be paid to the Contractor on the basis of contract performance during the respective award fee period. Unearned award fee will not carry over from one award fee period to the next.

B. Source of Data for Evaluations

1. Monthly Performance Evaluation Reports prepared by the PEG as they monitor Contractor performance. These reports will be based on observations and review of all Contractor reports, financing requests, and other deliverables received during the month.
2. Inputs provided by the Contractor describing their performance in specific areas during the award fee period.
3. Any other data provided in accordance with the contract or this plan, or any other sources.

C. Award Fee Determination

The amount of award fee earned will be based on the Contractor's performance as evaluated against the Performance Standards by the PEG and accepted by the CO. The PEG will monitor the Contractor's performance and evaluate performance monthly by the Performance Standards in Attachment A. They will notify the Contractor of any weaknesses as soon as they are identified. They will promptly document significant accomplishments, any weaknesses, or areas of concern on monthly Performance Evaluation Reports (Attachment C) and forward them to the CO by the 10^{th} calendar day of the following month.

Semi-annually, the PEG will evaluate the Contractor's performance and recommend their award fee earned to the CO. They will use results of the monthly Performance Evaluation Reports as source data for determining the end-of-period award fee evaluation ratings. Using a numerical scale from 1 to 10, each member of the PEG will rate Contractor performance in each Performance Standard in Attachment 1 and those ratings will be averaged. An average of 9 through 10 will result in the higher level Award Fee, and an average of 6 through 8 will result in the lower level Award. If the rating for services falls below 6, the Contractor will not receive any award fee for the rating period.

The PEG will use the Evaluation Report forms in Attachments 3 and 4 for recording the results of the evaluations. They will provide award fee recommendations to the CO within twenty (20) days after the end of an evaluation period. The CO may accept or modify the recommendations of the PEG based on additional information or PEG consensus. The CO is the final authority to determine the overall rating and amount of the award fee.

Within thirty-five (35) calendar days after each evaluation period, the CO will advise the Contractor, in writing, of the award decision and include an evaluation of the Contractor's performance as measured against the criteria. The notification also summarizes the Contractor's performance assessment and identifies significant strengths and weaknesses that influenced the determination. The CO will authorize payment of the award fee earned. The Contractor may then immediately submit a voucher for the entire award fee earned.

The Contractor may express disagreement with the Award fee determinations through a letter to the Contracting Officer. The Contractor's comments will be taken into consideration in the subsequent evaluation; however, the previous fee evaluation determination will not be changed or amended and the decision of the Contracting Officer will be final. The award fee determinations are not subject to the Disputes clause.

The Government's decision to pay or not to pay Award Fee in no way alters the Contractor's responsibilities to perform any functions or produce any deliverables required by this contract. The Government's decision to pay or not to pay award fee in no way alters the Government's obligation to reimburse the Contractor for allowable incurred costs in accordance with the resultant contract.

The award fee process is recognized to be subjective in nature, but every effort will be made to ensure fairness. CO and PEG reviews have been incorporated into the process to ensure that performance is evaluated and award fee is determined in accordance with this plan.

D. Revision to the Plan

The CO may unilaterally change this plan prior to the beginning of an evaluation period. The CO will notify the Contractor in writing of changes to the plan involving the evaluation criteria or percentages at least thirty (30) days before the start of the affected evaluation period. Changes to this plan that are applicable to a current evaluation period and made during that period will be documented and incorporated by mutual consent of both parties.

E. Contract Termination

If the contract is terminated for the convenience of the Government after the start of an award fee evaluation period, the CO shall determine the earned award fee amount using the normal award fee evaluation process. After termination for convenience, the remaining award fee amounts allocated to all subsequent award fee evaluation periods cannot be earned by the Contractor and, therefore, shall not be paid.

IV. PERFORMANCE GRADES AND AWARD FEE

The following award fee grades will be applied to assess the Contractor's performance during an award fee period. Each member of the PEG will evaluate the quality of the services provided using a numerical rating scale from 0 to 10 for each criterion then average the scores.

Grade	Average Numerical Rating	Percentage of Award Fee Amount Earned
Excellent - Contractor's performance exceeds standard by substantial margin.	9 - 10	100%
Satisfactory - Contractor's performance is standard or areas for improvement are offset by better performance in other areas.	6 - 8	70%
Unacceptable - Contractor's performance is less than standard, and the monitor can cite many areas for improvement.	0 - 5	0%

The following definitions describe, in general, the types of performance, which leads to the various ratings assessed by the PEG. These grade-rating definitions will be applied against the performance standards in order to provide an assessment of the Contractor's performance and resultant award fee.

Excellent Performance (average rating: 9-10)
Contractor's performance of virtually all contract tasks is consistently noteworthy and provides numerous significant, tangible or intangible, benefits to the Government. The few areas for improvement are all minor. There are no recurring problems. Contractor's management initiates effective corrective action whenever needed.

Satisfactory Performance (average rating: 6-8)
Contractor's performance of most contract tasks is adequate with some tangible benefits to the Government due to Contractor's effort or initiative. Although there are areas of good or better performance, these are more or less offset by lower-rated performance in other areas.

Unsatisfactory Performance (average rating: 0-5)
Contractor's performance of most contract tasks is inadequate and inconsistent. Quality, responsiveness, and timeliness in many areas require attention and action. Corrective actions have not been taken or are ineffective. Overall unsatisfactory performance shall not earn an award fee.

Attachments:
A. Performance Standards
B. Award Fee Allocation by Evaluation Periods
C. Monthly Performance Evaluation Report
D. End-of-period Evaluation Report for Award Fee

ATTACHMENT A

PERFORMANCE STANDARDS

Required Performance	Performance Standards	Method of Surveillance	Standard to be Met	Max. Rating
Performance Area #1: Monitor Quality Assurance in Clinical Trials				
Develop guidelines for Clinical Trial investigators to ensure data quality. Develop standard operating procedures manual.	High level of quality, comprehensive coverage, and timeliness of review and revisions	PEG will review draft and final documents.	Final products are judged to be technically correct, practical to use and timely.	10
Conduct site visits to monitor data quality in designated clinical trials. Provide technical and administrative assistance.	Site visits are performed timely. Detailed reports, with appropriate recommendations, are completed timely. High level of responsiveness to assist investigators and NINDS staff.	PEG will monitor and review reports.	Contractor is available, knowledgeable and helpful. Site visits, reports, and return calls are timely.	10
Performance Area #2: Clinical Project Tracking				
Develop and maintain a database and procedures. Identify and input information and generate reports.	Develops, maintains and effectively manages a useful and current database.	PEG will monitor database and procedures and review reports.	Development and modification of a useful database is successfully completed timely. Problems are identified early and innovative solutions are found.	10
Performance Area #3: Provide Support to Develop a Classification System of Research Projects				
Acquire research protocols and reports, analyze and classify active NINDS grants. Maintain this system.	Develops, maintains and effectively manages a useful and accurate system.	PEG will monitor system and procedures and review reports.	An acceptable and useful system is developed and maintained. Appropriate information is acquired. Grants are input and properly classified.	10
Performance Area #4: Statistical and Methodological Support				
Develop guidelines for prospective grant applicants and reviewers. Evaluate different methodologies, propose solutions, consult with NINDS staff	High level of quality, comprehensive, and useful guidelines. Timeliness of review and revisions and meetings with investigators and/or NINDS Staff	PEG will monitor and review draft and final documents.	Final products are judged to be technically correct, practical to use and timely. Proposed solutions reflect excellent knowledge of methodologies and NIH policies.	10
Conduct statistical analysis and report findings as needed.	Effectively manages and performs all processes associated with use of statistical methods and acquisition of data for analysis. Reports are detailed and timely.	PEG will monitor and review reports.	Final products are judged to be technically correct, practical to use and timely.	10
Performance Area #5: Clinical Data Acquisition and Archiving				
Acquire and store data in electronic form. Develop information for investigators about archiving data. Archive and analyze existing data.	Effectively manages and performs all processes associated with acquisition of data for analysis and the development and maintenance of databases and information.	PEG will monitor database and procedures and review reports.	Development and maintenance of a useful database is successfully completed timely. Data is acquired timely. Detailed analysis is performed and final products are judged to be technically correct, practical to use and timely.	10
Overall Contract Management				
- Availability of skilled personnel - Responsiveness to requests - Financing requests and progress reports - Cost control	Responsive to NINDS staff, monitors and controls costs, provides current and accurate information, and meets milestones. Reports and financing requests are submitted timely.	PEG will observe and review reports & financing requests (with CO input).	Overall evaluation of satisfactory or better	10

* PEG is the Government Performance Evaluation Group
CO is the Government Contracting Officer

ATTACHMENT B

AWARD FEE ALLOCATION BY EVALUATION PERIODS

The award fee earned by the Contractor will be determined at the completion of evaluation periods shown below. The percentage shown corresponding to each period is the maximum available award fee amount that can be earned during that particular period.

Evaluation Period	From	To	Annual Award Fee Amount (A)	Available Award Fee for the Period (B)	Award Fee for "Satisfactory" Performance	Award Fee for "Excellent" Performance
1	Jan 2002	Jun 2002	**A1**	**B1** = 50% of A1	70% of B1	100% of B1
2	Jul 2002	Dec 2002		**B2** = 50% of A1	70% of B2	100% of B2
3	Jan 2003	Jun 2003	**A2**	**B3** = 50% of A2	70% of B3	100% of B3
4	Jul 2003	Dec 2003		**B4** = 50% of A2	70% of B4	100% of B4
5	Jan 2004	Jun 2004	**A3**	**B5** = 50% of A3	70% of B5	100% of B5
6	Jul 2004	Dec 2004		**B6** = 50% of A3	70% of B6	100% of B6
7	Jan 2005	Jun 2005	**A4**	**B7** = 50% of A4	70% of B7	100% of B7
8	Jul 2005	Dec 2005		**B8** = 50% of A4	70% of B8	100% of B8
9	Jan 2006	Jun 2006	**A5**	**B9** = 50% of A5	70% of B9	100% of B9
10	Jul 2006	Dec 2006		**B10** = 50% of A5	70% of B10	100% of B10

*The available award fee (B) will be computed as the award fee percentage multiplied by the annual award fee amount (A).

ATTACHMENT C

MONTHLY PERFORMANCE EVALUATION REPORT

Contractor: _____ **Report Month/Year: _____**

SPECIAL CONDITIONS:
Relate any special circumstances that influence this month's performance.

PERFORMANCE STANDARDS:

STRENGTHS:
Briefly describe Contractor's strengths.

AREA OF IMPROVEMENT:
Identify trends if appropriate (i.e., improving, steady, or worsening). Briefly describe the problems in the Contractor's performance. Describe any corrective actions that are being planned or being taken if appropriate.

_____

EVALUATOR SIGNATURE DATE

ATTACHMENT D

END-OF-PERIOD EVALUATION REPORT FOR AWARD FEE

Contractor: _____ Period Covered: _____ **Rating Scale (from 0 to 10): Excellent (9-10) Satisfactory (6-8) Unsatisfactory (0-5)**	
PERFORMANCE EVALUATION	**NUMERICAL RATING**
_____ EVALUATOR SIGNATURE DATE	**Average Rating:** **_____**

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.)

(SUBMIT WITH TECHNICAL PROPOSAL)

SUMMARY OF LABOR AND DIRECT COSTS

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

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.

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH **PROPOSAL SUMMARY AND DATA RECORD**	Solicitation/CONTRACT NUMBER
PROJECT TITLE (Title or Solicitation or Contract Proposal)	
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	YES NO	
Institution's General Assurance re: Human Subjects	DATE APPROVED _____	PENDING
Institution's Review Board's Approval of this Proposal	DATE APPROVED _____	PENDING
An example of the informed consent for this study is enclosed	YES NO	
A Clinical Protocol is enclosed	YES NO	

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.

(SUBMIT WITH BUSINESS PROPOSAL)

SUMMARY OF ANNUAL COSTS

COST ELEMENTS	YEAR 01	YEAR 02	YEAR 03	YEAR 04	YEAR 05	TOTAL
DIRECT LABOR (List indivduals by name / labor category. Indicate hours or % effort for each. _____ _____ _____ _____ _____ _____ _____						
TOTAL LABOR COSTS	$_____	$_____	$_____	$_____	$_____	$_____
MATERIALS/SUPPLIES (Specify items and cost for each.)	$_____	$_____	$_____	$_____	$_____	$_____
TRAVEL COSTS (Specify trips and costs.)	$_____	$_____	$_____	$_____	$_____	$_____
EQUIPMENT (List separately)	$_____	$_____	$_____	$_____	$_____	$_____
CONSULTANTS (Identify name & amount)	$_____	$_____	$_____	$_____	$_____	$_____
SUBCONTRACTS (Identify name & amount)	$_____	$_____	$_____	$_____	$_____	$_____
OTHER DIRECT COST (Specify items & costs for all elements)	$_____	$_____	$_____	$_____	$_____	$_____
TOTAL DIRECT COST	$_____	$_____	$_____	$_____	$_____	$_____
OVERHEAD (%)*	$_____	$_____	$_____	$_____	$_____	$_____
G&A EXPENSE (%)*	$_____	$_____	$_____	$_____	$_____	$_____
TOTAL EST. COST	$_____	$_____	$_____	$_____	$_____	$_____
AWARD FEE (maximum for Superior performance)	$_____	$_____	$_____	$_____	$_____	$_____
TOTAL COST PLUS AWARD FEE	$_____	$_____	$_____	$_____	$_____	$_____

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: _____

Identifying Number	Agency	Total Effort Committed
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: _____

Identifying Number	Agency	Total Effort Committed
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.

Name	Title/Position	Total Proposed Effort
1.		
2.		
3.		
4.		

DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB
0348-0046

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

1. Type of Federal Action: a. contract b. grant c. cooperative agreement d. loan e. loan guarantee f. loan insurance	2. Status of Federal Action: a. bid/offer/application b. Initial award c. post-award	3. Report Type: a. initial filing b. material change For Material Change Only: year _____ quarter _____ date of last report _____

4. Name and Address of Reporting Entity: Prime Subawardee Tier_____, if known: Congressional District, if known:	5. If Reporting Entity in No. 4 is Subawardee, Enter Name and Address of Prime Congressional District, if known:
6. Federal Department/Agency:	7. Federal Program Name/Description CFDA Number, if applicable: _____
8. Federal Action Number, if known:	9. Award Amount, if known: $
10. a. Name and Address of Lobbying Entity (if individual, last name, first name, MI): (attach Continuation Sheet(s)	a. Individual Performing Services (including address if different from No. 10a) (last name, first name, MI) SF-LLL-A, if necessary)
11. Amount of Payment (check all that apply): $_____ actual planned	13. Type of Payment (check all that apply): a. retainer b. one-time fee c. commission d. contingent fee e. deferred f. other; specify: _____
12. Form of Payment (check all that apply): a. cash b. in-kind; specify: nature_____ value_____	

14. Brief Description of Services Performed or to be Performed and Date(s) of Service, including officer(s), employee(s), or Member(s) contacted, for payment indicated in Item 11:

(attach Continuation Sheet(s) SF-LLL-A, if necessary)

15. Continuation Sheet(s) SF-LLL-A attached: Yes No

16. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each failure.	Signature: _____ Print Name: _____ Title: _____ Telephone No.: _____Date: _____
Federal Use Only	Authorized for Local Reproduction Standard Form--LLL

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 of 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.

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.

INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING INSTRUCTIONS FOR NIH COST-REIMBURSEMENT TYPE CONTRACTS

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: (l) 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 and Date:** Insert the contract number 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 Form HHS-565, "Report of Accountable 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.

- Be preceded by an asterisk (*) 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

(a) Billing Office Name and Address

NATIONAL INSTITUTES OF HEALTH
National Institute of Neurological Disorders and Stroke
Contracts Management Branch, DEA
6001 Executive Blvd., Suite 3287 MSC 9531
Bethesda, MD 20892-9531

(e) Payee's Name and Address
ABC CORPORATION
100 Main Street
Anywhere, USA zip code

Attn:
Name, Title, & Phone Number of Official to Whom Payment is Sent

(b) Invoice/Financing Request No.
_____

(c) Date Invoice Prepared
_____

(d) Contract No.
_____

Effective Date
_____

(f) Total Estimated Cost
_____

(g) Total Fixed Fee
_____

(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 Completion 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